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Current Status of Antidepressant Drug Research and Development in China: A Feature Analysis Based on Drug Clinical Trial Registration and Information Disclosure Platform

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Abstract: *Objective*: To systematically review the clinical trial data of registered antidepressant drugs in China, conducted an in-depth analysis of their current status and development trends, and provided reference for the research and development of antidepressants. *Methods*: Clinical trials of registered antidepressant drugs registered from April 16,2013, to December 31,2025, were searched. The development status of antidepressant drug clinical trials in China was analyzed from various aspects, including drug types, indications, trial classification, phase, and design types. *Results*: A total of 675 trials were included, comprising 667 domestic multicenter trials and 8 international multicenter trials. Among them, chemical drugs accounted for 96.0%, while biological products were absent. There were 500 bioequivalence studies (74.1%), with Phase II and III trials employing parallel group, randomized, and double-blind designs. 501 (74.2%) clinical trials provided trial injury insurance for participants, and research resources were concentrated in leading psychiatric specialty hospitals. *Conclusion*: Although the overall development of antidepressant drug clinical trials in China has shown a steady trend, the number of international multicenter trials remains significantly low, while bioequivalence studies and early exploratory trials are more prevalent. Future efforts should focus on strengthening international cooperation and exchange, as well as innovative drug development, to accelerate the fulfillment of clinical needs for patients with depression in China.

Keywords: Depression; Drug clinical trial; Registration and information disclosure platform; Feature analysis

Online publication: Apr 3, 2026

1. Introduction

Major Depressive Disorder (MDD) is a prevalent psychiatric and neurological condition that imposes significant personal and socioeconomic burdens, affecting hundreds of millions of people worldwide [1].

China faces a challenge in preventing and treating depression across the entire lifespan. Survey data indicates that the detection rate of depression risk among adults in China is 10.6%, affecting approximately 90 million individuals. Influenced by various life and social factors, the annual increase in the rate of depression-related medical consultations among young people aged 18 to 35 is 18% [2]. Particularly noteworthy is that adolescence is emerging as a high-risk group for depression. Studies show a significant upward trend in the detection rate of depressive symptoms among children and adolescents in China, with this issue becoming increasingly prominent due to the interplay of multiple factors, including the psychological characteristics of adolescence, academic pressure, and the digital social environment [3]. Major public events such as the COVID-19 pandemic have further exacerbated mental health risks across the population, highlighting the urgency of addressing this major public health challenge [4].

However, current clinical treatment options remain inadequate. Traditional drugs based primarily on the "monoamine hypothesis", such as selective serotonin reuptake inhibitors (SSRIs), generally suffer from limitations including delayed onset of action, insufficient treatment efficacy, frequent residual symptoms, and prominent adverse effects. For adolescent patients whose brains are still developing, concerns about the safety and applicability of existing drugs are even more pronounced. This results in a large number of patients experiencing poor treatment response and high relapse rates, with clinical needs across different age groups far from being met.

Therefore, the development of innovative drugs with new targets, rapid onset of action, and improved safety profiles has become a strategic imperative for enhancing national health. In line with this trend, the National Medical Products Administration (NMPA) has issued the "Technical Guidelines for Clinical Trials of Antidepressant Drugs" to encourage the standardized development of innovative antidepressants [5].

This study aims to conduct a cross-sectional analysis of relevant clinical trials based on official data from the "Drug Clinical Trial Registration and Information Disclosure Platform" of the Center for Drug Evaluation (CDE) under the NMPA. By comprehensively reviewing the current status of research and development of registered innovative antidepressants, this study seeks to deeply analyze the bottlenecks they face, with particular attention to the specific needs of drug development for adolescents, ultimately providing effective references for the advancement of clinical trials for innovative antidepressants in China.

2. Materials and methods

2.1. General information

The data for this study were sourced from the Drug Clinical Trial Registration and Information Platform of the National Medical Products Administration (http://www.chinadrugtrials.org.cn/clinicaltrials.searchlist.dhtml). This platform serves as China's official and authoritative clinical trial registry, encompassing comprehensive information and research status of all drug clinical trials conducted within China.

2.2. Research methods and content

2.2.1. Data retrieval

Using "depression" as the primary search term, all registered drug clinical trials with initial announcement dates

ranging from April 16, 2013, to December 31, 2025, were retrieved from the Drug Clinical Trial Registration and Information Platform of the National Medical Products Administration.

2.2.2. Information collection

Key information was extracted, including trial status, lay/professional titles, applicants, announcement dates, drug types, indications, trial classifications, phases, design types, trial scopes, principal research institutions, reasons for suspension, etc.

2.2.3. Data processing

Data entry and organization were performed using Excel software, with two researchers independently extracting and cross-verifying the data to ensure accuracy. The registration date for all trials was based on the initial announcement date on the platform.

2.3. Statistical methods

Categorical statistics and data integration were performed using Excel as needed.

3. Results

3.1. Overall clinical trial status

3.1.1. General trends

A total of 675 registered drug clinical trials for depression were retrieved, including 667 domestic trials and 8 international multicenter trials. Data analysis revealed that drug development activities for depression have remained consistently high. Despite annual fluctuations, the average number of registered trials per year has remained above 70 since 2020, with registration numbers in 2024 and 2025 remaining at a high level, as shown in **Figure 1**. This trend indicates that the field of depression, as a core area of psychiatric drug development, continues to receive significant attention from both industry and academia.

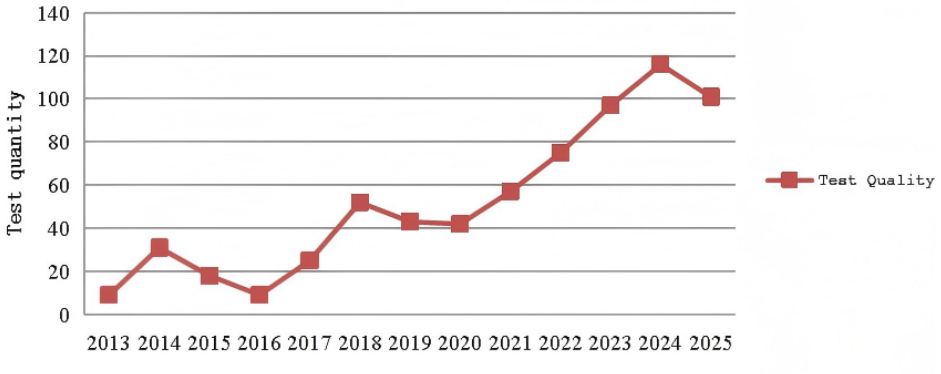


Figure 1. Annual distribution of drug clinical trials.

3.1.2. Trial status

Statistical data indicate that 500 projects have been completed, accounting for a high proportion of 74.1%. Meanwhile, 152 projects remain "in progress". Notably, the combined total of projects that have been

voluntarily suspended and voluntarily terminated is only 23, representing 3.4% of the total, which aligns with the objective laws of clinical research.

3.1.3. Drug types

According to the statistics, the distribution of drug types exhibits a highly uneven pattern. Chemical drugs (648 items) are the absolute research focus, which may be closely related to China's current pharmaceutical R&D industry landscape and policy orientation. Traditional Chinese medicine/natural drugs (27 items) maintain a certain level of vitality as a specialized field. The absence of biological product projects may reveal a gap and development potential in this specific area within the statistical period or scope.

3.1.4. Trial phases

Among the 675 registered drug clinical trials, bioequivalence drug clinical trials dominate (500 items, accounting for 74.1%), with 498 involving chemical drugs and only 2 involving traditional Chinese medicine/ natural drugs. Following this, the number of registered Phase I drug clinical trials is 97, accounting for 14.4%. A total of 75 drug clinical trials have entered Phase II and Phase III, representing 11.1% of the total. See **Table 1**.

Table 1. Distribution of trial phases for depression drug clinical trial projects from April 2013 to December 2025 (Items)

Drug type	Phase I	Phase II	Phase III	Phase IV	Other: Bioequivalence
Chemical drugs	93	30	25	2	498
Traditional Chinese medicine / Natural drugs	4	12	8	1	2
Total	**97**	**42**	**33**	**3**	**500**

3.1.5. Trial design

In bioequivalence drug clinical trials, 494 trials employed a crossover design, accounting for 98.8%; 499 trials were randomized, representing 99.8%; and 492 trials were open-label, making up 98.4%. Phase I projects primarily adopted a parallel-group, randomized, open-label trial design. Both Phase II and Phase III projects utilized a parallel-group, randomized, double-blind trial design. Phase IV projects mainly employed a single-arm, non-randomized, open-label trial design. See **Table 2**.

Table 2. Design of registered depression drug clinical trials in China from 2013 to 2025

Phase	Design type			Randomization		Blinding		
	Single-arm trial	Crossover design	Parallel group	Randomized	Non-randomized	Single-blind	Double-blind	Open-label
Phase I	11	34	52	81	16	2	45	49
Phase II	0	0	42	42	0	0	39	3
Phase III	1	0	32	32	1	0	32	1
Phase IV	2	0	1	1	2	0	1	2
Other: Bioequivalence	0	494	6	499	1	1	7	492

3.1.6. Safety protection measures for participants

From 2013 to 2025, the majority of registered drug clinical trials for depression did not establish a Data

Monitoring Committee (DMC). For 501 trials (74.2%), trial-related injury insurance was purchased for participants, while 174 trials (25.8%) did not purchase such insurance. The number of clinical trials that purchased trial-related injury insurance for participants significantly exceeded those that did not. See **Table 3**.

Table 3. Protection of participants in registered drug clinical trials for depression in China

Stage	With DMC	Without DMC	Purchased insurance	Did not purchase insurance
Stage I	4 (4.1%)	93 (95.6%)	71 (73.2%)	26 (26.8%)
Stage II	9 (21.4%)	33 (78.6%)	36 (85.7%)	6 (14.3%)
Stage III	6 (18.2%)	27 (81.8%)	27 (81.8%)	6 (18.2%)
Stage IV	0 (0%)	3 (100%)	2 (66.7%)	1 (33.3%)
Other: Bioequivalence	2 (0.4%)	498 (99.6%)	365 (73%)	135 (27%)

3.2. Distribution of sponsors

The top 10 participating institutions in terms of the number of clinical trials for depression drugs are presented.

The data reveal that domestic pharmaceutical companies hold an absolute dominant position, with significant differences in the R&D characteristics of leading institutions: Jiangsu Nhwa leads with 26 trials, establishing itself as a frontrunner in psychotropic drugs covering the entire development cycle; Zhejiang Huahai, Shandong Jingwei, and others focus on generic/specialty drugs, reflecting the industry's characteristic of "parallel development of generics and innovative drugs"; the industry-academia-research collaboration between the Academy of Military Medical Sciences and Shiyao Group, as well as Chengdu Kanghong's strategic positioning in biologics, underscore the diverse pathways of innovative R&D.

Meanwhile, the primary participation years of these institutions are concentrated between 2017 and 2025, aligning with the rapid growth trend in depression drug R&D in recent years and highlighting the core competitiveness of domestic enterprises in this field. See **Table 4**.

Table 4. Distribution of sponsors in registered drug clinical trials for depression in China

Rank	Sponsor name	Number of trials	Main participation years	Core features
1	Jiangsu Nhwa Pharmaceutical Co., Ltd.	26	2018–2025	Involved in Phase I-IV projects; generic drugs + innovative drugs
2	Zhejiang Huahai Pharmaceutical Co., Ltd.	18	2019–2024	Primarily bioequivalence studies
3	Shandong Jingwei Pharmaceutical Co., Ltd.	14	2020–2025	Primarily bioequivalence studies
4	Institute of Pharmacology and Toxicology, Academy of Military Medical Sciences, PLA / CSPC Pharmaceutical Group	11	2017–2023	Industry-academia-research collaboration
5	Jiangsu Hansoh Pharmaceutical Group Co., Ltd. / Shanghai Hansoh Biomedical	10	2019–2024	Innovative drug company; primarily Phase III trials
6	Hunan Dongting Pharmaceutical Co., Ltd.	9	2021–2025	Primarily bioequivalence studies
7	PKU HealthCare Corp., Ltd.	9	2020–2024	Primarily bioequivalence studies
8	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	9	2018–2023	Dual focus: biological products + chemical drugs
9	Shandong Luye Pharmaceutical Co., Ltd.	8	2022–2025	Phase I-III projects; primarily Phase I projects
10	Hebei Longhai Pharmaceutical Co., Ltd.	8	2021–2024	Primarily bioequivalence studies

3.3. Distribution of principal research institutions

From 2013 to 2025, among the registered drug clinical trials for depression, 235 principal research institutions undertook a total of 675 projects. The results show that Beijing Anding Hospital affiliated with Capital Medical University led with 58 trials (accounting for 8.6%), which was 2.2 times that of the second-ranked Shanghai Mental Health Center (26 trials). The top five institutions collectively undertook 131 trials (19.4%). See **Figure 2**.

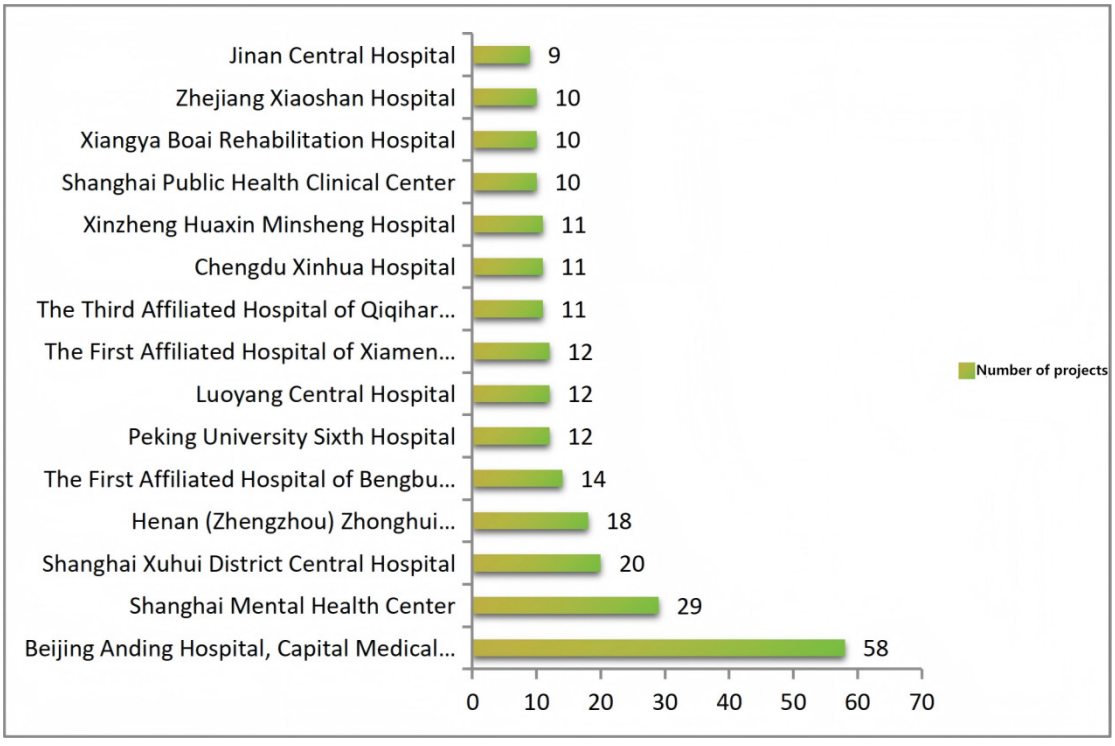


Figure 2. Distribution of principal research institutions in registered drug clinical trials for depression in China.

4. Discussion

This study included 675 drug clinical trials for depression registered between 2013 and 2025. The annual number of trial registrations has remained stable above 70 since 2020, with sustained high levels in 2024–2025, and a trial completion rate as high as 74.1%. Only 3.4% of projects were voluntarily suspended or terminated, reflecting not only the urgent clinical demand but also the stability and continuity of China's antidepressant research field. This trend is directly related to the substantial disease burden of depression in China and corresponds to the policy orientation of the National Medical Products Administration in recent years, which has successively introduced measures to encourage drug innovation and optimize the review and approval process [6,7]. Currently, chemical drugs remain the mainstream in depression drug R&D in China, with a notable absence of biological products. This may be due to the relative maturity of chemical drugs in R&D, production, and application, as well as their proven efficacy and stability. Although biological products account for a relatively low proportion in antidepressant clinical trials, their potential in depression treatment cannot be overlooked. This phenomenon may indicate that biological products are in the early stages of exploration and development for depression treatment, with the potential to offer new therapeutic breakthroughs in the future.

Data on the R&D stages show that bioequivalence trials account for a high proportion (74.1%),

significantly exceeding the proportions of early-stage innovative drug exploration (Phase I, 14.4%) and confirmatory research (Phase II/III, 11.1%). This reflects that the current domestic antidepressant drug R&D is primarily driven by the market launch of generic drugs and the improvement of dosage forms of existing drugs, highlighting the urgent need to strengthen R&D capabilities for innovative drugs targeting new targets. The clinical R&D pipeline for innovative drugs is relatively weak, with gaps compared to international breakthroughs in areas such as rapidly acting antidepressants (e.g., NMDA receptor antagonists) [8,9].

In terms of trial design, trials at each stage generally adhere to corresponding scientific design principles, with Phase II/III trials commonly adopting the "gold standard" design of randomized, double-blind, parallel-controlled trials. The Data Monitoring Committee (DMC) is crucial for independently assessing safety and efficacy data, trial progress, and protecting the rights and interests of participants during trials [10]. Among the trial phases, the design rate of DMCs is relatively high in Phase II and III trials. The 2006 DMC guidelines state that early-stage exploratory Phase I trials typically do not establish a DMC, whereas Phase III trials should more frequently incorporate a DMC [11]. As the number of participants increases from Phase I to Phase III, the complexity and risks of trials also rise. Phase I trials primarily focus on preliminary safety and efficacy assessments in small sample populations, while Phase III trials further evaluate drug efficacy and safety over longer periods, with larger sample sizes and higher failure risks. Therefore, establishing a DMC is more conducive to promptly identifying potential risks and better ensuring participant safety and trial progress.

Clinical trials are inherently accompanied by risks, and despite implementing a series of risk control measures, unexpected adverse events or other unforeseen circumstances may still occur. In the event of serious adverse events, sponsors and clinical research institutions may face substantial financial compensation [12]. Therefore, it is particularly important for sponsors to purchase trial injury insurance for participants. In China's depression drug clinical trials, 74.2% of trials involve the purchase of insurance, indicating that most sponsors comply with national regulations and purchase clinical trial injury insurance for participants. This not only effectively protects the rights and interests of participants but also transfers potential risks faced by sponsors during clinical trials. However, if the purchased insurance does not cover the compensation required for trial-related damages, sponsors remain fully responsible for the damages suffered by participants due to trial participation. Purchasing clinical trial insurance does not exempt sponsors from their legal obligations in the event of damages or disputes during trials; sponsors must continue to ensure timely and effective fulfillment of their protective and compensatory responsibilities towards participants [13].

The 675-antidepressant drug clinical trials included in this study were primarily applied for by domestic pharmaceutical companies. Among the top ten sponsors, companies such as Jiangsu Nhwa, Zhejiang Huahai, and Shandong Jingwei primarily focus on bioequivalence trials, reflecting that the current domestic antidepressant drug R&D is still primarily driven by the market launch of generic drugs and the improvement of dosage forms of existing drugs. This phenomenon is closely related to China's long-standing industrial foundation and policy environment centered on chemical generics [14]. However, it is noteworthy that some companies have shown a positive trend towards transitioning to innovative R&D. For example, Jiangsu Hansoh Pharmaceutical and Chengdu Kanghong Pharmaceutical not only focus on innovative chemical drugs but also explore new drug types such as biological products. The layout of "combining generics with innovation and exploring multiple avenues" reflects that domestic companies are gradually transitioning from "generic-dominated" to "balanced generics and innovation". However, overall, the clinical pipeline for original innovative drugs (especially biological products) with entirely new mechanisms of action remains weak, with

significant gaps compared to international frontiers [8,9].

Analysis of the distribution of principal research institutions shows that clinical trial resources are highly concentrated in top domestic psychiatric specialty hospitals. The top five institutions, including Beijing Anding Hospital affiliated with Capital Medical University and Shanghai Mental Health Center, undertake nearly 20% of trial projects. Sponsors typically prefer to select medical institutions with significant influence in the disease field as research units. These institutions not only possess solid professional expertise but also have researchers with high academic backgrounds and professional authority. Additionally, these institutions usually have abundant patient resources, facilitating the recruitment of eligible participants in a shorter time, thereby improving the efficiency and quality of clinical trial progress [15].

5. Conclusion

In summary, the number of clinical trials for antidepressant drugs in China has steadily increased, and the system operates generally stably. However, structural characteristics and challenges persist, including a low proportion of innovative drug R&D, a near-absence in the biological products field, concentrated distribution of R&D resources, a lack of international cooperation, and insufficient attention to key populations such as adolescents. There is significant room for exploration in this R&D field. It is hoped that pharmaceutical companies and R&D institutions will further enhance their sustained attention to depression drug research, increase R&D investment, promote innovative drug R&D, and diversify existing drug types, thereby providing more safe and effective treatment options for patients with depression.

Research Limitations: This study is a cross-sectional descriptive analysis based on a registration platform. While it can reflect the macroscopic characteristics and trends of registered trials, it cannot obtain specific efficacy and safety result data from the trials. Additionally, the completeness and timeliness of information updates on the platform may impact the analysis.

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Disclosure statement

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Analysis of Reasons for Suspension of Drug Clinical Trials Between China and Other Countries

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Abstract: *Objective*: To analyze the various reasons for the suspension of drug clinical trials, provide suitable solutions to reduce the incidence of such suspensions, prevent wastage of resources, and enhance the completion rate of clinical trials. *Method*: Relevant information on drug clinical trials suspended in China and other countries was retrieved from "Drug Clinical Trial Registration and Information Disclosure Platform" and "ClinicalTrials.gov". Various factors were statistically summarized, comparing the reasons for clinical trial suspensions between China and other countries, and analyzing differences among groups in various classification variables, including indications, years, trial phases, and types of drugs. *Result*: A total of 323,248 drug clinical trials were conducted internationally, with a suspension rate of 0.48% (1,564/323,248). Within this dataset, China reported 377 suspended clinical trials, constituting 1.66% (377/22,703) of its total studies, while other countries conducted a total of 300,545 clinical trials, resulting in a suspension rate of 0.39% (1,187/300,545). The primary cause of suspension in various countries was attributed to issues related to sponsors and funding. Notably, there existed a statistically significant difference in the number of suspended trials between China and other countries ($p < 0.05$). *Conclusion*: During the research preparation phase, sponsors should meticulously assess the feasibility of clinical trials and exercise prudence in development decisions. The clinical trial protocol design must prioritize safety and scientific validity. Research teams should be equipped with emergency risk control measures, adhere to pertinent laws and regulations governing clinical trial, and ensure adequate management. Thus, drug clinical trials can only be conducted with high quality, thereby ensuring the progression of drug marketing.

Keywords: Drug clinical trial; Suspension; Reasons; China and other countries; Measures

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1. Introduction

Development of a new drug necessitates progressing through the phases of clinical trials. Clinical trials involve systematic research on drugs, aiming to assess their efficacy, adverse reactions, and dynamic changes within the human body. It aims to determine whether the investigational drug poses significant health risks or produces expected therapeutic outcomes [1–3]. Clinical trials are usually conducted in distinct phases, encompassing phase I to IV, bioequivalence (BE) and bioavailability studies (BA) [4–6].

The first proposed definition of Clinical Hold (CH) was introduced by the United States Food and Drug Administration (FDA). It represents a mandatory directive, requiring applicants to suspend or delay the clinical trial [7,8]. Once the Investigational New Drug (IND) is submitted, the clinical trial will be initiated and progress through various phases. Throughout this entire period, the trial may be suspended at any time.

During the various phases, unforeseen factors or overlooked aspects may lead to suspension, resulting in irreversible losses for all parties involved. Studies have shown that the development of an innovative drug typically spans from 7.3 to 10.5 years, with costs ranging from $0.8 billion to $2.3 billion, escalating at an annual rate of 8.5% [9–11]. Notably, approximately 60% to 70% of these costs are attributed to the clinical trial phase, yet an alarming 80% of trials fail to meet their designated timelines [12,13]. The halting of clinical trials not only wastes financial resources, time, and effort invested, but also poses risks to the rights and health of the participants.

Although the suspension of trials may result in losses for sponsors, investors, companies, researchers, and participants, there is still a lack of further research on this issue, with few studies have provided comprehensive analyses of the reasons for clinical trial suspension [14]. Therefore, this paper provides a comprehensive review of clinical trials halted in China and other countries, analyze the factors causing trial suspension and propose several constructive solutions. In the final section this study will consider possible plans to prevent the suspension of clinical trials, intend to tackle this one of the significant challenges in the current drug development process.

2. Data and methods

2.1. Data

Chinese data were sourced from the “Drug Clinical Trial Registration and Information Disclosure Platform” (http://www.chinadrugtrials.org.cn/index.html). The search criteria were defined as “suspended,” including “voluntary suspension”, “IEC/IRB suspension”, and “ordered by oversight agencies”, screening clinical trials registered from January 1, 2014, to December 31, 2023.

The data from other countries were sourced from “ClinicalTrials.gov” (https://clinicaltrials.gov/), with the search criteria were consistent with those for Chinese data.

Based on the above terms, this study organized relevant research data and reasons for suspension, conducted summarization, and performed statistical analysis.

2.2. Analysis methods

The information from suspended clinical trials was collected and analyzed. Variables included drug type, indication, trial phase, site and location, and reasons for suspension. These variables were then compared between China and other countries.

2.3. Statistical methods

Based on specific variables, classification and statistical analysis were performed using SPSS software. Additionally, this study conducted a comprehensive assessment of clinical trials, comparing between China and other countries. The Chi-square (χ^2) statistic was utilized to examine count variables. Differences were determined using a significance level of $p < 0.05$.

3. Results

3.1. Current situation of suspension in China and other countries

This study conducted statistical analyses to determine the annual total number of clinical trials and suspended trials in China and other countries from January 1, 2014 to December 31, 2023. The results (**Figure 1**, **Figure 2**) indicate that since 2016, there has been a consistent annual rise in the number of clinical trials in China, accompanied by the highest suspension rate (5.20%) observed in that year, which is the highest proportion over the past decade. Subsequently, the suspension rate has shown a decreasing trend each year. On the other hand, clinical trials have remained active in other countries over the past decade, showing a continuous upward trend, and the suspension rate has also declined annually since 2019. Comparing the two groups reveals that the suspension rate of clinical trials is significantly lower in other countries than in China.

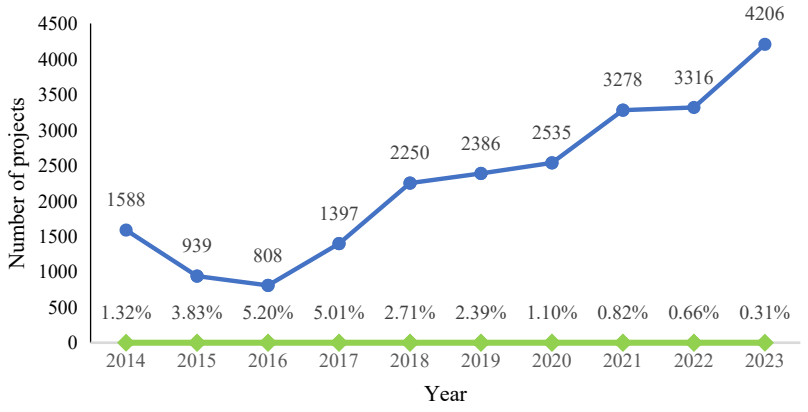


Figure 1. The quantity of drug clinical trials and the proportion of suspensions in China.

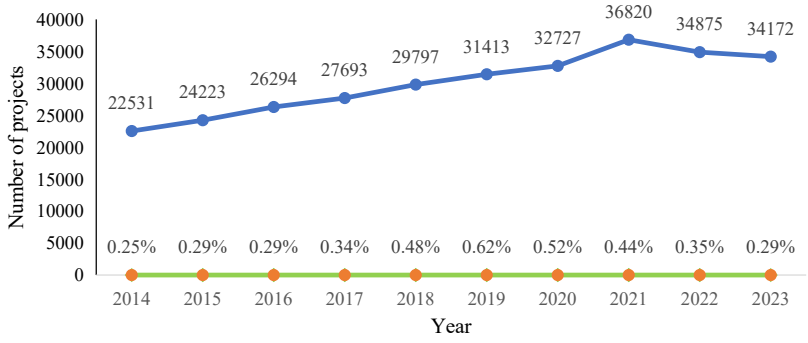


Figure 2. The quantity of drug clinical trials and the proportion of suspensions in other countries.

Over the past decade, China conducted a total of 22,703 drug clinical trials, with 377 trials suspended, accounting for 1.66% (377/22,703). In comparison, other countries conducted 300,545 drug clinical trials, with 1,187 trials suspended, accounting for 0.39% (1,187/300,545). Both countries conducted 323,248 clinical trials, with 1,564 trials suspended, the ratio is 0.48% (1,564/323,248).

These results indicate a higher proportion of suspended clinical trials in China compared to other countries. The chi-square test indicates a statistically significant difference between the two groups ($p < 0.05$) (**Table 1**).

Table 1. Chi square test of suspended drug clinical trials

	Whether drug clinical trials are suspended?		χ^2	p
	Yes	No		
China	377	22326	702.22	0.00
Other countries	1187	299358		

3.2. Characteristics and categorization of suspended clinical trials in China

The information regarding the suspended clinical trials was summarized into drug type, indication, trial phase, site and location, and registration year of the trial. **Table 2** shows that, in terms of drug type, chemical drugs constituted the largest proportion of suspension, at 77.94% (275/377), surpassing half of all trials suspended in China; biopharmaceutical products accounted for 20.69% (78/377), ranking second; and traditional Chinese medicine/natural drugs had the lowest proportion, at 6.37% (24/377). Regarding trial phase, the proportions of suspended clinical trials for Phase I, II, III, IV, BE, and other phases were 17.51% (66/377), 14.06% (53/377), 19.36% (73/377), 1.06% (4/377), 9.28% (35/377), and 38.73% (146/377) respectively. Although the proportion of other phases was the highest, encompassing a variety of trial phases, they were insufficient to pinpoint specific issues.

Therefore, they were excluded when comparing the two sets of data in the subsequent section. The second-highest proportion of suspended trials consisted of Phase III and Phase I clinical trials, while Phase IV clinical trials had the lowest proportion of suspensions. In terms of site and location, the highest proportion of suspended study centers was local, at 85.41% (322/377), while international multicenter trials accounted for a smaller proportion, at 14.59% (55/377). Regarding indications, oncology clinical trials had the largest proportion of suspensions among all types, at 24.40% (92/377), and it was the only type with a suspension proportion exceeding 20% among other indications.

Only cardiovascular and hematologic system, immune system or anti-infective agent, nervous system, and endocrine and metabolic system clinical trials had suspension proportions exceeding 10%. Concerning years, the highest proportion of suspended clinical trials occurred in 2017, at 18.57% (70/377), while the proportions for 2018 and 2019 were around 15% (61/377, 57/377). And for 2016, it was 11.14% (42/377). The proportions of suspension in other years did not exceed 10%. (**Table 2**).

Table 2. Information and categorical variables of suspended clinical trials in China

Information	Categorical variables	Number of suspended clinical trials	Suspension proportion
Drug type	Chemical drugs	275	72.94%
	Biological products	78	20.69%
	Traditional Chinese medicine/natural drugs	24	6.37%
Trial phase	Phase I	66	17.51%
	Phase II	53	14.06%
	Phase III	73	19.36%
	Phase IV	4	1.06%
	BE	35	9.28%
	Other phases	146	38.73%
Site and location	Local study centers	322	85.41%
	International multicenter trials	55	14.59%
Indications	Tumors	92	24.40%
	Cardiovascular and hematologic system	61	16.18%
	Respiratory system	16	4.24%
	Immune system or anti-infective agent	54	14.32%
	Endocrine and metabolic system	46	12.20%
	Digestive system	33	8.75%
	Nervous system	47	12.47%
	Urinary reproductive system	12	3.18%
	Musculoskeletal system	6	1.59%
	Other system	10	2.65%
Year	2014	21	5.57%
	2015	36	9.55%
	2016	42	11.14%
	2017	70	18.57%
	2018	61	16.18%
	2019	57	15.12%
	2020	28	7.43%
	2021	27	7.16%
	2022	22	5.84%
	2023	13	3.45%

3.3. Classification of reasons for suspended clinical trials in China and other countries

Due to the significant number of trials that have been suspended, the reasons for these suspensions vary. To facilitate analysis and statistics, we categorized the reasons for suspension in both countries into ten major categories, as outlined below [14–16]:

(1) Sponsor-related suspension

This includes decisions made by sponsors to suspend trials, insufficient funding for clinical trials, adjustments to research and development strategies, restarting trials in compliance with existing regulations and requirements, pessimistic market prospects for investigational drugs, voluntary suspension following sponsor inspections, failure to comply with government regulations or commercial decisions, etc.;

(2) Suspension related to participant recruitment

This encompasses difficulties in recruiting patients, a lack of eligible trial populations, and failure to meet expected recruitment targets, etc.;

(3) Suspension related to study results

This category involves non-significant study results, unsatisfactory outcomes, poor medical efficacy observed in the trial, lack of significant efficacy in interim analyses, and failure to achieve primary study outcomes, etc.;

(4) Safety concerns

This category pertains to the presence of safety hazards, occurrences of toxicities in patients after medication administration, and occurrence of serious adverse events (SAEs) or suspected unexpected serious adverse reactions (SUSARs) related to severe safety issues, etc.;

(5) Suspension related to protocol amendments

This includes modification to certain protocol contents, inadequacies in initial protocol design requiring amendments, and adjustments of control groups, etc.;

(6) Issues related to the investigational drugs

This category includes the requirement to adjust the drug manufacturing process, discovery of carcinogens in drugs, changes in production sites, inadequate drug supply, high variability in drugs, non-compliance of manufactured drugs, use of expired drugs during clinical trials, inability to provide new drugs before the expiration date of the last batch approaches, and replacement of drugs used in the trial, etc.;

(7) Related to clinical research units

This involves turnover of key investigators, investigators unwilling to participate in the research, researchers withdrawing from the study due to personal reasons, relocation of research sites, incomplete equipment at units, outdated equipment, etc.;

(8) Impact of the COVID-19 pandemic

This category relates to the outbreak of the pandemic resulting in stagnation of trials, etc.;

(9) Reasons that are unclearly specified;

(10) Other reasons

This includes issues with electronic data capture (EDC) systems, exemptions according to existing regulations and requirements, issues with collaborators, inability to perform laboratory tests or obstacles encountered during laboratory tests on patient samples, and expiration of clinical trial approvals, etc.

3.3.1. Reasons for suspension of drug clinical trials in China

In China, the primary reasons for suspending drug clinical trials are related to sponsors, including their decisions to suspend trials, insufficient funding to complete research, and adjustments to research and development strategies. This factor accounts for 32.63% (123/377) of clinical trial suspensions in China. Secondary reasons for suspension are issues related to trial results, such as non-significant outcomes, lack of efficacy, and failure to achieve expected study outcomes, accounting for 22.28% (84/377) of suspensions. Protocol amendments and issues related to investigational drugs also contribute to suspensions in China, representing 12.20% (46/377) and 10.61% (40/377) respectively. These findings suggest a close association between trial suspension in China and these factors. The proportions of other reasons for suspension are detailed in **Table 3**.

Table 3. Comparison of reasons for suspension of drug clinical trials in China and other countries

Reasons classification	China		Other countries	
	Number of suspended clinical trials	Suspension proportion	Number of suspended clinical trials	Suspension proportion
1. Sponsors	123	32.63%	205	17.27%
2. Participant recruitment and enrollment	21	5.57%	94	7.92%
3. Study results	84	22.28%	93	7.83%
4. Safety concerns	12	3.18%	25	2.11%
5.Protocol amendments	46	12.20%	45	3.79%
6. Investigational drugs	40	10.61%	58	4.89%
7. Clinical research units	23	6.10%	91	7.67%
8. Impact of the COVID-19 pandemic	7	1.86%	200	16.85%
9. Reasons that are unclearly specified	1	0.27%	275	23.17%
10. Other reasons	20	5.31%	101	8.51%
Total	377	100.00%	1187	100.00%

3.3.2. Reasons for suspension of drug clinical trials in other countries

In other countries, the highest proportion of drug clinical trials suspended is attributed to reasons not clearly specified, accounting for 23.17% (275/1187). These suspended trials did not specify exact reasons for the suspension, thus cannot serve as accurate grounds for assessing the reasons of trial suspension. In addition to this factor, another significant cause of suspension in other countries, similar to China, is suspension caused by sponsors, which account for 17.27% (205/1187). Furthermore, the impact of the COVID-19 pandemic on clinical trials has been substantial in other countries, with a suspension proportion reaching 16.85% (200/1187). Other reasons did not exceed 10% in proportion. Refer to **Table 3** for more details.

3.3.3. Comparative analysis of reasons for suspension of drug clinical trials in China and other countries

This study compared the reasons for suspension of drug clinical trials in China and other countries (**Table 3**), and the results indicated differences in the reasons leading to suspensions between two groups. In China, the primary reason for suspensions was sponsor-related, while in other countries, the leading cause remained unspecified. However, in China, only 0.27% (1/377) of suspensions were due to unspecified reasons,

substantially lower compared to other countries. The difference in trial suspensions due to safety reasons between the two groups is similar. Additionally, the second-largest reason for suspension in China was related to trial outcomes, whereas in this aspect, the suspension rate in other countries was much lower than in China (7.83% vs 22.28%).

4. Discussion

Sponsors play a pivotal role throughout the entirety of clinical trials, undertaking tasks such as initiating and organizing the trials. Additionally, they provide funding, contribute to the design of the trials, ensure the preparation of all required experimental materials, and manage various other responsibilities. Essentially, sponsors play a central role in ensuring the quality of drug development and expediting the market entry of new drugs [17,18]. Therefore, as a crucial aspect, an error or omission in any of these steps has the potential to disrupt the smooth progress of the clinical trial, resulting in its suspension. Based on the China Good Clinical Practice (GCP) guidelines and relevant guidance from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) , along with insights from this paper and related research [4,19,20]. The following recommendations are proposed to minimize trial suspensions attributed to sponsors.

(1) Sponsors should ensure that their personnel possess sufficient knowledge and basic skills, and undergo systematic management training, to ensure effective task fulfillment by the entire team;
(2) Prior to designing the trial, sponsors should ensure they are up-to-date with the principles and requirements governing drug market entry, and fully comply with relevant laws and regulations to minimize the risk of suspension;
(3) Sponsors should create appropriate risk management policies specific to the clinical trial, to proactively mitigate potential risks and respond promptly to emergencies;
(4) Sponsors should enhance monitoring and management throughout the trial implementation to promptly detect any issues and take preventive measures, identify suspicious risks, reduce the likelihood of errors, and increase the rate of completing the clinical trial.

Amendments to the clinical trial protocol may impact the progress and potentially result in delays or suspensions [21,22]. Given the professionalism and feasibility of each trial step, strict adherence to the official guidelines of protocol design is essential before protocol development. By integrating multiple articles, the following suggestions emerge [23,24].

(1) Engaging experienced medical writers with a robust knowledge base is vital for drafting the trial protocol. These writers should be well-versed in the process of clinical trials, ensuring precision and coherence in writing.
(2) Considering the intricate nature of protocol design spanning multiple domains, it is crucial to seek input from professionals across various fields. Collaborative engagement and discussion among multiple investigators are essential to bolster the robustness and feasibility of the protocol. This collaborative effort facilitates the seamless execution of the clinical trial protocol and helps minimize the need for protocol modifications during the trial, thereby preventing resource wastage.
(3) Medical writers of clinical trial protocols should thoroughly and accurately review relevant regulations to ensure compliance with government requirements and guidelines, thus avoiding the revisions of protocol due to non-compliance.

The COVID-19 pandemic underscored the critical need for clinical trials to be resilient to unexpected disruptions, prompting recommendations such as cultivating crisis awareness through regular training, improving dynamic emergency plans and crisis management systems, enhancing inter-departmental coordination to resolve issues systematically, leveraging electronic systems for remote trial management, and continuously summarizing past experiences to develop multiple contingency plans for future risks [25].

By systematically analyzing potential causes of suspensions during the clinical trial, and implementing appropriate interventions, the quality of clinical trial execution can be improved. This helps mitigate the impact of various risks during the research, thus minimizing the occurrence of clinical trial suspension and reducing research investment losses.

5. Conclusion

In conclusion, a meticulous and responsible approach to the clinical trial preparation phase is fundamental. By prioritizing safety, scientific validity, and regulatory compliance, and by ensuring robust emergency measures are in place, sponsors can guarantee the high-quality execution of trials. This disciplined process is essential for the successful and safe progression of drugs toward market approval.

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Intervention Study of Solution-Focused Approach on Negative Emotions and Self-Management in Patients with First-Episode Acute Ischemic Stroke

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Abstract: *Objective*: To evaluate the intervention effect of the Solution-Focused Approach (SFA) on negative emotions, emotional self-management ability, and self-efficacy in patients with first-episode acute ischemic stroke (AIS). *Methods*: A quasi-experimental study design was adopted. A total of 64 first-episode AIS patients with negative emotions were randomly divided into a control group and an intervention group. The control group received routine psychological nursing, while the intervention group received structured psychological intervention based on SFA in addition to routine nursing. Before the intervention and after the last intervention, the Self-Rating Anxiety Scale (SAS), Self-Rating Depression Scale (SDS), Emotional Self-Management Behavior Scale, and Stroke Self-Efficacy Questionnaire (SSEQ) were used for effect evaluation. *Results*: After the intervention, the decrease in anxiety and depression scores, as well as the increase in emotional self-management behavior and self-efficacy scores in the intervention group, were significantly better than those in the control group ($p < 0.05$). *Conclusion*: SFA can effectively alleviate anxiety and depression symptoms in patients with first-episode AIS, improve their emotional self-management ability and self-efficacy, and is a clinically valuable empowering psychological intervention method.

Keywords: Ischemic stroke; Negative emotions; Solution-focused approach; Psychological nursing; Self-efficacy

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1. Introduction

The incidence of negative emotions such as anxiety and depression after stroke is as high as 30–50%, which are independent risk factors affecting patients' rehabilitation process, quality of life, and long-term prognosis [1,2]. Patients with first-episode stroke are more prone to intense psychological stress reactions due to the sudden blow of the disease, uncertainty about prognosis, and sudden changes in family roles [3]. Clinical routine psychological nursing mainly focuses on supportive health education and counseling, which is insufficient in mobilizing patients'

own problem-solving abilities and internal potential, resulting in limited long-term effects.

The Solution-Focused Approach (SFA), as a short-term intervention method based on positive psychology, its core is to guide individuals to focus on their own resources and strengths, and strive to construct solutions rather than repeatedly analyzing the problem itself [4]. Studies have shown that SFA has achieved good results in emotional management and self-efficacy improvement of patients with chronic diseases [5–7]. However, its application effect in the acute phase and early recovery stage of patients with first-episode stroke remains to be verified. Based on this, this study aims to explore the intervention effect of SFA on improving negative emotions and psychosocial functions of patients with first-episode acute ischemic stroke, in order to provide a structured and empowering new psychological nursing strategy for clinical practice.

2. Objects and methods

2.1. Research objects

Using convenient sampling, first-episode AIS patients hospitalized in the Department of Neurology of a hospital in a district of Shanghai from June to December 2024 were selected.

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria of Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke 2023 [8];
(2) First onset;
(3) Age ≥ 40 years old;
(4) Clear consciousness, no communication barriers, and SAS standard score ≥ 50 points and/or SDS standard score ≥ 53 points;
(5) Informed consent

2.1.2. Exclusion criteria

(1) Severe organ dysfunction
(2) Severe cognitive impairment
(3) History of mental illness.

2.1.3. Grouping

Patients were divided into the intervention group and the control group using a random number table method.

2.2. Intervention methods

2.2.1. Control group

Routine psychological nursing in the Department of Neurology was implemented, including admission environment introduction, disease knowledge education, supportive emotional counseling, and rehabilitation guidance.

2.2.2. Intervention group

On the basis of routine nursing, nurses trained uniformly implemented SFA intervention, totaling 4 times. The

intervention framework is as follows:

(1) Describing problems and constructing goals (2–3 days after admission): Understanding patients' views on the disease and emotional distress, and jointly setting specific and positive short-term rehabilitation goals (such as "trying to walk for 5 minutes with family members' accompaniment within this week");
(2) Exploring exceptions and resources (1 day before discharge): Guiding patients to review past experiences of successfully coping with difficulties and exploring internal strengths of individuals and families;
(3) Feedback and adjustment (1 week after discharge, by phone/WeChat): Summarizing progress, providing positive feedback, and adjusting strategies for new problems;
(4) Consolidation and evaluation (3 weeks after discharge, by phone/WeChat): Assessing the degree of goal achievement, strengthening self-management confidence, and encouraging the application of the model to future challenges. Each intervention lasted 30–60 minutes.

2.3. Research tools and evaluation indicators

Data were collected before the intervention and after the 4th intervention.

(1) General information questionnaire
Self-designed.
(2) Self-rating anxiety scale (SAS) and Self-rating depression scale (SDS) [9]
Standard scores were used to evaluate the severity of anxiety and depression, with higher scores indicating more severe symptoms.
(3) Emotional self-management behavior scale [10]
5 items, using a 5-point scoring method, with higher total scores indicating better self-management behaviors.
(4) Stroke self-efficacy questionnaire (SSEQ) [11]
13 items, with a total score of 13–130 points, and higher scores indicating stronger self-efficacy.

2.4. Statistical methods

SPSS 25.0 software was used for analysis. Measurement data were described as $\overline{x} \pm s$, and inter-group comparison was performed using independent sample *t*-test or Mann-Whitney U test; intra-group pre- and post-comparison was performed using paired *t*-test or Wilcoxon signed-rank test. Count data were described as frequency and percentage, and χ^2 test was used. A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Baseline equilibrium of research objects

There were no statistically significant differences between the two groups of patients in general data, as well as anxiety, depression, self-management behavior, self-efficacy, and quality of life before the intervention ($p > 0.05$), indicating comparability, as shown in **Table 1**.

Table 1. Baseline comparison of general demographic data

Variables	Total (n = 64)	Intervention group (n = 32)	Control group (n = 32)	χ^2/t	p
Gender				0.577	0.448
Male	37 (57.81%)	17 (53.13%)	20 (62.50%)		
Female	27 (42.19%)	15 (46.88%)	12 (37.50%)		
Age (years)	57.20 ± 12.77	58.34 ± 11.91	56.06 ± 13.67	0.638	0.727
< 50	21 (32.81%)	9 (28.13%)	12 (37.50%)		
50–65	28 (43.75%)	15 (46.88%)	13 (40.63%)		
> 65	15 (23.44%)	8 (25.00%)	7 (21.88%)		
Place of residence				0.110	0.500
Urban	53 (82.81%)	26 (81.25%)	27 (84.38%)		
Rural	11 (17.19%)	6 (18.75%)	5 (15.63%)		
Educational level				1.016	0.602
Primary school and below	14 (21.87%)	6 (18.75%)	8 (25.00%)		
Junior high school/Senior high school/ Technical secondary school	36 (56.25%)	20 (62.50%)	16 (50.00%)		
College and above	14 (21.88%)	6 (18.75%)	8 (25.00%)		
Marital status				0.350	0.500
Married	61 (95.31%)	30 (93.75%)	31 (96.88%)		
Divorced/Widowed	3 (4.69%)	2 (6.25%)	1 (3.13%)		
Occupation				4.594	0.467
State organ cadres	6 (9.38%)	4 (12.50%)	2 (6.25%)		
Professional and technical personnel	12 (18.75%)	5 (15.63%)	7 (21.88%)		
Institution staff	7 (10.94%)	3 (9.38%)	4 (12.50%)		
Workers	25 (39.06%)	14 (43.75%)	11 (34.38%)		
Commercial service personnel	11 (17.19%)	6 (18.75%)	5 (15.63%)		
Unemployed	3 (4.69%)	0 (0.00%)	3 (9.38%)		
SAS	53.44 ± 5.53	53.79 ± 5.93	53.08 ± 5.18	0.480	0.633
SDS	56.14 ± 6.90	57.41 ± 6.80	54.87 ± 6.88	1.392	0.170
Self-efficacy	73.34 ± 11.50	72.75 ± 10.12	73.93 ± 12.90	-0.380	0.705
Self-management behavior	16.75 ± 3.11	16.18 ± 3.00	17.32 ± 3.20	-1.388	0.171
Emotional quality of life	17.21 ± 2.87	17.24 ± 2.73	17.19 ± 3.06	0.073	0.943

3.2. Comparison of indicators between the two groups before and after intervention

A total of 8 cases were lost during the study, and finally 29 cases in the intervention group and 27 cases in the control group completed the entire study. After the intervention, the SAS and SDS scores of both groups were significantly lower than those before the intervention ($p < 0.05$). However, the decrease in SAS and SDS in the intervention group was significantly greater than that in the control group ($p < 0.01$). The emotional self-

management behavior scores and SSEQ score of the intervention group were significantly improved after the intervention ($p < 0.05$), and the improvement range was significantly better than that of the control group ($p < 0.05$), as shown in **Table 2**.

Table 2. Comparison of anxiety and depression between the two groups before intervention

Intervention variables	Before intervention	After intervention	*t*	*p*	Difference (After-Before)	t (Difference)	p (Difference)
SAS						4.009	0.001
Intervention group	53.71 ± 5.84	48.75 ± 5.30	6.815	0.001	4.96 ± 3.92		
Control group	53.15 ± 5.26	51.81 ± 5.98	2.621	0.014	1.34 ± 2.66		
t	0.375	-2.026					
p	0.709	0.048					
SDS						3.006	0.004
Intervention group	56.85 ± 7.32	49.01 ± 7.83	6.412	0.001	7.85 ± 6.59		
Control group	55.37 ± 6.47	52.69 ± 8.72	0.806	0.034	2.69 ± 6.28		
t	0.801	-1.622					
p	0.426	0.102					
Self-management behavior						-2.394	0.020
Intervention group	16.34 ± 3.04	17.66 ± 2.35	-2.666	0.013	-1.31 ± 2.65		
Control group	17.19 ± 3.17	17.19 ± 2.77	0.000	0.999	0.00 ± 1.07		
t	-1.012	0.686					
p	0.316	0.496					
Self-efficacy						-8.230	0.001
Intervention group	72.72 ± 9.94	87.86 ± 14.39	-11.307	0.001	-15.14 ± 7.21		
Control group	74.00 ± 13.14	75.44 ± 15.93	-1.519	0.141	-1.44 ± 4.94		
t	-0.412	0.682					
p	3.053	0.003					
Quality of life						-2.422	0.019
Intervention group	17.24 ± 2.73	18.66 ± 2.87	-1.978	0.058	-1.41 ± 3.85		
Control group	17.19 ± 3.06	16.56 ± 3.46	1.509	0.143	0.63 ± 2.17		
t	0.073	0.942					
p	2.480	0.016					

4. Discussion

4.1. SFA can effectively alleviate post-stroke negative emotions

Compared with routine supportive nursing, SFA has shown better effects in reducing patients' anxiety and depression levels. The mechanism may be that SFA transforms patients' vague worries (such as "I'm finished") into specific and operable actions (such as "completing rehabilitation training today") through "constructing

goals", reshaping their sense of control over the disease. At the same time, "exploring exceptions" guides patients to focus on their past successful coping experiences rather than indulging in current problems, breaking the vicious cognitive cycle of "disease-negative emotions-functional withdrawal" [12]. The results of this study are consistent with the intervention effect of SFA in patients with other chronic diseases, confirming its effectiveness as a transdiagnostic and resource-oriented psychological intervention method [13,14].

4.2. SFA empowers patients by improving self-efficacy

A prominent finding of this study is that SFA significantly improved patients' self-efficacy. Self-efficacy is a core mediator of health behavior change and maintenance [15]. The intervention process of SFA is essentially a continuous "empowerment" process: the interventionist constantly strengthens patients' belief of "I can do it" by affirming every bit of their efforts and progress, such as "being able to think of that successful experience in the past is an ability in itself". When patients personally achieve preset small goals through their own efforts, their confidence in managing disease-related emotions is substantially consolidated. This improved self-efficacy may prompt patients to more actively apply the strategies learned in the intervention to daily emotional regulation, thereby forming a virtuous cycle of "skill mastery-enhanced efficacy → sustained behavior", which is a deeper benefit beyond symptom relief [16].

4.3. Clinical significance and limitations

This study provides preliminary evidence for the implementation of SFA in the early rehabilitation of stroke. The model has a clear process and relatively short time consumption, which is suitable for being carried out by trained nurses in clinical nursing work, and has good clinical transformation potential. The limitations of this study include small sample size and short follow-up time. In the future, multi-center, large-sample randomized controlled trials should be carried out, and the follow-up period should be extended to evaluate the long-term stability of the effect, as well as to explore its indirect impact on patients' neurological function rehabilitation, quality of life and other indicators.

5. Conclusion

SFA, as an empowering psychological intervention, can effectively alleviate anxiety and depression symptoms in patients with first-episode AIS, enhance their emotional self-management ability and self-efficacy. Therefore, it holds significant clinical value and warrants further application and promotion.

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The Efficacy of Flexible Negative Pressure Suction Sheath Combined with Flexible Ureteroscopy Lithotripsy in the Treatment of Upper Urinary Tract Calculi and Its Impact on Postoperative Quality of Life

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Abstract: *Objective*: To evaluate the therapeutic efficacy of Flexible Vacuum Suction Ureteral Access Sheath (FVSUAS) combined with Flexible Ureteroscopy Lithotripsy (FURL) for Upper Urinary Tract Calculi (UUTC). *Methods*: A total of 88 UUTC patients admitted between August 2024 and August 2025 were selected and equally divided using a random number table. The experimental group received FVSUAS combined with FURL treatment, while the reference group received conventional guide sheath combined with FURL treatment. The therapeutic effects of the two groups were compared. *Results*: The stone clearance rate in the experimental group was higher than that in the reference group, with shorter operative time and postoperative hospital stay, and lower postoperative pain scores ($p < 0.05$). The complication rate in the experimental group was lower than that in the reference group, with lower postoperative inflammatory factor levels and higher quality of life scores ($p < 0.05$). *Conclusion*: Implementing FVSUAS combined with FURL treatment for UUTC patients results in a high stone clearance rate, shorter operative time and postoperative hospital stay, alleviation of postoperative pain symptoms, fewer complications, mild postoperative inflammatory response, and a high quality of life.

Keywords: Flexible vacuum suction ureteral access sheath; Flexible ureteroscopy lithotripsy; Upper urinary tract calculi; Postoperative quality of life

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1. Introduction

Common causes of urinary system stones include urinary tract infections, metabolic abnormalities, and drug factors, with Upper Urinary Tract Calculi (UUTC) being a highly prevalent type [1]. The disease primarily affects the ureters and kidneys, presenting symptoms such as abnormal urination, lumbosacral and abdominal pain, and hematuria, which can have a long-term impact on patients' physical and mental health. Conservative drug therapy

and surgical treatment are the fundamental approaches for this condition. While these methods can remove stones, surgical techniques like Flexible Ureteroscopy Lithotripsy (FURL) can be employed to fragment the stones, facilitating their subsequent expulsion. The combination with Flexible Vacuum Suction Ureteral Access Sheath (FVSUAS) allows for flexible adjustment of the flexible ureteroscope's direction, precise localization of the stone's position, and efficient suctioning of the stones, thereby enhancing the success rate of the surgery [2]. Additionally, FVSUAS can thoroughly suction out the irrigation fluid and stone fragments during the procedure, ensuring clear visibility of the surgical field and thereby improving surgical safety. Based on this, this study selected 88 UUTC patients to evaluate the therapeutic efficacy of FVSUAS combined with FURL.

2. Materials and methods

2.1. General information

A total of 88 patients with upper urinary tract calculi (UUTC) who were admitted for treatment from August 2024 to August 2025 were selected and equally divided into two groups using a random number table. The experimental group consisted of 44 patients, including 23 males and 21 females, aged between 26 and 68 years with a mean age of (48.65 ± 4.18) years. The stone diameters ranged from 13 to 29 mm with a mean of (19.85 ± 3.57) mm. The stone locations were as follows: 18 cases at the ureteral orifice and 26 cases in the renal pelvis. The reference group also included 44 patients, with 24 males and 20 females, aged between 25 and 69 years with a mean age of (48.71 ± 4.22) years. The stone diameters ranged from 14 to 28 mm with a mean of (19.91 ± 3.50) mm. The stone locations were as follows: 17 cases at the ureteral orifice and 27 cases in the renal pelvis. There were no significant differences in the baseline data between the two groups ($p > 0.05$).

2.1.1. Inclusion criteria

Single stone with a diameter exceeding 10 mm; age under 70 years; first-time lithotripsy surgery; complete basic information; and high awareness of the study.

2.1.2. Exclusion criteria

Presence of surgical contraindications; organ dysfunction; intolerance to the anesthesia protocol; abnormal immune function; concurrent systemic infection; ureteral malformation or obstruction; and presence of consciousness disorders.

2.2. Methods

The reference group underwent conventional guide sheath combined with flexible ureteroscopy lithotripsy (FURL): General anesthesia was administered, and the patient was placed in the bladder lithotomy position. A rigid ureteroscope was inserted through the urethra into the bladder to comprehensively observe the bladder's internal condition, determine the location of the ureteral orifice, and insert a super-smooth guidewire under direct vision. The guidewire was carefully explored upwards to assess its satisfactory placement, determine the stone location, and observe for ureteral stenosis until reaching the renal pelvis. The upper ureteral stones were pushed upwards to the renal pelvis. The guidewire was retained, and the ureteroscope was slowly withdrawn to accurately measure the insertion length of the ureteroscope. A guide sheath of 11/13 Fr or 12/14 Fr was selected based on the lumen diameter and inserted along the guidewire. The inner core was removed, and a flexible ureteroscope was inserted.

The water pressure was appropriately adjusted using the irrigation pump's water inlet method, and the intrarenal pelvic pressure was dynamically monitored to ensure a clear surgical field. Simultaneously, the renal calyx status was observed, the stone location was identified, and the number of stones was recorded. The guidewire was removed, and a holmium laser fiber was inserted through the working channel of the flexible ureteroscope. The energy was set at 0.8–1.6 J, and the fiber frequency was set at 20–30 Hz to fragment the stones into fine particles. A stone basket was used to directly remove large stones, ensuring no large stone residues remained in the renal pelvis and calyces before withdrawing the ureteroscope. A guidewire was inserted using a conventional guide sheath, and after removing the channel sheath, a 5F double-J stent was placed, ensuring the distal end was within the bladder. A urinary catheter was then left in place, and the surgery was completed.

The experimental group underwent flexible vacuum suction ureteral access sheath (FVSUAS) combined with FURL: The patient's position, anesthesia method, and flexible ureteroscope insertion process were the same as those in the reference group. After inserting the flexible ureteroscope, the central negative pressure was connected to the outer end of the software, and the parameters of the negative pressure suction sheath were set to a central negative pressure of 0.01–0.03 MPa. The holmium laser was used to fragment the stones, and the fragments were fully aspirated using the negative pressure sheath. The renal pelvis and calyces were checked for large stones. After withdrawing the negative pressure suction sheath and flexible ureteroscope, a 5F double-J stent was placed, and the surgery was completed.

2.3. Observation indicators

(1) Perioperative indicators

The stone clearance rate was observed (follow-up for 3 months; color Doppler ultrasound showing a colored urinary flow signal at the physiological stenosis of the ureter with a comet-tail sign behind and no stone residue, or a residual stone diameter not exceeding 0.3 cm, was considered clearance), surgical time, postoperative hospital stay, and pain scores on postoperative days 1–3 (using the Visual Analog Scale, with scores ranging from 0 to 10 and higher scores indicating greater pain intensity).

(2) Complication rate

The incidence of complications such as hydronephrosis, hematuria, urinary tract infection, fever, renal function impairment, and perirenal hematoma was observed.

(3) Inflammatory factor level

Before surgery and on postoperative day 3, venous blood (3 mL, fasting) was collected, centrifuged at 3000 r/min for 10 minutes, and the supernatant was taken to measure the levels of C-reactive protein (CRP) and procalcitonin (PCT). Venous blood was also collected to measure the white blood cell count (WBC) using a blood cell analyzer.

(4) Quality of life score

Follow-up for 3 months was conducted using the General Quality of Life Inventory-74 (GQOL-74), which includes dimensions of physical function, psychological function, material life, and social function, each scored out of 100 with higher scores indicating better quality of life.

2.4. Statistical analysis

Data were processed using SPSS 28.0 software. Continuous variables were compared using the *t*-test, and categorical variables were compared using the chi-square test, χ^2. A statistically significant result was considered

when $p < 0.05$.

3. Results

3.1. Comparison of perioperative indicators between the two groups

The perioperative indicators in the experimental group were superior to those in the reference group ($p < 0.05$). See **Table 1**.

Table 1. Comparison of perioperative indicators between the two groups [n/%, $\overline{x} \pm s$]

Group	Number of cases	Stone clearance rate	Operation time (min)	Postoperative hospital stays (d)	Postoperative pain score (points)		
					Post-op day 1	Post-op day 2	Post-op day 3
Test group	44	39 (88.64)	67.85 ± 4.18	4.88 ± 1.52	3.25 ± 0.41	2.30 ± 0.35	1.04 ± 0.28
Reference group	44	31 (70.45)	97.33 ± 4.27	6.30 ± 1.66	4.37 ± 0.46	3.02 ± 0.37	2.13 ± 0.33
χ^2/t		4.470	32.726	4.185	12.057	9.377	16.706
p		0.035	0.000	0.000	0.000	0.000	0.000

3.2. Comparison of complication rates between the two groups

The complication rate in the experimental group was lower than that in the reference group ($p < 0.05$). See **Table 2**.

Table 2. Comparison of complication rates between the two groups [n/%]

Group	Number of cases	Hydronephrosis	Hematuria	Urinary tract infection	Fever	Renal function impairment	Perirenal hematoma	Incidence rate [n (%)]
Test group	44	0	0	1 (2.27)	1 (2.27)	1 (2.27)	0	6.82 (3/44)
Control group	44	1 (2.27)	1 (2.27)	2 (4.55)	3 (6.82)	2 (4.55)	1 (2.27)	22.73 (10/44)
χ^2 value	-	-	-	-	-	-	-	4.423
p value	-	-	-	-	-	-	-	0.036

3.3. Comparison of inflammatory factor levels between the two groups

Three days after surgery, the inflammatory factor levels in the experimental group were lower than those in the reference group ($p < 0.05$). See **Table 3**.

Table 3. Comparison of inflammatory factor levels between the two groups [$\overline{x} \pm s$]

Group	Number of cases	CRP (mg/L)		PCT (μg/L)		WBC ($\times 10^9$/L)	
		Before surgery	After surgery	Before surgery	After surgery	Before surgery	After surgery
Experimental group	44	12.05 ± 1.36	4.51 ± 1.06	9.06 ± 1.74	0.29 ± 0.04	9.44 ± 1.65	9.59 ± 1.94
Reference group	44	12.08 ± 1.41	6.50 ± 1.17	9.10 ± 1.78	0.71 ± 0.12	9.47 ± 1.62	11.34 ± 1.98
t		0.102	8.361	0.107	22.025	0.086	4.188
p		0.919	0.000	0.915	0.000	0.932	0.000

3.4. Comparison of quality-of-life scores between the two groups

Three months after surgery, the quality-of-life scores in the experimental group were higher than those in the reference group ($p < 0.05$). See **Table 4**.

Table 4. Comparison of quality-of-life scores between the two groups [$\overline{x} \pm s$, points]

Group	Number of cases	Physical function		Psychological function		Material life		Social function	
		Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Experimental group	44	71.38 ± 6.84	88.72 ± 7.31	70.24 ± 6.52	89.16 ± 7.05	72.66 ± 6.93	90.28 ± 7.12	69.81 ± 6.47	87.53 ± 6.98
Reference group	44	70.92 ± 6.79	83.67 ± 7.26	69.87 ± 6.48	81.35 ± 6.94	72.14 ± 6.88	85.41 ± 7.08	69.32 ± 6.42	80.64 ± 6.91
t		0.317	3.251	0.267	5.237	0.353	3.217	0.357	4.653
p		0.752	0.002	0.790	0.000	0.725	0.002	0.722	0.000

4. Discussion

Upper urinary tract calculi (UUTC) is a prevalent urinary system disease, primarily composed of calcium oxalate stones. These stones can cause urinary tract bleeding or mucosal congestion, leading to urinary flow obstruction and increasing the risk of urinary tract infections. Surgery is a common treatment modality for this condition, aiming to remove stones, alleviate disease symptoms, and thereby improve urinary function [3,4].

Flexible ureteroscopy lithotripsy (FURL) is a novel endoscopic surgical procedure that allows the insertion of a flexible ureteroscope through the urethra to reach the renal pelvis. Subsequently, holmium laser fibers are utilized for lithotripsy, and stone baskets are employed to extract the stone fragments. This surgical approach leverages the body's natural cavities, offering strong minimally invasive characteristics. It reduces surgical trauma, minimizes intraoperative blood loss, and thereby protects renal function [5]. However, during the procedure, the stone removal channel is relatively narrow, and the impact water flow velocity is slow, making it difficult to immediately clear stone debris and blood, which can reduce surgical clarity and subsequently affect surgical precision. Flexible vacuum suction ureteral access sheath (FVSUAS) connects the distal end of the flexible ureteroscope to a negative pressure pump, creating an intrarenal negative pressure environment. It utilizes negative pressure suction to aspirate stone fragments, ensuring their complete evacuation and enhancing surgical efficiency. The FVSUAS tip is flexible, allowing for angle adjustments in coordination with the flexible ureteroscope to slowly and precisely enter the renal calyces and pelvis [6]. Additionally, the sheath opening can be positioned close to the stones, enabling complete removal of stone fragments under negative pressure suction, preventing them from obstructing the surgical field, and thereby improving the smoothness of surgical operations.

The results demonstrated that the perioperative indicators in the experimental group were superior to those in the reference group, and the complication rate was lower in the experimental group ($p < 0.05$). The reason for this is that the combined treatment approach enables accurate lithotripsy and stone removal under the guidance of FVSUAS, minimizing excessive manipulation of the stones. This shortens the overall surgical procedure time, avoids damage to surrounding tissues, and thereby reduces postoperative recovery time [7]. The highly flexible tip of FVSUAS matches the anatomical characteristics of the urinary tract, reducing the limitations of flexible ureteroscopy treatment and improving stone localization efficiency. Performing lithotripsy under negative pressure

prevents stone displacement, thereby enhancing the stone clearance rate [8]. Furthermore, negative pressure suction can regulate intrarenal pelvic pressure, preventing extravasation of irrigation fluid and promptly aspirating stone debris to avoid irritation to the urinary tract mucosa, thereby preventing adverse events such as hematuria and reducing the risk of complications, enhancing surgical safety. Three days after surgery, the inflammatory factor levels in the experimental group were lower than those in the reference group ($p < 0.05$). The reason for this is that FVSUAS can flexibly adjust its angle according to the anatomical structure of the ureter, reducing surgical stress responses and preventing urinary tract mucosal damage during stone removal. Its strong minimally invasive advantage helps alleviate postoperative inflammatory responses [9].

Three months after surgery, the quality-of-life scores in the experimental group were higher than those in the reference group ($p < 0.05$). The reason for this is that FVSUAS offers high operability, with a tip capable of large-angle bending and a small-diameter suction sheath, providing a wide observation range. This significantly improves surgical efficiency, promotes rapid patient recovery, and thereby avoids long-term impacts of the disease on daily life, enhancing the patient's quality of life [10].

5. Conclusion

In conclusion, FVSUAS combined with FURL offers significant therapeutic effects for patients with UUTC. It accelerates postoperative recovery, reduces inflammatory responses and postoperative complications, and improves the patient's postoperative quality of life.

Disclosure statement

The author declares no conflict of interest.

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The Impact of HFHD on Calcium-Phosphorus Metabolism and Nutritional Indicators in Patients with Chronic Kidney Disease

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Abstract: *Objective*: To analyze the effects of high-flux hemodialysis (HFHD) on calcium and phosphorus metabolism and nutritional indicators in patients with chronic kidney disease (CKD). *Methods*: A total of 86 CKD patients diagnosed in our hospital's Nephrology Department between January 2024 and December 2025 and undergoing HFHD were enrolled. Using a random number table, all patients were divided into a control group (n = 43, receiving conventional hemodialysis) and a study group (n = 43, receiving HFHD). SPSS 26.0 statistical software was used to compare calcium-phosphorus metabolism and nutritional indicators between the two groups. *Results*: After 6 months of treatment, the PTH level in the study group was significantly lower than that in the control group, while serum calcium and phosphorus levels were significantly higher ($p < 0.05$). The Alb and Hb levels in the study group were higher than those in the control group, but the difference was not statistically significant ($p > 0.05$). *Conclusion*: HFHD maintains calcium-phosphorus metabolism balance in CKD patients while significantly improving nutritional indicators.

Keywords: HFHD; Chronic kidney disease; Calcium-phosphorus metabolism; Nutritional indicators

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1. Introduction

Chronic Kidney Disease (CKD) represents a significant global public health challenge, with its incidence showing a consistent upward trend year after year [1]. Epidemiological data indicates that the prevalence of CKD among adults in China has reached 10.8%, with the number of patients suffering from End-Stage Renal Disease (ESRD) increasing by over 8% annually [2]. ESRD patients experience complete failure of renal filtration, excretion, and endocrine regulation functions. Calcium-phosphorus metabolism disorders and malnutrition are the most common complications, forming core bottlenecks that impact long-term survival rates and diminish quality of life

[3]. Therefore, effectively correcting calcium-phosphorus metabolic imbalance and improving nutritional status represent critical challenges requiring breakthroughs in both clinical treatment and basic research for ESRD. High-Flux Hemodialysis (HFHD), as an innovative dialysis modality, leverages its high-flux, biocompatible membrane properties to effectively broaden toxin clearance. It not only efficiently removes small-molecule toxins but also significantly enhances clearance of medium-to-large-molecule toxins and protein-bound phosphorus, offering a novel therapeutic pathway for correcting calcium-phosphorus metabolism disorders in ESRD patients [4,5]. Based on this, this study selected CKD patients as subjects to analyze the effects of HFHD on calcium-phosphorus metabolism and nutritional indicators in CKD patients.

2. Subjects and methods

2.1. Study population

A total of 86 CKD patients diagnosed in the Nephrology Department of our hospital between January 2024 and December 2025 and undergoing HFHD were enrolled. Using a random number table, all patients were divided into a control group and a study group, each comprising 43 subjects. No significant differences were observed between the two groups in terms of general characteristics ($p > 0.05$). Detailed data are presented in **Table 1**.

Table 1. Comparison of general characteristics between the two groups of patients

Group	Number of cases	Male/Female	Mean age (years)	Mean course of disease (years)
Control group	43	23/20	54.12 ± 4.30	2.78 ± 0.34
Study group	43	26/17	53.97 ± 4.51	2.75 ± 0.37
χ^2/t value		0.427	0.158	0.391
p value		0.514	0.875	0.696

2.2. Diagnostic criteria

(1) Meets the diagnostic criteria for CKD outlined in the Guidelines for Early Screening, Diagnosis, and Prevention of Chronic Kidney Disease (2022 Edition) [6];

(2) Confirmed diagnosis of CKD based on clinical symptoms, renal function tests, and imaging findings.

2.3. Inclusion and exclusion criteria

2.3.1. Inclusion criteria

(1) Meeting the aforementioned diagnostic criteria;

(2) Good treatment compliance;

(3) Complete and traceable clinical records;

(4) Absence of other conditions potentially affecting bone metabolism.

2.3.2. Exclusion criteria

(1) Patients with concomitant acute kidney injury;

(2) Abnormal liver function within the past month;

(3) Severe cardiovascular or cerebrovascular disease;

(4) Psychiatric disorders.

2.4. Research methods

The control group received conventional hemodialysis treatment, with the following operational protocols: Dialysis equipment comprised Nipro Corporation's hemodialysis machine, model 150 G, set with an ultrafiltration coefficient of 9.8 mL/(h·mmHg) and a controlled dialyzer surface area of 1.5 m^2. Dialysis fluid removal volume was flexibly adjusted based on the patient's pre-dialysis weight, oedema severity, and urine output, with a range controlled between 3000–6000 mL. Blood flow rate was regulated at 250–300 mL/min. Dialysate employed was bicarbonate-based dialysate produced by Shijiazhuang Siyuan Pharmaceutical Co., Ltd., with a fixed dialysate flow rate of 500 mL/min. Dialysate concentration and temperature were closely monitored throughout the dialysis process to ensure compliance with clinical treatment standards. Dialysis sessions were scheduled for 4 hours each, with three treatments per week.

The study group received HFHD therapy, employing identical baseline symptomatic treatment and fundamental dialysis parameters to the control group. The core distinction lay in the selection of dialysis equipment and ultrafiltration coefficient settings, with specific operational protocols as follows: Dialysis equipment comprised the FX60 high-flux hemodialysis machine manufactured by Fresenius Medical Care AG & Co. KG, Germany. The dialyzer model matched the control group's specifications, with an equivalent surface area of 1.5 m^2. Dialysis fluid removal volume, blood flow rate, dialysate type, and flow rate were uniformly maintained consistent with the control group. Unlike the control group, the ultrafiltration coefficient for the experimental group was no longer fixed. Instead, it was individually tailored for each dialysis session based on the patient's actual pre-treatment weight, oedema severity, estimated fluid removal target, and individual tolerance. Dialysis treatment duration and frequency were identical to the control group: 4 hours per session, 3 times weekly.

2.5. Observation indicators

(1) Calcium and phosphorus metabolism indicators

Assessed prior to treatment and at 6 months post-treatment. Serum phosphorus levels were measured using the molybdate method, with all samples uniformly centrifuged prior to testing. Phosphorus concentration was determined via colorimetric analysis. Serum calcium levels were measured using the ion-selective electrode method, separately quantifying free and bound calcium concentrations. Electrodes were calibrated prior to testing, with strict control of ambient temperature and humidity throughout the procedure. Parathyroid hormone (PTH) levels were determined via enzyme-linked immunosorbent assay (ELISA).

(2) Nutritional indicators

Assessed prior to treatment and at 6 months post-treatment. On an empty stomach in the morning, healthcare personnel drew 3 mL of peripheral venous blood from patients. The collected venous blood was immediately placed into sterile centrifuge tubes, which were then loaded into a medical centrifuge. The centrifuge was set to 3500 rpm for 10 minutes, with a centrifugal radius of 8 cm. Following centrifugation, the supernatant serum was aspirated into a fresh sterile centrifuge tube to remove sediment impurities. Serum albumin (Alb) and hemoglobin (Hb) levels were measured using a fully automated biochemical analyzer.

2.6. Statistical methods

Data were processed and analyzed using SPSS 26.0 statistical software. Chi-square tests were employed to assess the association between categorical variables across different groups. Paired *t*-tests were used to evaluate the significance of differences in quantitative variables between groups. Throughout the statistical analysis, $p < 0.05$ indicated statistically significant differences between groups.

3. Results

3.1. Comparison of calcium and phosphorus metabolism indicators between the two groups

Results indicated that after six months of treatment, the PTH level in the study group was significantly lower than that in the control group, while serum calcium and serum phosphorus levels were significantly higher than those in the control group ($p < 0.05$). See **Table 2** and **3**.

Table 2. Comparison of calcium and phosphorus metabolism indicators between the two groups of patients ($\overline{x} \pm s$)

Group	Number of cases	Serum calcium (mmol/L)		Serum phosphorus (mmol/L)	
		Pre-treatment	6 months post-treatment	Pre-treatment	6 months post-treatment
Control group	43	2.23 ± 0.45	2.94 ± 0.56	2.25 ± 0.34	1.82 ± 0.29
Study group	43	2.26 ± 0.51	3.83 ± 0.60*	2.27 ± 0.42	1.57 ± 0.36*
χ^2/t value		0.289	7.111	0.243	3.546
P value		0.773	0.000	0.809	0.001

Note: Compared with the control group after 6 months of treatment, $^*p < 0.05$.

Table 3. Comparison of PTH level between the two groups of patients ($\overline{x} \pm s$)

Group	Number of cases	PTH (pmol/L)	
		Pre-treatment	6 months post-treatment
Control group	43	417.30 ± 65.83	347.02 ± 58.45
Study group	43	415.44 ± 64.59	253.61 ± 54.48*
χ^2/t value		0.132	7.666
p value		0.895	0.000

Note: Compared with the control group after 6 months of treatment, $^*p < 0.05$.

3.2. Comparison of nutritional indicators between the two groups

Results indicated that after six months of treatment, the study group exhibited higher levels of albumin (Alb) and hemoglobin (Hb) than the control group. However, the difference between the two groups was not statistically significant ($p > 0.05$). See Table 4.

Table 4. Comparison of nutritional indicators between the two groups of patients ($\overline{x} \pm s$)

Group	Number of cases	Alb (g/L)		Hb (g/L)	
		Pre-treatment	6 months post-treatment	Pre-treatment	6 months post-treatment
Control group	43	39.12 ± 4.33	40.66 ± 4.21	105.60 ± 7.55	109.84 ± 9.32
Study group	43	38.76 ± 4.35	42.39 ± 4.78	106.58 ± 7.69	113.74 ± 9.08
χ^2/t value		0.385	1.781	0.596	1.965
p value		0.701	0.079	0.553	0.053

Note: Compared with the control group after 6 months of treatment, $^*p < 0.05$.

4. Discussion

This study employed the HFHD treatment protocol, focusing on its impact on patients' calcium and phosphorus metabolism indicators while analyzing its efficacy in improving nutritional parameters, as detailed below.

Calcium and phosphorus metabolism disorders represent one of the most critical complications in CKD patients. Their underlying mechanism involves impaired renal filtration and excretion functions, leading to impaired phosphorus excretion and insufficient activation of active vitamin D, subsequently triggering hypocalcemia and hyperphosphatemia. This activates compensatory parathyroid hormone (PTH) secretion. Persistent metabolic imbalance further exacerbates hyperparathyroidism, inducing severe complications that directly impact long-term patient survival rates [7,8]. Conventional hemodialysis, as a traditional dialysis modality, has core limitations due to its smaller membrane pore size and lower ultrafiltration coefficient. It can only effectively remove small, water-soluble toxins from the blood, with extremely low clearance efficiency for medium-to-large molecular toxins and protein-bound phosphorus. This results in most patients failing to achieve target calcium and phosphorus metabolic parameters over the long term, which is also the core reason for the poor improvement in calcium and phosphorus metabolic parameters in the control group patients after treatment [9].

As a novel dialysis modality clinically promoted in recent years, HFHD's core advantage lies in its use of high-flux, highly biocompatible membranes featuring larger pore sizes and higher ultrafiltration coefficients. This significantly broadens the range of toxins removed, constituting the key mechanism by which HFHD markedly improves calcium and phosphorus metabolism indicators in CKD patients [10]. In this study, the HFHD group exhibited significantly lower PTH levels and significantly higher serum calcium and phosphorus levels compared to the control group. These findings align with the conclusions of domestic researchers such as Luo Liuping et al., who compared the effects of HFHD versus conventional hemodialysis in 80 CKD dialysis patients. Their study revealed that post-treatment, the HFHD group demonstrated a 32.1% reduction in PTH levels and while serum calcium and phosphorus levels increased by 10.3% and 8.7%, respectively [11]. All differences were statistically significant ($p < 0.05$), confirming HFHD's more pronounced regulatory effect on calcium and phosphorus metabolism in CKD patients. Regarding the mechanism of action, the high-flux dialysis membrane in HFHD effectively removes medium-to-large molecular weight PTH from the blood, reducing its positive feedback stimulation on the parathyroid glands and inhibiting the progression of hyperparathyroidism. Simultaneously, it significantly enhances the clearance efficiency of protein-bound phosphorus, lowering serum phosphorus levels and alleviating the inhibitory effect of hyperphosphatemia on calcium absorption. This promotes the restoration of serum calcium levels, thereby progressively breaking the vicious cycle of calcium-phosphorus metabolic disorder [12,13]. Furthermore, the dialysis membranes used in HFHD exhibit superior biocompatibility, reducing complement activation and inflammatory cytokine release during dialysis. This minimizes the interference of inflammatory responses on calcium-phosphorus metabolic regulation mechanisms, further enhancing improvements in calcium-phosphorus metabolic indicators [14].

Compared with relevant domestic and international studies, the findings of this research are largely consistent with most conclusions, though certain differences exist. In a study by Armani et al., 105 CKD patients underwent HFHD treatment for 6 months, resulting in a significant decrease in PTH levels and a trend toward normalization of serum calcium and phosphorus levels [15]. with serum calcium and phosphorus levels tending toward normalization, consistent with our findings. However, their study also noted that improvements in calcium and phosphorus metabolism indicators were more pronounced after one year of HFHD treatment, suggesting a time-dependent regulatory effect of HFHD on calcium-phosphorus metabolism. This observation provides direction for

extending follow-up periods in future studies to observe changes in these indicators after one year of treatment. However, another study by Tang Xiaofang et al. reported that after 3 months of HFHD treatment for end-stage renal disease patients, although serum calcium and phosphorus levels improved, the differences compared to the conventional dialysis group were not statistically significant [16]. Only PTH levels showed a significant decrease, differing from the findings of this study. Possible reasons for this discrepancy may be related to sample size, duration of dialysis, baseline disease severity, and HFHD dialysis parameter settings. That study included only 60 patients with an average dialysis duration exceeding 3 years, where irreversible parathyroid damage had already occurred. In contrast, this study enrolled 86 patients, with all patients having a dialysis duration of less than 1 year, preserving some compensatory capacity of parathyroid function. Furthermore, the study group employed individualized ultrafiltration coefficient settings, better tailored to each patient's condition, resulting in more pronounced improvements in calcium and phosphorus metabolism indicators. This suggests that when applying HFHD therapy clinically, individualized dialysis parameters should be set based on the patient's dialysis duration and underlying disease severity to enhance treatment efficacy.

Regarding HFHD's impact on nutritional indicators in CKD patients, our findings show that after 6 months of treatment, although the study group exhibited higher albumin (Alb) and hemoglobin (Hb) levels than the control group, the differences were not statistically significant. This result differs from some domestic and international studies and requires in-depth analysis considering the pathophysiological mechanisms of malnutrition in CKD patients and the intervention characteristics of HFHD. The pathogenesis of malnutrition in CKD patients is complex, primarily involving factors such as nutrient loss during dialysis, inflammatory responses, decreased appetite, and inadequate protein intake. Theoretically, HFHD's highly biocompatible dialysis membrane may reduce the release of inflammatory cytokines, mitigate the inhibitory effects of inflammation on gastrointestinal function and nutrient absorption, and decrease the loss of nutrients like albumin during dialysis, thereby potentially improving patients' nutritional status [17,18]. However, no statistically significant differences in nutritional indicators were observed between the two groups in this study. This discrepancy is likely attributed to the relatively short observation period of only 6 months. Improvements in malnutrition exhibit a certain degree of lag, making it challenging to demonstrate significant intergroup differences within a short timeframe.

The innovation of this study lies in overcoming the limitation of traditional research focusing solely on baseline calcium and phosphorus indicators. By integrating the dynamic changes in nutritional indicators, it clarifies the synergistic improvement of HFHD on calcium and phosphorus metabolism and nutritional status in CKD patients. This provides reliable clinical evidence and theoretical support for formulating personalized dialysis treatment plans and optimizing long-term management strategies for CKD patients.

5. Conclusion

In summary, HFHD, as a more efficient and safer dialysis modality, demonstrates significant advantages in correcting calcium-phosphorus metabolism disorders and improving patient nutritional status. However, this study has certain limitations. All subjects were recruited from the nephrology department of our hospital, resulting in a single-center bias and limited representativeness of the sample. Future studies should expand to multicenter settings, enrolling CKD patients from different regions and hospitals of varying levels to enhance the clinical applicability of the findings. Moreover, the observation period was limited to 6 months, failing to capture long-term trends in calcium-phosphorus metabolism and nutritional indicators after one year of HFHD treatment. Future

studies should extend follow-up durations to further clarify the long-term intervention effects of HFHD.

Disclosure statement

The authors declare no conflict of interest.

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Evaluation of Individualized Nursing Based on the IKAP Model on Cardiac Function Improvement in Patients with Chronic Heart Failure

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Abstract: *Objective*: To investigate the impact of individualized nursing based on the IKAP model on cardiac function in patients with chronic heart failure. *Methods*: A total of 112 patients with chronic heart failure admitted from January 2024 to September 2025 were selected and grouped using the random number table method. The control group (56 cases) received conventional nursing, while the observation group (56 cases) received individualized nursing based on the IKAP model. Cardiac function and quality of life were compared between the groups. *Results*: After three months of nursing, the left ventricular ejection fraction (LVEF) in the observation group was significantly higher than that in the control group, while the left ventricular end-systolic diameter (LVESD) and left ventricular end-diastolic diameter (LVEDD) were significantly lower than those in the control group ($p < 0.05$). The quality-of-life score in the observation group was significantly lower than that in the control group ($p < 0.05$). *Conclusion*: Individualized nursing based on the IKAP model can effectively improve cardiac function and quality of life in patients with chronic heart failure, and is thus worthy of promotion.

Keywords: Conventional nursing; Chronic heart failure; Individualized nursing based on the IKAP model; Cardiac function; Quality of life

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1. Introduction

Chronic heart failure (CHF) is the primary cause of death and recurrent hospitalizations among patients with cardiovascular diseases [1]. This condition is not an independent disease but rather the end stage of various heart diseases. Due to its prolonged onset, tendency to recur, and poor prognosis, CHF significantly reduces patients' quality of life and leads to continuous deterioration of cardiac function [2]. Early treatment, timely correction of various symptoms, and improvement of quality of life are crucial for enhancing cardiac function and accelerating recovery. Traditionally, routine nursing care has been implemented to support both in-hospital and out-of-hospital treatment; however, it fails to address issues such as information discrepancies and negative emotions in patients, resulting in generally moderate nursing outcomes [3]. The Information-Knowledge-Attitude-Practice (IKAP) theory,

built upon systematic health education, employs progressive nursing to gradually transform health information into patients' internal beliefs, thereby facilitating behavioral changes. In recent years, individualized nursing based on the IKAP concept has been applied in the treatment of chronic diseases such as hypertension, achieving favorable results. However, its application in the management of chronic heart failure remains limited. Therefore, this study selected 112 patients with chronic heart failure to analyze the effects of individualized nursing based on the IKAP model.

2. Materials and methods

2.1. General information

This study employed a prospective nursing design aimed at evaluating the impact of different nursing protocols on patients with chronic heart failure. A total of 112 patients admitted between January 2024 and September 2025 were included in the study. The sample size was calculated using the formula $n1 = n2 = 2[(u\alpha + u\beta) / (\delta/\sigma)]^2 + 0.25\mu\alpha^2$, where n1 and n2 represent the sample sizes of the observation group and the control group, respectively. Initially, the estimated sample size was n1 = n2 = 45 cases, resulting in a total of 90 cases. However, issues such as insufficient data and sample attrition during the study led to an increase in the sample size to n1 = n2 = 56 cases, ultimately determining a total patient sample size of 112 cases.

2.1.1. Control group

(1) Gender

32 males and 24 females

(2) Age

54–81 years, mean (67.84 ± 2.53) years

(3) Disease duration

3–21 years, mean (12.38 ± 2.56) years

(4) Cardiac function classification

Grade III (31 cases), Grade IV (25 cases)

(5) Educational level

Junior high school or below (27 cases), above junior high school (29 cases)

2.1.2. Observation group

(1) Gender

34 males and 22 females

(2) Age

56–80 years, mean (68.43 ± 2.69) years

(3) Disease duration

3–20 years, mean (11.82 ± 2.40) years

(4) Cardiac function classification

Grade III (32 cases), Grade IV (24 cases)

(5) Educational level

Junior high school or below (24 cases), above junior high school (32 cases).

No significant differences were observed between the two groups ($p > 0.05$).

2.1.3. Inclusion criteria

(1) Meeting the diagnostic criteria outlined in the "Guidelines for Primary Care Diagnosis and Treatment of Chronic Heart Failure (2019)" [4].
(2) Normal communication and expression abilities.
(3) Compliance with treatment, nursing, and follow-up instructions as prescribed by the physician.
(4) Informed consent to participate in the study.

2.1.4. Exclusion criteria

(1) Mental disorders
(2) Malignant tumors
(3) Visual or auditory impairments
(4) Loss to follow-up for various reasons during the study

2.2. Methods

2.2.1. Control group

Conventional Nursing: This included dietary management, symptomatic management, vital sign monitoring, medication education, etc. The positive impact of healthy behaviors on the patient's condition and prognosis were repeatedly emphasized to enhance the patient's awareness of their condition. Patients were urged to adhere to the latest medical advice for accurate medication use, maximize the efficacy of medications, monitor for post-medication reactions, and identify and manage various adverse reactions. Active follow-up was conducted after discharge, with telephone or WeChat follow-ups every 4 weeks to understand changes in the patient's condition and patiently answer their disease-related questions.

2.2.2. Observation group

Individualized Nursing Based on the IKAP Model

(1) Information phase

Precise and personalized assessments of patient needs were conducted. One-on-one interviews were held with patients, during which chronic heart failure knowledge questionnaires, self-efficacy scales, and Hamilton Anxiety/Depression Scales were flexibly applied to comprehensively collect patient information, including disease cognition, self-efficacy, emotional state, and lifestyle behaviors. Based on the assessment results, nursing protocols were formulated. For patients with lower educational levels, explanations were provided using visually engaging PPT presentations, knowledge booklets, and videos, with simplified language to reduce understanding difficulties for patients and their families. For patients with higher educational levels, in addition to PPT presentations and booklets, they were arranged to attend lectures and read content uploaded to WeChat official accounts. For patients with significant anxiety or depression, active appease and psychological counseling were provided, with one-on-one communications scheduled every 2 days to release physical and mental stress, during which the impact of negative emotions on the heart was emphasized.

(2) Knowledge phase

Patients were stratified based on their educational level and learning comprehension abilities for reasonable education and interaction. For patients with strong learning comprehension abilities, they were arranged to

participate in group discussions, where real-life typical cases were used to emphasize the positive impact of medication adherence on heart failure control and the beneficial effects of healthy behaviors such as low-fat and salt-restricted diets on symptom control and prognosis improvement. For patients with poor learning comprehension abilities, activities such as simulated medication boxes and on-site calculation of sodium intake were used to enhance their awareness of diet and medication. Chronic heart failure rehabilitation knowledge, including heart failure warning signals, weight recording and management, and healthy behavior recording and management, was regularly pushed through WeChat mini-programs and WeChat groups, with 2–3 online Q&A sessions set up weekly to continuously reinforce patient memory.

(3) Belief phase

The Health Belief Model was utilized to help patients establish the belief that "healthy behaviors can improve prognosis and control the condition". For example, the progression process and speed of chronic heart failure were demonstrated on-site using heart models, and comparative analyses were conducted using healthy behavior heart failure progression models and unhealthy behavior heart failure progression models to fully inform patients and their families of the hazards of unhealthy behaviors. Personalized goals were set based on the patient's physical condition, such as losing 1 jin (0.5 kg) per week, and family members were asked to supervise the patient to help achieve this goal. Nurses conducted telephone follow-ups once a week, using open-ended questions for interviews to understand the resistance faced by the patient at this stage and resolve various obstacles to help the patient strictly adhere to each medical advice.

(4) Behavior phase

A behavior plan was formulated based on the patient's actual situation, such as a morning exercise plan for patients, starting with a 10-minute morning walk and gradually increasing to 30 minutes, during which heart rate was continuously monitored using a smart bracelet. A favorable home environment was created, and family members were jointly involved in cultivating a low-fat and salt-restricted dietary environment, with family members actively participating as health supervisors. Patients were required to create a chronic heart failure self-management diary, recording the time of writing and daily symptoms, medication, diet, and exercise. The diary was brought for review during monthly check-ups, and nurses read the diary, pointed out issues, and provided positive incentives to the patient.

Both groups received continuous nursing for 3 months.

2.3. Observation indicators

2.3.1. Cardiac function

Cardiac function was assessed using cardiac ultrasound, with a total of three indicators.

2.3.2. Quality of life

Quality of life was evaluated using the Minnesota Living with Heart Failure Questionnaire, which includes three dimensions: physical total score (0–40 points), social support total score (0–40 points), and emotional dimension (0–25 points). Lower scores indicate better quality of life [5].

2.4. Statistical methods

Data analysis was performed using SPSS 27.0.

After confirming normal distribution via the Shapiro-Wilk test, measurement data were expressed as mean ±

standard deviation ($\overline{x} \pm s$) and compared using *t*-tests. Count data were expressed as frequencies (percentages) and compared using χ^2 tests. A *p*-value < 0.05 was considered statistically significant.

3. Results

There was statistical significance ($p < 0.05$). There was no statistical significance ($p > 0.05$).

3.1. Comparison of cardiac function between the two groups

As shown in **Table 1**, after three months of nursing, the left ventricular ejection fraction (LVEF) in the observation group was significantly higher than that in the control group, while the left ventricular end-systolic diameter (LVESD) and left ventricular end-diastolic diameter (LVEDD) were significantly lower than those in the control group ($p < 0.05$).

Table 1. Cardiac function of the two groups ($\overline{x} \pm s$)

Group	Number of cases	LVEF (%)		LVESD (mm)		LVEDD (mm)	
		Before care	After 3 months of care	Before care	After 3 months of care	Before care	After 3 months of care
Observation group	56	32.12 ± 5.36	45.37 ± 5.99[a]	51.06 ± 5.24	40.02 ± 4.11[a]	59.79 ± 5.68	48.23 ± 4.07[a]
Control group	56	32.96 ± 5.51	40.01 ± 5.83[a]	50.34 ± 5.10	44.38 ± 4.38[a]	59.02 ± 5.53	53.07 ± 4.26[a]
t value	-	0.818	4.799	0.737	5.432	0.727	6.147
p value	-	0.415	< 0.001	0.463	< 0.001	0.469	< 0.001

Note: Compared with the same group before nursing intervention, [a]$p < 0.05$. LVEF refers to left ventricular ejection fraction, LVESD refers to left ventricular end-systolic diameter, and LVEDD refers to left ventricular end-diastolic diameter.

3.2. Comparison of quality of life between the two groups

As shown in **Table 2**, after three months of nursing care, the quality-of-life score in the observation group was significantly lower than that in the control group ($p < 0.05$).

Table 2. Quality of life in the two groups ($\overline{x} \pm s$)

Group	Number of Cases	Physical		Social support		Emotional	
		Before Care	3 Months After Care	Before Care	3 Months After Care	Before Care	3 Months After Care
Observation group	56	23.76 ± 3.48	13.02 ± 3.07	24.86 ± 3.87	12.16 ± 3.00	14.68 ± 2.67	8.02 ± 2.11
Control group	56	23.21 ± 3.35	17.63 ± 3.18	24.12 ± 3.75	16.54 ± 3.26	14.17 ± 2.52	10.45 ± 2.28
t value	-	0.852	7.805	1.028	7.398	1.040	5.854
p value	-	0.396	< 0.001	0.306	< 0.001	0.301	< 0.001

Note: Compared with the same group before nursing intervention, [a]$p < 0.05$.

4. Discussion

In this study, the improvement in cardiac function was more pronounced in the observation group compared to the control group. The underlying reason is that patients with chronic heart failure exhibit significant pathological changes in cardiac function, prompting clinical treatment and nursing care to focus closely on alterations in cardiac function. The key to enhancing cardiac function lies in the individualized intervention of nursing care on the pathophysiological processes [6]. Conventional nursing care tends to prioritize clinical treatment and in-hospital management, which, although effective in rapidly controlling the patient's condition and initiating early treatment, encounters substantial challenges in correcting information discrepancies and addressing psychological issues [7]. These aspects can profoundly impact the patient's healthy behavioral habits and disease symptom management [8]. In contrast, individualized nursing care based on the IKAP model facilitates progressive communication and personalized management, heightening the patient's awareness of the disease, treatment, medication, and behaviors, rectifying all actions that affect cardiac function, and creating a conducive environment for improving cardiac function, thus yielding remarkable results. In this study, the improvement in quality of life was also more significant in the observation group compared to the control group. The reason is that chronic heart failure typically has a prolonged course, severely affecting the patient's normal life [9]. However, conventional nursing care places greater emphasis on in-hospital care, with relatively infrequent follow-up visits outside the hospital, resulting in poor management outcomes and a slow recovery in quality of life [10]. In contrast, individualized nursing care based on the IKAP model, in addition to addressing the patient's cognitive and psychological issues, assists the patient in correcting unhealthy lifestyle habits and resuming normal life.

5. Conclusion

In summary, the implementation of individualized nursing care based on the IKAP model in patients with chronic heart failure leads to significant improvements in cardiac function and quality of life recovery, demonstrating remarkable application effects. However, this study has certain limitations, including a short observation period and a lack of indicators such as complications, which hinder a comprehensive analysis of the nursing value. Further in-depth clinical research is warranted.

Disclosure statement

The author declares no conflict of interest.

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Analysis of Factors Influencing the Return of Spontaneous Circulation and Prognosis in Patients with In-Hospital Cardiac Arrest Under a Rapid Response System

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Abstract: *Objective*: To investigate the influencing factors and prognosis of the return of spontaneous circulation (ROSC) in patients with unexpected in-hospital cardiac arrest (IHCA) under the rapid response system. *Methods*: According to the Utstein template, a retrospective analysis was conducted on the clinical data of 263 patients with unexpected IHCA from a tertiary-level hospital in Zhenjiang City from May 2019 to May 2024. The primary outcomes were categorized into the ROSC group and the Non-ROSC group based on post-resuscitation outcomes, while the secondary outcomes were divided into the discharged alive group and the non-discharged alive group. Logistic regression analysis was employed to identify the influencing factors and prognosis of ROSC, and the Kaplan-Meier method was used to plot survival curves. *Results*: (1) A total of 263 patients with IHCA were included in this study, with 166 cases (63.5%) achieving ROSC and 54 cases (32.5%) surviving for 7 days, among whom 42 cases (15.9%) were discharged alive. (2) Multivariate regression analysis revealed that age, abnormal BMI, duration of cardiopulmonary resuscitation (CPR), ventilation method during resuscitation, and the initial cumulative dosage of epinephrine were independent influencing factors for Non-ROSC in IHCA patients ($p < 0.05$). The NRS2002 score, recurrent resuscitation events, initial cumulative dosage of epinephrine, and duration of CPR were independent influencing factors for non-discharge alive in IHCA patients ($p < 0.05$). *Conclusion*: The ROSC rate of IHCA under the rapid response system has improved, but the rate of discharged alive remains relatively low. The system plays a certain role in reducing in-hospital mortality; however, further strengthening of the links in each stage is necessary to enhance patient prognosis.

Keywords: Rapid response system; In-hospital cardiac arrest; Return of spontaneous circulation; Emergency; Survival

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1. Introduction

In-hospital cardiac arrest (IHCA) refers to the sudden cessation of mechanical activity of the heart's pumping function that occurs within a hospital setting, resulting in the interruption of systemic blood circulation, cessation of respiration, and loss of consciousness [1]. It represents a critical in-hospital event that severely endangers patient lives and is associated with high mortality rates [2]. The incidence of IHCA abroad ranges from 1.2 to 9–10 per 1,000 hospital admissions [3–5]. The survival rate to discharge ranges from 15% to 34%. In contrast, China reports a higher IHCA incidence of 1.75%, with a discharge survival rate of only 9.1%, indicating a significant gap compared to developed countries [6]. Since the introduction of the survival chain for IHCA patients in 2015, patient outcomes have significantly improved, although only a small proportion of patients survive with good neurological function.

Return of spontaneous circulation (ROSC) is a core indicator for judging the success of resuscitation and evaluating patient prognosis, representing the first step towards long-term survival, neurological recovery, and favorable outcomes. Previous studies have indicated that the time to defibrillation and cardiopulmonary resuscitation in cardiac arrest patients is inversely proportional to survival chances, while delayed response times due to incorrect disease identification and delayed calls are primary contributors to poor outcomes in IHCA patients [7,8]. In 2023, expert consensus proposed the establishment of a rapid response system (RRS) to achieve early warning and timely management of in-hospital emergencies through standardized and systematic management, aiming to reduce the incidence of adverse events and improve patient survival rates [9]. Some studies have also confirmed the role of the rapid response system in reducing IHCA and improving rescue success rates, although controversy remains regarding its impact on mortality reduction [10].

Reports on the implementation effects of RRS in domestic hospitals are scarce. Since 2015, our hospital has established a "24-hour in-hospital life rescue team" (hereinafter referred to as the "Life Rescue Team") to further improve the emergency medical service system (EMSS). This study has consistently adhered to standardized management, focusing on restoring spontaneous circulation and achieving discharge survival. Monthly statistics and information tracking of emergency rescue data have been conducted, and the system has been operating effectively for nearly a decade. Therefore, the purpose of this article is to explore the status of spontaneous circulation recovery and discharge survival among IHCA patients across the hospital under the rapid response system. Through retrospective clinical research analysis, this study aimed to summarize experiences and evaluate outcomes.

2. Materials and methods

2.1. Study subjects

Medical records of patients with unexpected in-hospital cardiac arrest (IHCA) from May 2019 to May 2024 were continuously collected from a tertiary hospital in Zhenjiang. Potential IHCA cases were identified by retrieving cardiac arrest-related medical orders from the hospital's HIS system. Based on resuscitation outcomes, patients were divided into the ROSC group, Non-ROSC group, survival-to-discharge group, and non-survival-to-discharge group.

2.1.1. Inclusion criteria

All patients aged 18 and above (410 cases).

2.1.2. Exclusion criteria

(1) Out-of-hospital cardiac arrest, including patients who underwent cardiopulmonary resuscitation (CPR) on

the way to the hospital via 120 emergency services (89 cases);

(2) Patients with obvious signs of irreversible diseases (e.g., advanced cancer) (7 cases);

(3) Patients with incomplete data (12 cases);

(4) Patients who received a do-not-resuscitate order (39 cases).

2.1.3. Details

Ultimately, 263 patients were included in this study. This study was approved by the Ethics Committee of the Affiliated People's Hospital of Jiangsu University (Ethics Approval Number: K-2025038-W).

2.2. Study tools and indicators

Data were collected using a self-made form based on the Utstein template for study variables.

(1) Sociodemographic data

Age, gender, BMI, BI, NRS2002 score, Charlson comorbidity index (CCI), underlying diseases, educational level, smoking and alcohol history, and bedridden status.

(2) Disease-related information: length of hospital stay, location of cardiac arrest (emergency department, ICU, general ward), time period of cardiac arrest, CPR performed by the first witness, etiology of cardiac arrest (cardiogenic, non-cardiogenic), initial rhythm, duration of CPR (min), whether mechanical ventilation was administered before arrest, whether emergency tracheal intubation was performed during arrest, cumulative initial epinephrine dosage (mg), whether mechanical support was used during resuscitation, and recurrent resuscitation events.

(3) Prognostic indicators included the ROSC rate and survival-to-discharge rate.

ROSC was defined as the sustained return of spontaneous circulation for more than 20 minutes after resuscitation, during which no external chest compressions were performed [11].

Ventricular fibrillation (VF) and ventricular tachycardia (VT) were classified as shockable rhythms, while pulseless electrical activity (PEA) and asystole were classified as non-shockable rhythms. If a patient experienced more than one cardiac arrest during hospitalization, only the first episode was included. The resuscitation time was defined as the interval from the first chest compression (or recognition of the need for defibrillation when the initial rhythm was ventricular tachycardia or ventricular fibrillation) to sustained ROSC (> 20 minutes) or termination of resuscitation efforts. The cause of cardiac arrest was considered "determined" if the emergency physician reported it in the ED discharge diagnosis. Patients who abandoned treatment and requested discharge with tracheal intubation or other tubes in place were considered deceased.

2.3. Statistical methods

All data processing and statistical analyses in this study were performed using SPSS 25.0 statistical software. Continuous data were expressed as mean ± standard deviation ($\overline{x} \pm s$), categorical data were described as "rate (%) or composition ratio (%)", and non-normally distributed continuous data were expressed as median (interquartile range) [M (Q1, Q3)]. Differences between categorical data groups were compared using the χ^2 test. Survival curves were plotted using the Kaplan-Meier method, and multivariate analysis was performed using binary logistic regression to analyze the correlation between resuscitation success rate and in-hospital mortality. A significance level of $\alpha = 0.05$ was selected, and a p-value < 0.05 was considered statistically significant.

3. Results

3.1. General data analysis

This study included a total of 263 patients who experienced unexpected in-hospital cardiac arrest (IHCA). Among them, there were 178 males (71.1%) and 85 females (32.3%). The age of the included subjects was (74 ± 14.25) years, with a minimum age of 21 years and a maximum age of 99 years. Among the causes of IHCA, 49 cases (18.6%) were due to cardiogenic cardiac arrest. The median length of hospital stay before cardiac arrest was 3 days (interquartile range: 1, 11), and the duration of CPR was (19.5 ± 19.03) minutes. Return of spontaneous circulation (ROSC) was achieved in 166 patients (63.1%), with a median survival period of 72 hours. Among these patients, 54 (32.5%) survived for 7 days, and 42 (16%) were discharged alive.

3.2. Univariate logistic regression analysis

Univariate analysis indicated that among the factors influencing ROSC after resuscitation, age, BMI, BI index, NRS2002 score, comorbid diabetes, length of hospital stays, whether the cardiac arrest was cardiogenic, location of cardiac arrest, time period of cardiac arrest, duration of CPR, cumulative initial epinephrine dosage, and ventilation method during resuscitation showed statistically significant differences ($p < 0.05$). Regarding patient survival to discharge, the NRS2002 score, bedridden status before admission, length of hospital stays, whether the cardiac arrest was cardiogenic, location of cardiac arrest, CPR duration ≥ 30 minutes, cumulative initial epinephrine dosage, and recurrent resuscitation events showed statistically significant differences ($p < 0.05$). See **Table 1** for details.

3.3. Multivariate logistic regression analysis

Values with a univariate p-value < 0.05 were used as independent variables, and the occurrence of endpoint events (Non-ROSC = 1, death = 1) was used as the dependent variable. A stepwise forward regression method was employed, with the assignment methods for independent variables detailed in **Table 2**. Multivariate logistic regression analysis revealed that BMI, the cause of IHCA, duration of CPR, ventilation method during resuscitation, and the initial cumulative dosage of epinephrine were independent influencing factors for Non-ROSC in IHCA patients ($p < 0.05$), as shown in **Table 3**. The final chi-square value (14.560, $p = 0.068$) indicated a relatively high goodness-of-fit for the model. Additionally, the NRS2002 score, recurrent resuscitation events, initial cumulative dosage of epinephrine, and ventilation method during resuscitation were influencing factors for the survival to discharge of IHCA patients, as shown in **Table 4**.

Table 1. Univariate analysis of factors affecting the recovery of autonomic circulation (n = 263)

Variable	Total N = 263	ROSC (n = 166)	Non-ROSC (n = 97)	Statistic	*p*-value	Survived to Discharge (n = 42)	Did not survive to Discharge (n = 162)	Statistic	*p*-value
Age	263	72 (61, 82)	77.5(68.25, 85)	-3.115	0.002	72 (56.75, 79.5)	74 (64, 84)	-1.430	0.153
Gender	Male 178 (67.7) Female 85 (32.3)	107 (64.1) 60 (35.9)	71 (74) 25 (26)	2.724	0.099	28 (66.7) 14 (33.3)	150(67.9) 71(32.1)	0.023a	0.878
BMI	18.5–23.9 = 219 (83.3) < 18.5 = 23 (8.7) 24.0–27.9 = 17 (6.5) ≥ 28.0 = 4 (1.5)	151 (90.4) 8 (4.8) 6 (3.6) 2 (1.2)	68 (70.8) 15 (15.6) 11 (11.5) 2 (2.1)	17.139	0.001	37 (88.1) 3 (7.1) 1 (2.4) 1 (2.4)	182 (82.4) 20 (9.0) 16 (7.2) 3 (1.4)	1.819a	0.611
Barthel index (BI)	No Dependence = 33 (12.5) Mild Dependence = 36 (13.7) Moderate Dependence = 22 (8.4) Severe Dependence = 172 (65.4)	17 (10.2) 19 (11.4) 11 (6.6) 120 (71.9)	16 (16.7) 17 (17.7) 11 (11.5) 52 (54.2)	8.476	0.037	3 (7.1) 3 (7.1) 3 (7.1) 33 (78.6)	30 (13.6) 33 (14.9) 19 (8.6) 139 (62.9)	4.143a	0.246
NRS2002 score	< 3 = 166 (63.1) ≥ 3 = 97 (36.9)	95 (56.9) 72 (43.1)	71 (74) 25 (26)	7.632	0.006	26 (61.9)	74 (33.5)	12.097a	0.001
CCI	1 = 32 (12.2) 2 = 75 (28.5) 3 = 156 (59.3)	23 (13.8) 52 (31.1) 92 (55.1)	9 (9.4) 23 (24) 64 (66.7)	3.448	0.178	8 (19) 15 (35.7) 19 (45.2)	24 (10.9) 60 (27.1) 137 (62)	4.522a	0.104
Number of comorbidities	0 = 75 (28.5) 1–2 = 127 (48.3) ≥ 3 = 61 (23.2)	45 (26.9) 78 (46.7) 44 (26.3)	30 (31.3) 49 (51) 17 (17.7)	2.595	0.273	17 (40.5) 14 (33.3) 11 (26.2)	58 (26.2) 113 (51.1) 50 (22.6)	5.015a	0.081
Comorbidities									
CAD	45	27	18	0.287	0.592	19	26	0.335a	0.563
Hypertension	144	95	49	0.214	0.643	52	92	0.707a	0.401
diabetes mellitus	88	64	24	3.045	0.027	34	54	0.003a	0.956
AMI	5	4	1	0.599	0.439	3	2	1.005a	0.316
Renal insufficiency	24	18	5	0.986	0.321	11	13	0.616a	0.432
COPD	14	9	5	0.004	0.950	5	9	0.045a	0.832
Stroke	47	29	18	0.080	0.778	16	31	0.460a	0.498
Heart failure	9	6	3	0.040a	0.841	4	5	0.144a	0.705

Table 1 (Continued)

Variable	Total N = 263	ROSC (n = 166)	Non-ROSC (n = 97)	Statistic	*p*-value	Survived to Discharge (n = 42)	Did not survive to Discharge (n = 162)	Statistic	*p*-value
arrhythmia	35	22	13	0.007a	0.933	11	20	0.127a	0.722
	Illiterate = 16 (6.1)	13 (7.8)	3 (3.1)			13 (31)	105 (47.5)		
	Primary School = 118 (44.9)	71 (42.5)	47 (49)			15 (35.7)	64 (29)		
Educational level	Middle School = 79 (30)	52 (31.3)	27 (28.1)	8.840a	0.065	7 (16.7)	4 (9.5)	5.907a	0.206
	High School = 24 (9.1)	19 (11.4)	5 (5.1)			4 (9.5)	22 (10)		
	College or Above = 26 (9.9)	12 (7.2)	14 (14.6)			13 (31)	105 (47.5)		
Smoking	41 (15.6)	27 (16.2)	14 (14.6)	0.116	0.733	6 (14.3)	35 (15.8)	0.065a	0.799
Alcohol consumption	26 (9.9)	17 (10.2)	9 (9.4)	0.044a	0.833	7 (16.7)	19 (8.6)	2.580a	0.108
bedridden	21 (8)	15 (9.0)	6 (6.3)	0.619a	0.431	0 (0)	21 (9.5)	4.337a	0.037
Length of hospital stay	263	2 (1, 6)	8 (2, 17)	-5.768	< 0.001	1 (1, 3)	4 (1, 12)	-3.562	< 0.001
Bystander CPR present	232 (88.2)	148 (88.6)	84 (87.5)	0.074	0.786	37 (88.1)	195 (88.2)	0.001	0.979
	ICU = 47 (17.9)	33 (19.8)	14 (14.6)			6 (14.3)	41 (18.6)		
Location of cardiac arrest	Emergency/Examination Room = 68 (25.9)	63 (37.7)	5 (5.2)	41.232a	< 0.001	23 (54.8)	45 (20.4)	22.207a	< 0.001
	General Ward = 148 (56.3)	71 (42.5)	77 (80.2)			13 (31)	135 (61.1)		
Cardiac etiology of arrest	49 (18.6)	21 (12.6)	28 (29.2)	11.069	0.001	3 (7.1)	46 (20.8)	4.351	0.037
	08:00-15:59 = 111 (42.2)	71 (42.5)	40 (41.7)			20 (47.6)	91 (41.2)		
Time of cardiac arrest	16:00-23:59 = 69 (26.2)	53 (31.7)	16 (16.7)	10.181a	0.006	14 (33.3)	55 (24.9)	3.786a	0.151
	00:00-07:59 = 83 (31.6)	43 (25.7)	40 (41.7)			8 (19)	75 (33.9)		
CPR duration ≥ 30 min	87 (33.2)	32 (19.3)	55 (57.3)	39.630a	< 0.001	6 (14.3)	81 (36.8)	8.073	0.004
Initial cumulative epinephrine dose	263	2 (1, 3)	3 (2, 5)	-5.083	< 0.001	1 (0.75, 2)	2 (1, 4)	-3.259	< 0.001

Table 1 (Continued)

Variable	Total N = 263	ROSC (n = 166)	Non-ROSC (n = 97)	Statistic	*p*-value	Survived to Discharge (n = 42)	Did not survive to Discharge (n = 162)	Statistic	*p*-value
Shockable rhythm	No = 206 (78.3)	128 (76.6)	78 (81.3)	0.761a	0.383	9 (21.4)	48 (21.7)	0.002a	0.967
	Yes = 57 (21.7)	39 (23.4)	18 (18.8)						
Ventilation mode pre-arrest	Non-endotracheal intubation = 226 (87.3)	145 (89.0)	81 (84.4)	1.141a	0.285	39 (95.1)	187 (85.8)	2.709a	0.100
	Endotracheal intubation = 33 (12.7)	18 (11.0)	15 (15.6)			2 (4.9)	31 (14.2)		
Ventilation mode during resuscitation	Bag-Valve-Mask Ventilation = 44 (16.7)	13 (7.8)	31 (32.3)	26.281a	< 0.001	3 (7.1)	41 (18.6)	2.709a	0.100
	Endotracheal Intubation = 219 (83.3)	154 (92.2)	65 (67.7)			39 (92.9)	180 (81.4)		
Mechanical support during resuscitation	No = 241 (91.6)	152 (91.0)	89 (92.7)	0.227a	0.634	39 (92.9)	202 (91.4)	0.097a	0.755
	Yes = 22 (8.4)	15 (9.0)	7 (7.3)			3 (7.1)	19 (8.6)		
Recurrent resuscitation Events	85 (32.3)	-	-	-	-	3 (7.1)	82 (37.1)	14.484a	< 0.001
CRRT after ROSC	57	-	-	-	-	11 (26.2)	46 (20.8)	0.601a	0.438

Table 2. Assignment of independent variables

Variable		Quantitative assignment
Age	X1	Enter original value
BMI (kg/m^2)	X2	1 = 18.5– ≤ 23.9, 2 = < 18.5, 3 = 24.0– ≤ 27.9, 4 = ≥ 28.0
Barthel Index (BI)	X3	1 = 100 points, 2 = 61–99 points, 3 = 41–60 points, 4 = 0–40 points
NRS2002 Score ≥ 3	X4	No = 0, Yes = 1
Comorbid with diabetes	X5	No = 0, Yes = 1
Length of hospital stay	X6	Enter original value
IHCA department	X7	1 = ICU, 2 = Emergency room/Examination department, 3 = General ward
Cardiac cause of arrest	X8	No = 0, Yes = 1
IHCA time period	X9	1 = 08:00–15:59, 2 = 16:00–23:59, 3 = 00:00–07:59
CPR duration ≥ 30 min	X10	No = 0, Yes = 1
Cumulative dose of first epinephrine administered	X11	Enter original value
Ventilation method during resuscitation	X12	1 = Bag-mask ventilation, 2 = Emergency endotracheal intubation
Bedridden status	X13	No = 0, Yes = 1
Repeated resuscitation events	X14	No = 0, Yes = 1
Non-ROSC	Y1	No = 0, Yes = 1
Not surviving to discharge	Y2	No = 0, Yes = 1

Table 3. Multifactorial analysis affecting the recovery of autonomic circulation

Variable	B	S.E.	Wald χ^2	p	OR	95% CI
Constant	-0.972	0.634	2.354	0.125	0.378	-
BMI			12.167	0.007		
BMI (1)	1.773	0.604	8.612	0.003	5.888	1.802 – 19.242
BMI (2)	1.351	0.661	4.178	0.041	3.860	1.051 – 14.098
BMI (3)	1.235	1.264	0.955	0.329	3.440	0.289 – 40.993
Cardiac cause of arrest	-1.270	0.431	8.691	0.003	0.281	0.121 – 0.653
CPR duration ≥ 30 min	1.238	0.369	11.257	0.001	3.448	1.673 – 7.106
Ventilation method during resuscitation	-2.235	0.447	21.988	< 0.001	0.107	0.042 – 0.272
Cumulative initial epinephrine dose	0.274	0.077	12.484	< 0.001	1.315	1.130 – 1.530

Table 4. Multifactorial analysis of survival to discharge

Variable	B	S.E.	Wald χ^2	p	OR	95% CI
Constant	2.128	0.839	6.434	0.011	8.396	-
NRS ≥ 3 points	-0.832	0.411	4.105	0.043	0.435	0.195 – 0.973
Recurrent resuscitation events	2.467	0.649	14.438	< 0.001	11.792	3.303 – 42.103
Cumulative dose of initial epinephrine use	0.373	0.127	8.595	0.003	1.452	1.132 – 1.863
Ventilation method during resuscitation	-1.505	0.689	4.774	0.029	0.222	0.058 – 0.856

3.4. Kaplan-Meier survival curve

Among the 263 patients with cardiac arrest who underwent cardiopulmonary resuscitation (CPR), 166 patients (63.5%) achieved ROSC. Of these, 132 patients (79.5%) survived within 24 hours, 54 patients (32.5%) survived within 7 days, and 40 patients (24%) survived to discharge. The survival rate of patients with cardiac arrest decreased significantly within 24 hours after CPR, and then gradually declined over time, as illustrated in **Figure 1**.

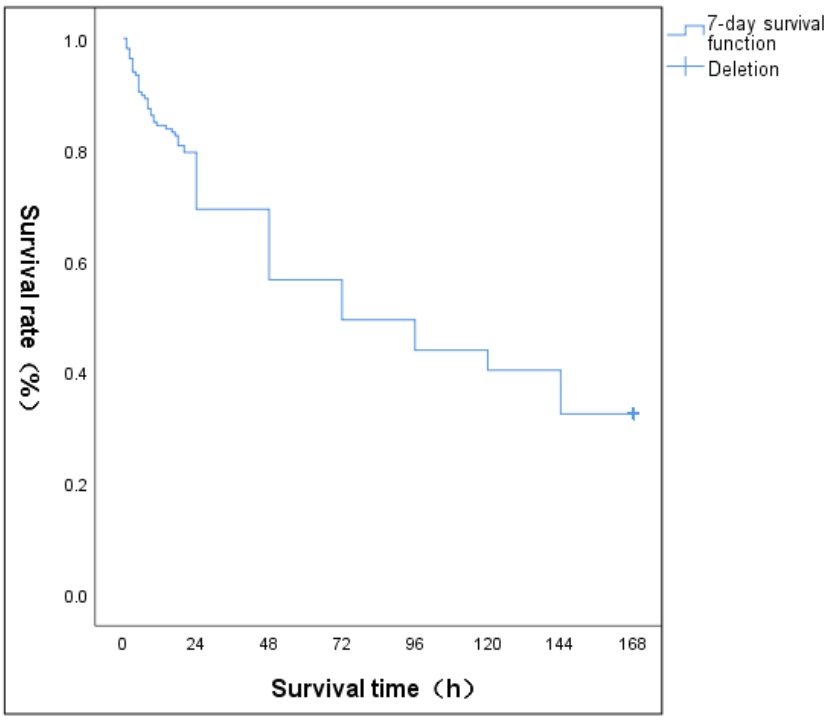


Figure 1. 7-day survival scale.

4. Discussion

This study reveals that the rates of return of spontaneous circulation (ROSC) and survival to hospital discharge among patients with in-hospital cardiac arrest (IHCA) under the rapid response system are 63.5% and 15.9%, respectively (**Table 1**). In comparison, the ROSC rate is higher than that reported in other studies, confirming that the ROSC rate among IHCA patients under rapid response system intervention is higher than usual, though the survival to hospital discharge rate requires further validation, consistent with previous research findings [12–15].

The rapid response system plays a crucial role in the rescue of IHCA patients, particularly in non-monitoring and auxiliary departments. Promptly initiating an integrated, multi-departmental collaborative in-hospital rapid rescue system in emergencies is essential for shortening response times, improving the rate of spontaneous circulation recovery, and enhancing prognosis. Our hospital has established an in-hospital emergency rescue team involving multiple departments, dividing the entire hospital into regions based on the layout of the ward buildings and considering the principle of proximity. When cardiac arrest occurs anywhere in the hospital, the witness implements a primary care responsibility system, assessing the vital signs of patients with cardiac arrest and critical signs, and immediately initiating cardiopulmonary resuscitation (CPR). A unified emergency call

number and call language are specified to report the incident location. Meanwhile, the operator on duty at the switchboard repeats and confirms the information before initiating an emergency call to the rescue team, directing the elevator to stand by, and ensuring that team members responsible for the region arrive at the scene within 5 minutes. The general principle of "first rescue on-site, then transfer nearby" is implemented. Guided by the goals of restoring spontaneous circulation and survival to hospital discharge, this study describes the influencing factors of ROSC and outcomes in IHCA patients under the in-hospital rapid response team. It reveals that the etiology of IHCA, body mass index (BMI), CPR duration, ventilation method during rescue, and the initial cumulative dose of epinephrine are independent influencing factors for Non-ROSC in IHCA patients; whereas the NRS2002 score, recurrent resuscitation events, initial cumulative dose of epinephrine, and ventilation method during rescue are influencing factors for survival to hospital discharge in IHCA patients.

The etiology of IHCA is typically recorded according to clinical data using the Utstein mode, categorized into cardiac and non-cardiac causes. According to an international literature review, multiple studies tend to classify cardiac arrest (CA) of unknown etiology as cardiac causes [16]. In this study, we define cardiac causes of IHCA as cardiac arrest resulting from a clearly identified primary cardiac disease. **Table 1** shows that non-cardiac diseases account for 81.4% of IHCA cases, consistent with the conclusions of multiple studies, suggesting that IHCA is mostly caused by non-cardiac diseases such as severe electrolyte and acid-base balance disorders, hypoxia, and stroke [17,18]. A three-year retrospective study in Denmark shows that compared to patients with non-cardiac causes of cardiac arrest, those with cardiac causes have a higher rate of favorable neurological outcomes [19]. Additionally, logistic regression results in this study indicate that cardiac causes of cardiac arrest are an independent protective factor for Non-ROSC but do not show an impact on survival prognosis. This may be because most patients with cardiac diseases have completed cardiac function tests before arrest and are under monitoring equipment detection; furthermore, patients with cardiac IHCA have a high incidence of ventricular tachycardia, ventricular fibrillation, and myocardial infarction, with the former showing a shockable rhythm during cardiac arrest, which can be intervened with defibrillation, and the latter undergoing percutaneous coronary intervention, which also helps improve prognosis [20].

Previous studies have shown that an increased BMI in IHCA patients is positively correlated with a favorable prognosis, known as the "obesity paradox", which refers to the association of mildly elevated BMI with favorable outcomes [21,22]. However, other studies have shown a negative correlation between increased BMI and favorable prognosis. **Table 3** shows that in this study, patients with a BMI < 18.5 have a nearly six-fold higher chance of Non-ROSC compared to patients with a normal BMI, and those with a mildly elevated BMI of 24.0– ≤ 27.9 have a nearly four-fold higher chance of Non-ROSC compared to patients with a normal BMI, similar to other research findings. Wang believes that IHCA patients with a BMI > 23.2 kg/m^2 have a lower likelihood of a favorable outcome [23]. Another meta-analysis found that both obesity and underweight are associated with higher in-hospital mortality, with underweight also being associated with worse neurological outcomes [24]. The reason may be that BMI is positively correlated with the anterior-posterior depth of subcutaneous adipose tissue, and increased BMI makes resuscitation more difficult. Compared to patients with a normal BMI, those with a high BMI likely receive shallower chest compressions, suggesting that for IHCA patients with a high BMI, end-tidal carbon dioxide partial pressure and other physiological parameters should be monitored in conjunction during rescue to monitor CPR. Additionally, the relationship between BMI and mortality remains unclear and requires further stratified research. The NRS2002 score in this study shows a protective effect for survival to hospital discharge in IHCA patients (OR = 0.435). Another study did not find a relationship between this score and prognosis, and due to the limited sample

size in this study, further validation is needed [23].

Previous studies consider a CPR duration of 20–30 minutes as an important cutoff point. Ahmad believes that CPR lasting more than 20 minutes may be clinically meaningless, and the survival rate of patients with in-hospital cardiac arrest exceeding 30 minutes significantly decreases [25]. Recently, Okubo M quantified the time-dependent probability of survival and favorable functional outcomes, concluding that when CPR duration exceeds 39 minutes, the survival probability drops below 1%, and the probability of favorable functional outcomes also decreases below 1% when CPR duration exceeds 32 minutes, providing important quantitative evidence for clinical decision-making on whether to continue CPR at specific time points for IHCA patients [26]. However, different individuals may still benefit from prolonged CPR, and there is currently controversy over the optimal duration of CPR. This study shows that patients with a CPR duration < 30 minutes have a 3.5-fold higher chance of ROSC and a 4.5-fold higher chance of survival to hospital discharge compared to those with a duration ≥ 30 minutes (**Table 4**). The possible reason is that prolonged CPR exceeds physiological compensation, leading to ischemia and hypoxia in organs such as the heart and brain, as well as reperfusion injury, increasing the risk of irreversible damage and reducing the success rate of resuscitation [27]. Additionally, in this study, 21% of cardiac arrest patients have a CPR duration ≥ 30 minutes without restoring spontaneous circulation. How should the optimal cessation time be monitored for such patients?

In resuscitation science, ventilation research lags behind studies on chest compressions and defibrillation. This study shows that emergency tracheal intubation during CPR can serve as a protective factor for ROSC, consistent with previous research findings. Both chest compressions and ventilation during CPR are crucial for promoting oxygen delivery. A prospective observational study found a dose-dependent relationship between baseline and dynamic changes in oxygen content and the likelihood of restoring spontaneous circulation (ROSC) [28]. However, in clinical practice, the etiology of CA is also one of the factors to consider when choosing a ventilation method. Expert consensus indicates that for cardiac diseases, residual oxygen is present during cardiac arrest, and restoring circulation should be prioritized. As the body's stored oxygen is depleted, assisted ventilation is required to achieve oxygen transport. For pulmonary-induced CA, which is caused by the depletion of the body's stored oxygen leading to cardiac arrest, assisted ventilation and chest compressions should be performed simultaneously to restore circulation. Andersen analyzed the intubation time in 43,314 cases of IHCA and found that patients who completed emergency intubation within 15 minutes had lower ROSC and survival to hospital discharge rates compared to those who did not complete intubation within that time [26]. However, some studies have reported that early tracheal intubation is beneficial for the outcome of CA. Qian Shaobing improved the ROSC success rate to 40.00% in IHCA patients after early tracheal intubation, compared to 22% in those without intubation [29]. In summary, early tracheal intubation can quickly establish effective ventilation and oxygen uptake channels, provide airway protection for patients, prevent insufficient carbon dioxide and blood oxygen saturation, and enhance the effectiveness of CPR. However, the academic community holds different views, and implementation should be based on guideline recommendations combined with clinical practice.

The 2022 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care continue to recommend epinephrine as a first-line rescue medication for cardiac arrest. During cardiac arrest, epinephrine can improve myocardial blood supply through its α-adrenergic effects, causing peripheral vasoconstriction, dilating the bronchi, and improving cerebral perfusion, thereby promoting ROSC, and is widely used in clinical practice. The results of this study suggest that a lower initial cumulative dose of epinephrine is a protective factor for ROSC and survival to hospital discharge in patients. This is consistent with

the findings of most studies on adult in-hospital cardiac arrest [30–32]. The guidelines for epinephrine use indicate that for non-shockable rhythms, epinephrine should be administered early, with survival rates increasing by 4% for every minute earlier the drug is given. In summary, the dose of epinephrine is crucial for restoring spontaneous circulation, but clinical use should be based on the patient's specific condition and the latest research evidence, with reasonable dose adjustments to improve the success rate of resuscitation and the patient's long-term survival rate.

Additionally, **Table 4** shows that recurrent resuscitation events in IHCA patients are an independent risk factor affecting survival to hospital discharge (OR = 11.55). The incidence of recurrent cardiac arrest is 32.3%, similar to other research findings [33]. A significant proportion of patients who achieve spontaneous circulation recovery will experience cardiac arrest again due to various causes, with a low success rate of rescue and poor clinical prognosis for recurrent cardiac arrest, remaining a major challenge. This emphasizes and suggests that careful management of patients who have successfully

5. Conclusion

In summary, the establishment of a rapid response system within the hospital can enhance the rate of return of spontaneous circulation (ROSC) in patients. By analyzing the current status of in-hospital cardiac arrest (IHCA), it provides objective indicators for evaluating post-resuscitation outcomes. It also suggests the need to strengthen the connections between various rescue links, improve the clinical early warning scoring system, and promptly activate the rapid response team, with the aim of shortening the time to initiate cardiopulmonary resuscitation and improving the success rate of resuscitation outcomes.

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The Impact of Therapeutic Communication Based on Humanistic Care on Nursing Satisfaction and Negative Emotions in Patients with Acute Renal Colic

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Abstract: *Objective*: To analyze the nursing effect of therapeutic communication guided by humanistic care on patients with acute renal colic. *Methods*: A total of 84 patients with acute renal colic admitted to the observation room from November 2022 to November 2024 were selected and evenly divided using a random number table. The experimental group received therapeutic communication guided by humanistic care, while the reference group received routine nursing care. Nursing indicators were compared between the two groups. *Results*: The experimental group exhibited higher nursing satisfaction than the reference group, lower scores for negative emotions after nursing, higher scores for knowledge mastery, lower scores for disease uncertainty, and superior scores for coping strategies ($p < 0.05$). *Conclusion*: Implementing therapeutic communication guided by humanistic care for emergency patients can enhance their nursing satisfaction, improve negative emotions, increase their knowledge mastery, reduce disease uncertainty, and correct inappropriate disease coping strategies.

Keywords: Humanistic care; Therapeutic communication; Emergency patients; Nursing satisfaction; Negative emotions; Renal colic

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1. Introduction

The emergency department admits critically ill patients, with a wide range of nursing tasks and a heavy workload, making it prone to adverse events such as nurse-patient disputes [1]. Additionally, patients and their families in the emergency department often exhibit significant negative emotions, and their understanding and acceptance of emergency nursing procedures are often inadequate, which directly affects their treatment compliance, particularly in patients experiencing acute episodes of renal colic. Therefore, it is necessary to strengthen nursing interventions for emergency patients, engaging in comprehensive and targeted communication under the concept of humanistic

care to effectively improve the quality of nursing. Therapeutic communication is a relatively novel means of nurse-patient communication that can bring the nurse-patient relationship closer, comprehensively assess the patient's physical and mental state, and enable individualized communication in various forms, demonstrating high scientific nursing value [2]. Based on this, this study selected 84 emergency patients to evaluate the implementation effects of therapeutic communication guided by humanistic care.

2. Materials and methods

2.1. General information

Eighty-four patients with emergency renal colic admitted to the hospital between November 2022 and November 2024 were selected and evenly divided using a random number table into an experimental group and a reference group, with 42 cases in each. In the experimental group, there were 25 males and 17 females; their ages ranged from 25 to 76 years, with an average age of (42.65 ± 3.74) years; regarding educational attainment, 12 cases had completed junior high school or below, 19 cases had completed high school to undergraduate studies, and 11 cases had completed education beyond undergraduate level. In the reference group, there were 26 males and 16 females; their ages ranged from 24 to 75 years, with an average age of (42.71 ± 3.62) years; regarding educational attainment, 11 cases had completed junior high school or below, 20 cases had completed high school to undergraduate studies, and 11 cases had completed education beyond undergraduate level. There were no significant differences in the data between the two groups ($p > 0.05$).

2.1.1. Inclusion criteria

Stable vital signs; normal consciousness and communication ability; complete basic information; able to cooperate throughout the study; informed and consented to participate in the study.

2.1.2. Exclusion criteria

Transferred to a specialized department for further treatment due to worsening condition; abnormal heart, liver, or kidney function; presence of malignant tumors; presence of mental disorders; withdrawal from the study midway.

2.2. Methods

The reference group received routine nursing care, which included detailed explanations of disease knowledge and treatment plans, informing patients of precautions during emergency treatment, increasing the frequency of rounds, irregularly inquiring about patients' physical discomfort, and providing targeted nursing care.

The experimental group received therapeutic communication guided by humanistic care:

(1) Establishment of a nursing team

The team leader was the head nurse of the emergency department, and the team members consisted of five senior nursing staff. The team conducted nursing rounds, optimized the admission and observation processes for patients with emergency renal colic, and provided psychological care, among other tasks. The head nurse provided unified training, elaborating on the principles and precautions for nursing patients with emergency renal colic, ensuring that all nursing staff were qualified after assessment before starting their duties.

(2) Relational communication

Nursing staff comprehensively collected patients' basic information within 15 minutes, established

electronic medical records, and recorded detailed information about patients' diseases, treatment plans, and past medical histories. Subsequently, they introduced the qualifications of medical staff, explained the rules and regulations as well as precautions for observation in the emergency department, and inquired about patients' feelings regarding the emergency environment. They provided items such as tissues and vomit bags to improve patient comfort. They patiently and friendly explained methods of nursing cooperation, guided patients in monitoring the aggravation or alleviation of their pain and vital signs, and instructed them to immediately report any worsening discomfort to medical staff.

(3) Evaluative communication

Before each treatment procedure, nursing staff communicated with patients to assess their past medical and treatment histories, gaining a comprehensive understanding of their physical condition. They evaluated patients' personality traits, educational levels, and family backgrounds, analyzed the causes of their negative psychological states, encouraged patients to express their inner feelings, actively listened to their concerns, and used methods such as verbal counseling, emotional diversion, or interest cultivation to improve patients' negative emotions, such as discussing topics of interest or encouraging them to listen to music.

(4) Therapeutic communication

Based on clinical diagnostic results, utilize video presentations, knowledge brochures, and other formats to explain disease-related information to patients, or guide them to follow the hospital's official account to view popular science knowledge on the platform. During and after treatment, communicate with patients multiple times to introduce common complications of the treatment plan and coping strategies, inform them of the purposes, clinical significance, and cooperation methods of common examination items, and alleviate their resistance. Actively inquire about patients' concerns or doubts regarding the treatment plan and provide one-on-one answers from clinical doctors. After emergency treatment is completed, provide rehabilitation guidance based on the patient's recovery status, listing precautions related to diet, treatment, hydration, exercise, etc., and explaining medication methods and treatment duration to improve patients' medication compliance.

2.3. Observation indicators

(1) Nursing satisfaction

A self-designed nursing satisfaction questionnaire was used, covering aspects such as service attitude and communication frequency, with a total score of 100 points [3]. Scores above 85 indicate high satisfaction, scores between 45 and 85 indicate moderate satisfaction, and scores below 45 indicate dissatisfaction. The Cronbach's α coefficient of this questionnaire is 0.968, and the test-retest reliability is 0.850, indicating good reliability and validity.

(2) Negative emotions

The Hospital Anxiety and Depression Scale (HADS) was selected, which includes anxiety (7 items) and depression (7 items) subscales. Each item is scored from 0 to 3, with negative emotions positively correlated with the score.

(3) Knowledge mastery level

A self-developed "Health Education Knowledge Assessment Scale" was used, encompassing disease knowledge, treatment plans, common complications, key points of nursing cooperation, and self-care methods, each section carrying a score of 20 points, with positive scoring for mastery level [4]. The Cronbach's α coefficient of this scale was 0.857, and its test-retest reliability was 0.851, indicating good

reliability and validity.

(4) Uncertainty in illness

The Mishel Uncertainty in Illness Scale (MUIS) was selected, which includes complexity factors (ranging from 10 to 50 points) and ambiguity factors (ranging from 15 to 75 points), with positive scoring for uncertainty in illness.

(5) Coping styles

The Medical Coping Modes Questionnaire (MCMQ) was chosen, which includes subscales for resignation (5 items), confrontation (8 items), and avoidance (7 items), with each item scored from 1 to 4 points and positive scoring for coping styles.

2.4. Statistical analysis

Data were processed using SPSS 28.0 software. Continuous variables were compared/tested using *t*-values, while categorical variables were compared/tested using chi-square (χ^2) values. Statistical significance was considered as $p < 0.05$.

3. Results

3.1. Comparison of nursing satisfaction between the two groups

The nursing satisfaction level in the experimental group was higher than that in the reference group ($p < 0.05$), refer **Table 1**.

Table 1. Comparison of nursing satisfaction between the two groups [n/%]

Group	n	Very satisfied	Basically satisfied	Dissatisfied	Satisfaction rate
Experimental group	42	22 (52.38)	19 (45.24)	1 (2.38)	97.62 (41/42)
Control group	42	18 (42.86)	17 (40.48)	7 (16.67)	83.33 (35/42)
χ^2	-	-	-	-	4.974
p value	-	-	-	-	0.026

3.2. Comparison of negative emotion scores between the two groups

Before nursing care, there was no significant difference in negative emotion scores between the two groups ($p > 0.05$). After nursing care, the negative emotion scores in the experimental group were lower than those in the reference group ($p < 0.05$). refer **Table 2**.

Table 2. Comparison of negative emotion scores between the two groups [$\overline{x} \pm$ s, points]

Group	n	Anxiety		Depression	
		Before care	After care	Before care	After care
Experimental group	42	14.15 ± 2.61	7.16 ± 1.77	12.53 ± 2.06	6.17 ± 1.35
Control group	42	13.95 ± 2.53	9.42 ± 1.81	12.59 ± 2.10	7.98 ± 1.41
t-value	-	0.357	5.785	0.132	6.009
p value	-	0.722	0.000	0.895	0.000

3.3. Comparison of knowledge mastery scores between the two groups

The knowledge mastery scores in the experimental group were higher than those in the reference group ($p < 0.05$) refer **Table 3**.

Table 3. Comparison of knowledge mastery scores between the two groups [$\overline{x} \pm s$, points]

Group	n	Disease knowledge	Treatment plan	Common complications	Key points of nursing cooperation	Self-care methods
Experimental group	42	17.21 ± 1.73	17.05 ± 1.33	16.37 ± 1.82	16.59 ± 2.11	17.28 ± 1.46
Control group	42	15.03 ± 1.61	15.19 ± 1.25	14.02 ± 1.80	14.04 ± 2.06	15.10 ± 1.34
t-value	-	5.978	6.604	5.950	5.604	7.129
p value	-	0.000	0.000	0.000	0.000	0.000

3.4. Comparison of disease uncertainty scores between the two groups

Before nursing care, there was no significant difference in disease uncertainty scores between the two groups ($p > 0.05$). After nursing care, the disease uncertainty scores in the experimental group were lower than those in the reference group ($p < 0.05$) refer **Table 4**.

Table 4. Comparison of disease uncertainty scores between the two groups [$\overline{x} \pm s$, points]

Group	n	Complexity factors		Ambiguity factors	
		Before care	After care	Before care	After care
Experimental group	42	26.54 ± 3.41	11.15 ± 2.07	38.65 ± 4.19	13.45 ± 2.93
Control group	42	25.97 ± 3.52	14.39 ± 2.10	39.01 ± 4.22	17.16 ± 2.97
t-value	-	0.754	7.121	0.392	5.763
p value	-	0.453	0.000	0.696	0.000

3.5. Comparison of coping style scores between the two groups

Before nursing care, there was no significant difference in coping style scores between the two groups ($p > 0.05$). After nursing care, the coping style scores in the experimental group were better than those in the reference group ($p < 0.05$) refer **Table 5**.

Table 5. Comparison of coping style scores between the two groups [$\overline{x} \pm s$, points]

Group	n	Yield		Face		Avoidance	
		Before care	After care	Before care	After care	Before care	After care
Experimental group	42	13.42 ± 2.18	8.69 ± 1.72	18.25 ± 2.97	24.19 ± 3.41	20.15 ± 3.64	14.05 ± 2.74
Control group	42	13.18 ± 2.20	10.22 ± 1.84	18.29 ± 2.91	21.33 ± 3.35	20.07 ± 3.69	16.97 ± 2.80
t-value	-	0.502	3.937	0.062	3.877	0.100	4.830
p value	-	0.617	0.000	0.950	0.000	0.921	0.000

4. Discussion

There are many types of diseases causing acute pain in patients in the emergency department, with rapid disease progression that can easily lead to various complications, posing a high disease risk. Most patients with acute renal colic have limited understanding of their own conditions. When entering an unfamiliar environment for the first time, they may experience psychological issues such as anxiety and depression. Coupled with the complexity of disease development, this significantly increases their psychological burden, thereby affecting treatment compliance. For this reason, clinical practice often involves providing routine care to emergency patients, paying close attention to their physical and mental states, and offering targeted nursing guidance to improve their cooperation with care. However, routine care has limited content and a relatively singular form, failing to meet the diverse care needs of emergency patients, thus having limitations [5].

Humanistic care is a widely used nursing method that provides individualized guidance based on the patient's disease condition and psychological state. It emphasizes nursing initiative, requiring nursing staff to actively communicate with patients, understand their current care needs, and reasonably optimize the nursing process, thereby embodying the concept of humanistic care in various nursing details and improving the quality of care [6]. Therapeutic communication is a planned and purposeful communication process centered around the needs of patients. It utilizes specific communication skills to establish a close nurse-patient relationship, actively guiding patients to express their inner feelings and nursing needs, thereby alleviating their negative emotions, assisting them in resolving nursing issues, and ultimately promoting their physical and mental well-being. Humanistic care-guided therapeutic communication highly aligns with the disease characteristics and nursing needs of emergency patients, demonstrating high professionalism and feasibility in nursing [7].

The results showed that the nursing satisfaction in the experimental group was higher than that in the reference group, while the scores for negative emotions were lower. The scores for knowledge mastery were higher in the experimental group, whereas the scores for disease uncertainty were lower. Additionally, the coping style scores were superior in the experimental group compared to the reference group ($p < 0.05$). The analysis attributes these results to the fact that humanistic care-guided therapeutic communication can enhance patients' awareness of relevant knowledge, strengthen their understanding of their own diseases, nursing plans, and treatment procedures, thereby increasing their sense of disease control and reducing negative emotions [8]. Strengthening nurse-patient communication allows for dynamic assessment of patients' nursing needs, enabling appropriate adjustments to treatment plans and nursing content based on their inner expectations. This involvement of patients in treatment and nursing decision-making enhances their treatment confidence and reduces disease uncertainty [9]. Moreover, during the communication process, nursing staff can convey positive energy to patients, provide them with emotional counseling, psychological comfort, and informational support, and deliver disease-related knowledge through multiple channels. As a result, patients tend to have a better grasp of knowledge. At the same time, therapeutic communication can guide patients to correctly cooperate with disease examination and treatment procedures, enhance their understanding of potential complications associated with treatment plans, enabling them to face their diseases rationally and optimistically, actively change their coping strategies from avoidance or submission, and maximize the role of nursing participation [10]. Under the aforementioned nursing interventions, patients can fully experience humanistic care, actively communicate with nursing staff, and express their nursing opinions, leading to higher satisfaction levels.

5. Conclusion

In summary, providing humanistic care-guided therapeutic communication nursing for patients with emergency renal colic yields high satisfaction levels, corrects negative emotions, improves their knowledge and disease coping abilities, and eliminates their uncertainty about the disease, demonstrating significant nursing value.

Disclosure statement

The authors declare no conflict of interest.

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Summary of the Best Evidence for Treatment and Management of Drooling in Children with Cerebral Palsy Based on Evidence-Based Approach

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Abstract: *Objective*: Literature review on the treatment and management of drooling in children with cerebral palsy was conducted. The literature was screened, evaluated, and compiled into an optimal evidence table to provide evidence-based reference for the treatment and management of drooling in children with cerebral palsy. *Methods*: A systematic search was conducted in the following databases for relevant evidence on the treatment and management of drooling in children with cerebral palsy: BMJ Best Practice, CINAHL, Cochrane Library, Clinical Trials, Embase, PubMed, UpToDate, Web of Science, GIN (Global Institution for Instruction), NGC (National Center for Health and Care Excellence), NICE (National Institute for Health and Care Excellence), JBI (Journal of the Institute of Evidence-Based Healthcare), Ontario Registered Nurses Association, SIGN (Scotland Institute of Instructions), Med live, CNKI (China National Knowledge Infrastructure), Chinese Medical Association, China Biomedical Research Center, Wan fang Data, and VIP (VIP Database). The literature types included guidelines, expert consensus, best clinical practice, evidence summaries, systematic reviews and randomized controlled trials. The search period was from database inception to July 30, 2025. All evidence related to the treatment and management of drooling in children with cerebral palsy was compiled, identified, and summarized to form the best evidence system. *Results*: A total of 22 articles were included, comprising 5 guidelines, 9 systematic reviews and systematic summaries, 3 expert consensus statements, and 5 randomized controlled trials. The optimal evidence framework contained 28 pieces of best evidence covering 10 aspects, including multidisciplinary team collaboration, comprehensive step-by-step assessment, overall treatment principles, behavioral therapy, physical therapy, drug therapy, intraglandular botulinum toxin injection, surgical treatment, radiotherapy, and dynamic follow-up. *Conclusion*: The best evidence

summarized in this study is scientific and systematic. Healthcare professionals can use this best evidence to develop targeted interventions to alleviate drooling symptoms, reduce complications, and improve treatment efficacy and quality of life in children with cerebral palsy. Furthermore, when developing treatment plans, it is crucial to comprehensively consider the specific clinical context of the child with cerebral palsy, treatment effectiveness, follow-up adjustment results, and the wishes of both the child and caregivers.

Keywords: Cerebral palsy; Neurodevelopmental disorder; Drooling; Saliva; Evidence summary

Online publication: Apr 21, 2026

1. Introduction

Cerebral palsy is a disorder characterized by abnormal muscle tone, abnormal posture, and movement. Its neonatal incidence is 0.15%, which is even higher in low- and middle-income countries and regions [1]. Patients with CP or neurodevelopmental disorders often exhibit varying degrees of oral motor dysfunction or dysphagia, with drooling being one of the most common complications [2]. Studies have shown that more than 40% of CP children over four years of age experience drooling [3]. Drooling can be classified into three types: anterior drooling, posterior drooling, and combined drooling. Anterior drooling is defined as unintentional loss of saliva in the oral cavity , occurring in approximately 44% of CP children [4,5]. Posterior drooling refers to saliva overflowing from the base of the tongue into the pharynx, leading to saliva accumulation, choking, recurrent pulmonary infections, and other life-threatening conditions, which require urgent intervention. And combined drooling can present with symptoms of both anterior and posterior drooling [6,7]. Long-term drooling can cause skin ulcers, difficulty eating, perioral maceration, choking, and other problems, which not only affect a child's physical health but also lead to low self-esteem, social isolation, and embarrassment. This creates numerous problems for the child and their family's daily life and mental well-being, increasing the burden of care and severely impacting the quality of life for both the individual and the family [8,9]. Therefore, it is crucial to take effective measures to manage drooling in children with cerebral palsy. In recent years, numerous studies have been conducted domestically and internationally on treatment protocols for drooling, yet the available evidence remains fragmented. This study systematically reviewed and synthesized the best available evidence based on evidence-based protocols, aiming to provide a scientific and standardized basis for healthcare professionals to formulate evidence-informed management measures. In addition, the series of complications caused by drooling described in this study, such as skin problems around the mouth and chin, oral health problems, and even psychological and social barriers, are all caused by Anterior drooling or Combination. so, all the best evidence summarized in this study is for these two types of drooling.

2. Materials and methods

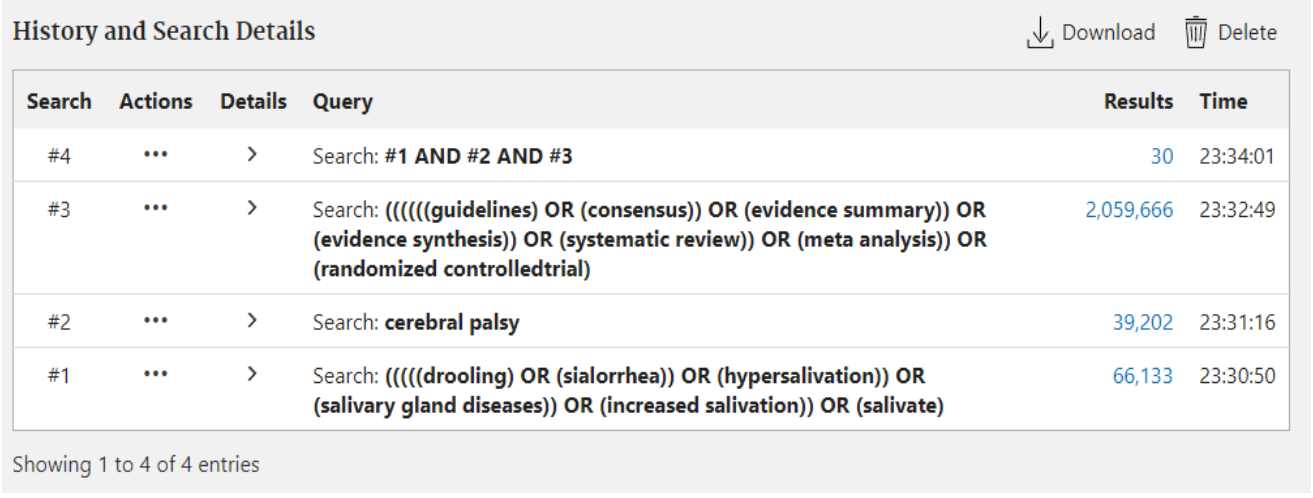
2.1. Evidence-based problem identification

The research question was defined based on the PIPOST model. The study population (P) consisted of children aged 0–14 years with cerebral palsy and drooling symptoms. The intervention (I) included measures and methods to alleviate drooling symptoms. The evidence applicator (P) was healthcare professionals or rehabilitation therapists in pediatrics or pediatric rehabilitation departments. The outcome measures (O) included the rate and

volume of drooling, aspiration or choking, and quality of life. The evidence application setting (S) was hospitals, pediatric or pediatric rehabilitation wards, or households. The evidence types (T) included clinical decision-making, evidence summaries, guidelines, best practices, expert consensus, systematic reviews, and randomized controlled trials.

2.2. Retrieval strategy

Using the 6S Model of the Evidence Pyramid, we conducted a top-down evidence search. For drooling, we used the following English search terms: drooling, drool, sialorrhea, hyper salivation, salivary gland diseases, salivate, salivation, salivation disorder, clear salivation, increased salivation, excessive salivation, saliva spillage. For cerebral palsy, we used the following English search terms: cerebral palsy, brain paralysis, spastic cerebral palsy. The search was conducted in databases including BMJ Best Practice, CINAHL, Cochrane Library, Clinical Trials, Embase, PubMed, UpToDate, Web of Science, Guidelines International Network (GIN), and the National Guideline Clearinghouse. Databases such as the National Geospatial Database (NGC), the website of the National Institute for Health and Clinical Excellence (NICE) in the UK, the Joanna Briggs Institute (JBI) Evidence-Based Healthcare Centre database in Australia, the Registered Nurses' Association of Ontario (RNAO) website in Canada, and the Scottish Intercollegiate Guide-lines Network (SIGN) in Scotland. Using the Chinese search terms "drooling/drooling disorder/drooling disease/saliva flow/salivary disorders/saliva clearance/salivary hypersecretion/salivary overflow/cerebral palsy drooling/childhood cerebral palsy drooling" to retrieve relevant evidence from databases and websites such as Yimaitong, China CNKI, Chinese Medical Association website, China Biomedical Literature, Wanfang database, and VIP database. The search language was Chinese and English. The search time frame was from the database establishment to July 30,2025. Taking the PubMed database as an example, the search strategy is shown in **Figure 1**.



History and Search Details

Download Delete

Search	Actions	Details	Query	Results	Time
#4	•••	›	Search: **#1 AND #2 AND #3**	30	23:34:01
#3	•••	›	Search: **((((((guidelines) OR (consensus)) OR (evidence summary)) OR (evidence synthesis)) OR (systematic review)) OR (meta analysis)) OR (randomized controlledtrial)**	2,059,666	23:32:49
#2	•••	›	Search: **cerebral palsy**	39,202	23:31:16
#1	•••	›	Search: **(((((drooling) OR (sialorrhea)) OR (hypersalivation)) OR (salivary gland diseases)) OR (increased salivation)) OR (salivate)**	66,133	23:30:50

Showing 1 to 4 of 4 entries

Figure 1. PubMed literature retrieval strategy.

2.3. Literature inclusion and exclusion criteria

2.3.1. Inclusion criteria

(1) Study subjects were children aged 0–14 years with cerebral palsy and drooling;

(2) The primary research content focused on alleviating or improving drooling symptoms in children with cerebral palsy;

(3) The types of literature involved in the research include clinical decision-making, evidence summaries, guidelines, best practices, expert consensus, systematic reviews, and randomized controlled trials.

2.3.2. Exclusion criteria

(1) Literature that was duplicated across different databases;
(2) Literature with low quality assessment scores;
(3) Non-Chinese/English literature;
(4) Literature for which full-text access was unavailable.

2.4. Literature quality evaluation

The JBI Guidelines for Research & Evaluation Instrument (AGREE II) was used to evaluate the guidelines, with each item scored on a 1–7 scale. The JBI Systematic Reviews of Methodological Quality (SRM) tool was applied to systematic review literature, comprising 11 items, each assessed with "yes, no, unclear, or uncertain". The Cochrane Collaboration's Risk of Bias Assessment for Randomized Controlled Trials (RCTs) tool was utilized for 7 items, requiring judgments of low, high, or unclear bias risk for each item. The JBI Methodological Quality Assessment for Expert Opinions and Professional Consensus (MEPAC) tool was employed for 6 items, each evaluated with "yes, no, unclear, or uncertain" [10]. Two researchers with evidence-based methodology training independently assessed the literature quality, followed by cross-evaluation. In case of disagreement, a third expert with senior professional title and systematic evidence-based training participated in discussions to reach a consensus.

2.5. Evidence extraction and integration

The two researchers independently extracted and consolidated relevant evidence from the literature, with a third researcher conducting semantic and content verification. When cross-cultural or adaptive differences arise, a senior evidence-based expert in the team should conduct a re-evaluation and propose a team-wide analysis and discussion until a consensus is reached. The extracted information mainly includes the publication time, source, type, and topic of the literature, as well as the best relevant evidence. The best approach to evidence compilation follows these principles: evidence that is consistent and complementary is merged based on content and logic; mutually exclusive evidence is merged according to the principles of high quality, high grade, and most recently published [10].

Firstly, the included studies were pre-classified using the Australian JBI Pre-Classification and Recommendation Level System (2014 version), categorizing evidence into levels 1–5, with level 1 being the highest and level 5 the lowest. Then, based on the system's recommendation strength grading principles and guided by the JBI FAME structure (feasibility, appropriateness, clinical significance, and effectiveness of evidence), the recommendation strength for each item was determined to be either Level A (strong recommendation) or Level B (weak recommendation). Evidence derived from evidence summaries and guidelines was directly graded according to their original evidence levels. Secondly, based on the evidence downgrading and upgrading principles of the GRADE system (Grades of Recommendations Assessment, Development and Evaluation, GRADE) (5 factors that reduce quality and 3 factors that increase quality), the included literature was further upgraded or downgraded. Finally, the best evidence compiled by our team was assessed for its level of evidence.

3. Results

3.1. Literature screening process and general characteristics of included studies

This study initially retrieved 644 articles, of which 413 were retained after deduplication. Following review of titles and abstracts, 345 articles were excluded for being unrelated to the topic, and 68 articles were preliminarily included. After full-text reading, 22 articles were ultimately selected. The literature retrieval and screening process is illustrated in **Figure 2**, and the general characteristics of the included articles are presented in **Table 1**.

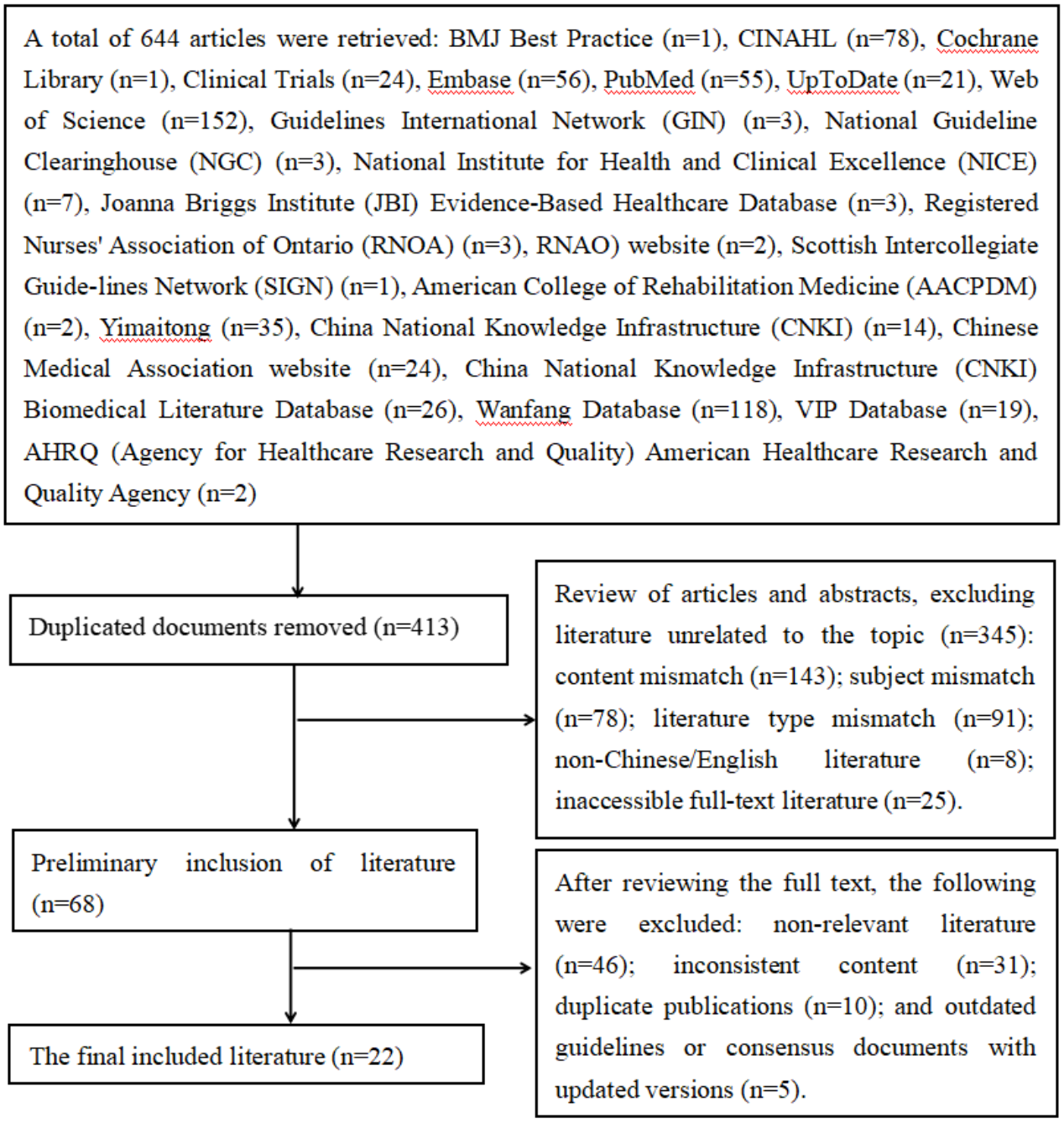


Figure 2. Literature retrieval and screening process.

Table 1. General characteristics of the included literature (n = 22)

No.	Included literature	Year of publication	Source of literature	Type of literature	Literature topics
1	Gibson N et al. [11]	2021	Medlive Guide Network	Guidelines	Prevention and Management of Respiratory Diseases in Children with Cerebral Palsy
2	NICE [12]	2017	NICE	Guidelines	Assessment and Management of Cerebral Palsy in Children Under 25 Years of Age
3	Zhang Jiankui et al. [13]	2022	Medlive Guide Network	Guidelines	Interpretation of Core Content in the Rehabilitation Guidelines for Cerebral Palsy (2022)
4	Bekkers S et al. [14]	2020	PubMed	randomized controlled trial	Cost-effectiveness of botulinum toxin A and surgical treatment for sialorrhea
5	Bekkers S et al. [15]	2021	PubMed	randomized controlled trial	Surgical treatment and botulinum toxin A injections are used to reduce drooling.
6	Xu Kaisou et al. [16]	2020	CNKI	specialist consensus	Rehabilitation recommendations for children with cerebral palsy who experience motor impairments.
7	Rodwell K et al. [17]	2012	PubMed	systematic review	Treatment of Sialorrhea in Children with Cerebral Palsy and Neurodevelopmental Disorders by Botulinum Toxin Injection
8	Lam KTT et al. [18]	2024	PubMed	systematic review	The effect of elastic therapeutic patches on reducing drooling in children
9	Walshe M et al. [2]	2012	Cochrane Library	systematic review	Intervention Measures for drooling in Children with Cerebral Palsy
10	Oad H et al. [19]	2024	PubMed	systematic assessment	Treatment of drooling in Children with Botulinum Toxin A (BoNT-A) Injection
11	Dias BLS et al. [20]	2017	PubMed	randomized controlled trial	Sublingual atropine sulfate is used to treat drooling in children with cerebral palsy.
12	Hung SA et al. [21]	2021	PubMed	systems assessment	Treatment of drooling in Children with Botulinum Toxin A (BoNT-A) Injection
13	Banzato A et al. [22]	2022	PubMed	systematic review	Efficacy Evaluation of Functional Chewing Training and Standard Treatment in Children with Cerebral Palsy
14	Fan Qiongli et al. [23]	2020	CNKI	randomized controlled trial	A prospective randomized controlled study on the treatment of oral motor dysfunction in children with cerebral palsy by chewing function training
15	Fayoux P et al. [24]	2024	PubMed	randomized controlled trial	Application of 320ug/mL Glycine Bromide in Children with Severe drooling and Neurological Diseases
16	Orriens LB et al. [25]	2024	PubMed	specialist consensus	Interdisciplinary Assessment and Treatment of Sialorrhea in Children
17	NICE [26]	2017	NICE	Guidelines	Oral glycyl bromide is used to treat severe drooling in children with chronic neurological disorders.
18	NICE [27]	2019	NICE	Guidelines	Treatment for chronic sialorrhea by Botulinum Toxin A (BoNT-A) Injection
19	Sforza E et al. [28]	2022	PubMed	systematic review	Outcome Measurement of Sialorrhea in Children
20	Bai Zirong et al. [29]	2024	CNKI	systems assessment	A systematic review of the efficacy of intrasalivary gland injection of botulinum toxin in the treatment of drooling in cerebral palsy.
21	Meningaud JP et al. [30]	2006	Upto date	systems assessment	Etiology and Treatment of Sialorrhea
22	Riva A et al. [31]	2022	PubMed	specialist consensus	The Influence and Management of Sialorrhea in Children with Neurological Disorders

3.2. Quality evaluation results of included literature

A total of 5 guidelines were included, with the quality assessment results of the literature presented in **Table 2**; 9 systematic reviews and meta-analyses were included, with the quality assessment results of the literature presented in **Table 3**; 3 expert consensus articles were included, with the quality assessment results of the literature presented in **Table 4**; and 5 randomized controlled trials (RCTs) were included, with the quality assessment results of the literature presented in **Table 5**.

Table 2. Quality assessment results of inclusion criteria (n = 5)

Include in guidelines	Standardized percentage (%) of scores in each field						≥ 60% of fields	≥ 30% and < 60% of the fields	< 30% number of fields	Overall quality of guideline	Recommended level
	Scope and Purpose	Participant	Rigor of formulation	Clarity of expression	Practicability	Editor independence					
Gibson N et al.	84.37	89.78	85.44	87.47	90.12	86.78	6	0	0	6	A
NICE	100	93.54	88.79	85.41	92.31	84.42	6	0	0	6	A
Li Xiaojie et al.	88.78	85.32	83.54	79.84	94.28	80.54	6	0	0	6	A
NICE	95.78	81.25	90.21	89.68	85.11	91.20	6	0	0	6	A
NICE	100	92.30	93.04	92.33	88.78	93.20	6	0	0	6	A

Note: NICE is the National Institute for Health and Care Excellence

Table 3. Quality assessment results of included systematic reviews (n = 9)

Inclusion in systematic review	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
Rodwell K et al.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
LamKTT class	yes	yes	yes	yes	yes	NK	yes	yes	yes	yes	yes
Walshe M et al.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
OadH class	yes	yes	yes	yes	yes	yes	yes	yes	NK	yes	yes
HungSA class	yes	yes	yes	yes	yes	yes	NK	yes	yes	yes	yes
Banzato A et al.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Sforza E et al.	yes	yes	yes	yes	yes	yes	yes	yes	NK	yes	yes
Bai Zirong et al.	yes	yes	yes	yes	NK	yes	yes	yes	yes	yes	yes
Meningaud JP et al.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

Note: (1) Is the proposed evidence-based question clearly defined? (2) Are the inclusion criteria for the literature appropriate? (3) Is the search strategy used appropriate? (4) Is the source of the research papers appropriate? (5) Are the quality criteria for the literature appropriate? (6) Was the literature quality assessment independently completed by two or more evaluators? (7) Were measures taken to minimize errors during data extraction? (8) Is the method of synthesizing/ merging studies accurate? (9) Was potential publication bias assessed? (10) Were recommendations for policies and/or practices supported by reported data? (11) Were suggestions for further research directions provided?

Table 4. Quality assessment results of expert consensus (n = 3)

Included expert consensus	(1)	(2)	(3)	(4)	(5)	(6)
Xu Kaishou et al.	yes	yes	yes	yes	yes	NK
Orriens LB et al.	yes	yes	yes	yes	NK	NK
RivaA class	yes	yes	yes	yes	yes	NK

Note: (1) Is the source of the viewpoint clearly cited? (2) Does the viewpoint originate from influential experts in the field? (3) Does the proposed viewpoint center on the interests of the relevant population? (4) Are the conclusions based on analytical results, and is the expression of the viewpoint logically sound? (5) Are other literature references included? (6) Does the proposed viewpoint contradict previous literature?

Table 5. Quality assessment results of included randomized controlled trials (n = 5)

Inclusion in randomized controlled trials	(1)	(2)	(3)	(4)	(5)	(6)	(7)	Include
Bekkers S et al.	low	low	low	low	Gao	low	low	yes
Bekkers S et al.	low	NK	low	low	NK	low	low	yes
Dias BLS et al.	low	low	NK	low	low	low	low	yes
Fan Qiongli et al.	low	low	low	NK	low	low	NK	yes
Fayoux P et al.	low	NK	low	low	low	low	low	yes

Note: (1) generation of random sequences; (2) concealment of randomization assignments; (3) blinding of study subjects and interveners; (4) blinding of outcome assessors; (5) completeness of outcome data (loss to follow-up); (6) possibility of selective reporting of study results; (7) other sources of bias.

3.3. Summary of evidence

This study synthesized 28 pieces of evidence from 10 aspects, including multidisciplinary team collaboration, comprehensive stepwise evaluation, general treatment principles, behavioral therapy, physical therapy, pharmacotherapy, intradermal botulinum toxin injection, surgical treatment, radiotherapy, and dynamic follow-up. See **Table 6**.

Table 6. Summary of best available evidence for drooling management in children with cerebral palsy

Classification of evidence	Content of evidence	Evidence grade	Evidence recommendation strength
Multidisciplinary team collaboration	1. It is recommended to adopt a multidisciplinary team collaboration model, with team members including pediatric neurologists, pediatricians, plastic surgeons, speech therapists, otolaryngologists, occupational therapists, psychologists, nurses, and teachers. When necessary, consultation with specialized dentists, physical therapists, dietitians, or gastroenterologists should be sought [2,11,25].	1a	A
Comprehensive stepwise evaluation	2. Conduct professional evaluation. It is recommended to first perform a professional assessment, including detailed medical history collection, physical examination, age of onset, developmental age and dental age, posture, medication use, reflux, duration of disease course, triggering factors, accompanying symptoms, developmental history, medication use, family history, perinatal experience, as well as evaluations of children's learning ability, self-management skills, social functioning (e.g., interaction with social environments, self-awareness, coping with negative reactions to drooling), and oral motor assessment [2,12,25].	1a	A

Table 6 (Continued)

Classification of evidence	Content of evidence	Evidence grade	Evidence recommendation strength
	3. Determine the type of drooling. It is recommended to first identify the type of drooling in children (Anterior drooling, Posterior drooling, or both), as Posterior drooling may be life-threatening and should be prioritized over Anterior drooling [2,25]. For children under 4 years of age, the use of percentile scores from the Drooling Rating Inventory for Infants and Preschoolers (DRIPS) is recommended to quantify the presence of pathological drooling.	1a	A
	4. Quantifying the severity, frequency, and actual impact of drooling symptoms. The assessment of Anterior drooling employs a combination of semi-objective and subjective methods [28,30]. The 5-minute Drooling Questionnaire (DQ5A) has been validated as an effective and reliable tool for objectively measuring drooling frequency in children with moderate to severe cerebral palsy [18,28]. The Drooling Impact Scale (DIS), French version of the Drooling Impact Scale (DIS-F), and the Modified Drooling Scale are currently the only assessment tools with responsive data, capable of effectively detecting clinically significant changes over time, serving as reliable tools for evaluating drooling severity and social acceptability [28]. The assessment of daily wet wipe usage frequency, however, is subject to debate due to the reliance on subjective judgment for replacement decisions, and its reliability remains questionable [18].	1b	A
	5. Assess the impact on children and/or caregivers. This includes evaluating the degree of impact on their lives, satisfaction with the intervention measures, and improvements in quality of life and mental health [2,28]. It is recommended to use assessment tools that comply with psychological measurement standards.	1c	B
	6. Assess the treatment preferences of the child and caregiver and establish treatment goals. Consider comprehensively the type and severity of drooling, the child's age, cognitive level, oral motor skills, self-awareness, and communication abilities, and involve the child or caregiver in the decision-making process to determine the optimal treatment plan [2,25].	1c	B
Principle of treatment	7. There is no clear consensus on safe and effective interventions for treating drooling in children with cerebral palsy, making it difficult to determine which intervention is the safest and most effective [2]. No authoritative accounts directly linking these interventions have been identified.	1b	B
	8. Methods to improve drooling typically include behavioral therapy, physical therapy, orthodontic appliances, pharmacotherapy, botulinum toxin injections for salivary glands, surgical procedures [2,14,15], radiotherapy and acupuncture [2,30]. It is recommended to prioritize less invasive interventions such as behavioral and pharmacological therapies, which can serve as preparatory steps for invasive treatments or as supplementary options for subsequent therapies [25]. Only then should more invasive treatments, such as botulinum toxin injections or surgical procedures, be considered [14,15].	1b	A
	9. The treatment plan is formulated progressively based on the patient's needs, adhering to the principle of "conservative treatment as the priority, drug intervention as the secondary option, and surgical treatment as the last resort" [2].	1a	A
	10. For children with a developmental age ≥ 6 years, guidance should be provided for daily self-management of salivation to enhance intrinsic control over saliva secretion. For children ≤ 12 years of age, pharmacological treatment is more preferred over surgical intervention for salivary secretion control. When a child presents for the first time with an age > 12 years and a developmental age < 6 years, surgical treatment may be the most appropriate therapeutic option [25].	1a	B

Table 6 (Continued)

Classification of evidence	Content of evidence	Evidence grade	Evidence recommendation strength
Behavior therapy	11. Behavioral therapies include swallowing exercises, head posture control, mouth closure, self-regulation of drooling, oral function training, speech therapy, swallowing coordination training, chewing function training, dysarthria treatment, and feeding therapy, all aimed at enhancing target behaviors and improving self-control of drooling [2,13,22,23,29]. Regardless of the treatment approach, intermittent oral sensory-motor therapy is recommended as an adjunctive intervention.	1b	B
Naturopathy	12. For interventions such as physical therapy, the primary goals are to improve lip and jaw closure function, enhance tongue control, reduce tongue thrusting, regulate muscle tone, and restore facial and oral sensory functions. Key approaches include: neurostimulation therapy, electromyographic biofeedback training, elastic therapy patches, acupuncture, massage, and oral sucking training. It is important to avoid forceful or forceful kneading of the face in children with cerebral palsy, and to promptly change bibs, etc [13,18,29,30].	1b	B
	13. The recommended elastic therapeutic taping combined with speech therapist-guided oral training techniques can rapidly improve oral motor skills and salivation control, with superior efficacy compared to monotherapy. The application of taping is more effective when applied to the orbicularis Oris muscle, suprasternal thyroids muscle, or both. The tension of the taping should be set at approximately 40%, with a duration ranging from 2.5 hours to 3 days. Prior to implementation, the physician should evaluate individual factors such as the patient's clinical diagnosis, allergy history, oral motor function, swallowing function, available resources, and needs to determine whether to adopt this therapy and the specific implementation method, including the application site, duration, and course length [18].	1a	A
	14. Orthodontic appliances (such as the Exeter lip sensor, palatal training appliance, Innsbruck sensory-motor activation regulator, and Castillo-Morales appliance) should be selected based on their shape, wearing position, and required duration, and are often used in combination with oral motor therapy [2].	1b	A
Medication	15. Prior to medication administration, it is essential to accurately assess the indications and contraindications for drug use, evaluate potential influencing factors such as medication history, reflux, dental issues, etc, and administer drugs individually, starting with a low dose and gradually increasing it. Regularly review the efficacy, tolerability, and side effects of all medications used for salivary control [12,26,29].	1b	A
	16. When botulinum toxin therapy is ineffective or contraindicated, anticholinergic drugs are recommended under the guidance of a specialist [12,15]. Administration routes include oral, transdermal, sublingual, intramuscular injection, and nebulization inhalation. Commonly used drugs include atropine sulfate, glucobromide, scopolamine, and trihexyphenidyl [20,24].	1a	B
	17. Bromocyclidine (administered orally or via enteric catheter), horseradish cholinesterase inhibitor (HRCI) transdermal formulation, or trihexyphenidyl hydrochloride are recommended. Bromocyclidine should be administered at least 1 hour before meals or 2 hours after meals, or at fixed times before or after meals. The dosage should be calculated based on the child's body weight, with an initial dose of 16 μg per kilogram of body weight, administered three times daily. The dose should be increased weekly over 4 weeks and continued at the maximum tolerated dose for another 4 weeks unless adverse reactions occur. For bromocyclidine bromide, the oral solution should be initiated at 0.02 mg/kg and increased by 0.02 mg/kg weekly until the optimal tolerated dose is reached, with a maximum dose of 1.5–3.0 mg, administered three times daily. After reaching the optimal dose level, the same drug and dose should be continued for a total of 8 weeks [24,26].	1a	A

Table 6 (Continued)

Classification of evidence	Content of evidence	Evidence grade	Evidence recommendation strength
	18. Anticholinergic drugs show limited efficacy in patients with severe drooling and are associated with a high incidence of adverse reactions during treatment. They are only suitable for short-term use in children, with close monitoring of adverse reactions [30]. Adverse reactions are often dose-dependent and difficult to assess in children with disabilities. Treatment should be discontinued if constipation, urinary retention, or pneumonia occurs.	1a	A
Intradermal injection of botulinum toxin for treatment	19. There is no unified or standardized approach regarding the selection of botulinum toxin types, optimal injection sites, solution preparation, ideal therapeutic doses, dilution ratios, and safest administration methods [17].	1b	B
	20. Clinically, botulinum toxin type A (BTX-A) is predominantly selected for application, although some scholars also suggest that BTX-A exhibits equivalent therapeutic efficacy to BTX-B [14,16,19]. The standard injection dose of BTX-A typically ranges from 55 to 250 IU, with 30 IU administered to each parotid gland and 20 IU to each submandibular gland [27]. For pediatric patients weighing less than 15 kg, the recommended dose is 15 IU per gland; for those weighing 15–25 kg, 20 IU per gland; and for those exceeding 25 kg, 25 IU per gland. A recommended injection interval of 6 to 12 months is advised [30].	1a	A
	21. When selecting the site for injection, the submandibular gland is the preferred choice, and the parotid gland may also be injected simultaneously [30]. Medical institutions with adequate resources recommend ultrasound-assisted localization. For ultrasound-guided localization, a high-frequency (5–10 MHz) probe should be used. The patient is typically positioned in the supine position during injection. For uncooperative children, sedation may be administered, or general anesthesia may be considered. The submandibular gland is divided into two quadrants (superior and inferior) for injection, while the parotid gland is divided into 4 quadrants (2 for superior and 2 for inferior). Care must be taken to avoid major blood vessels and nerves [12,30].	1a	A
	22. Caution should be exercised regarding the adverse effects of botulinum toxin, including local pain, altered salivary viscosity, and dry mouth. A minority of medical records have reported cases of cellulitis, dysphagia, and facial nerve palsy. If such symptoms occur, prompt notification to the physician is advised [2,12,30]. Adverse effects may be dose dependent. Botulinum toxin B can alleviate the frequency and severity of salivary secretion in children with cerebral palsy. Lower doses are ineffective, while higher doses do not enhance efficacy but may increase the incidence of additional adverse effects [21,27,31].	1b	B
Operative treatment	23. The surgical indications primarily include children with severe drooling who have failed conservative treatment, are over 6 years old, have undergone correction of triggering factors, and have shown no improvement after at least 6 months of exercise therapy, as well as those who may require lifelong pharmacotherapy, with insufficient benefit or discomfort from anticholinergic drugs and botulinum toxin A injections [12].	1a	B
	24. Surgical interventions regulate salivary secretion by reducing or eliminating neural stimulation of salivary glands, altering saliva flow patterns, employing ligations to block salivary flow and induce glandular atrophy, or directly excising salivary glands to terminate secretion. These procedures can be performed unilaterally or bilaterally and require general anesthesia. Common techniques include submandibular gland repositioning, submandibular gland ligation, submandibular gland excision, sublingual gland excision, parotid duct diversion, parotid duct ligation, and parasympathetic nerve sectioning. Combined surgical approaches demonstrate favorable outcomes, with comprehensive treatment regimens frequently adopted in clinical practice, particularly bilateral submandibular duct ligation [2,14,15].	1c	A

Table 6 (Continued)

Classification of evidence	Content of evidence	Evidence grade	Evidence recommendation strength
Radiotherapy	25. Radiotherapy can be used to control drooling, but its application in children is not recommended due to risks such as xerostomia, loss of taste, mucositis, radiation-induced caries, and radiation damage [30].	1b	B
Dynamic follow-up	26. Dynamic follow-up is recommended and scheduled after all pharmacological and/or surgical treatments, including short-term (8 weeks) and long-term (32 weeks) follow-ups, to evaluate the efficacy of interventions, adverse reactions, subjective feelings and satisfaction of the child or family members, as well as to assess new or ongoing treatment and care needs [2,25]. Treatment should be adjusted promptly based on the evaluation results.	1a	B
	27. For children receiving cholinergic medication, conduct a telephone assessment every 3 months to ensure treatment appropriateness [25].	1b	B
	28. To evaluate the long-term effects of interventions, a follow-up period of at least 18 months is recommended [2].	1b	A

4. Discussion

4.1. Multidisciplinary team collaboration is the key to managing drooling

Evidence 1 demonstrates that the treatment and management of drooling in children with cerebral palsy requires multidisciplinary collaboration and emphasizes the importance of establishing a multidisciplinary team. The group of children with cerebral palsy who drool is complex and diverse, and hides a series of neuromuscular dysfunction problems, such as oral motor dysfunction, primary neurological dysfunction, epilepsy and aspiration risk. It is difficult for a single specialty to balance various factors in clinical decision-making. However, the establishment and collaboration of a multidisciplinary team can largely complement the blind spots of treatment and management in various disciplines, so as to achieve the best possible comprehensiveness. This study emphasizes the advantages of the systematic and collaborative nature of multidisciplinary cooperation. The individualized treatment plan developed from multiple perspectives, including the patient's condition, psychological and social factors, can achieve the greatest therapeutic effect in complex clinical situations. This study also suggests that, in addition to medical staff, professionals with experience in caring for children with disabilities and special needs should be included in the drooling treatment management team [25,32]. Based on more than 20 years of work experience, the Dutch Orriëns LB et al. team proposed a structured algorithm model for MDT clinical decision-making, including step-by-step decision-making, baseline comprehensive assessment and family participation in shared decision-making [25]. Its core principle is not to pursue a single "stop drooling", but to pursue an individualized plan with the core goal of improving the quality of life of children and their families, preventing the occurrence of complications and promoting the social integration of children. At the same time, the NICE guidelines also emphasize that all decisions need to take into account the needs of the child and caregiver, as well as family preferences and values [12]. Therefore, it is recommended that multidisciplinary collaboration be further developed from a concept into an important decision support tool for the treatment and management of drooling in children with cerebral palsy. It could also be considered to incorporate it into a standardized clinical pathway centered on the child and family, based on structured assessment and decision algorithms, in order to bridge the gap between best evidence and family practice and promote more comprehensive, systematic and effective treatment and management of

drooling.

4.2. Comprehensive and stepwise evaluation of sialorrhea symptoms is the prerequisite for improving sialorrhea symptoms

Evidence 2–6 summarizes the assessment strategy for drooling in children with cerebral palsy. A step-by-step and comprehensive pre-treatment assessment is a prerequisite for safe and precise treatment. The assessment can be conducted in the following steps. First, classification of children with cerebral palsy according to the European Cerebral Palsy Surveillance (SCPE) and the Gross Motor Function Classification System (GMFCS-E&R) [33,34]. Second, according to the international consensus statement, different types of drooling should be distinguished. For the posterior type that requires special treatment, accurate identification and proper handling are necessary. The evidence summarized in this study is all for anterior type drooling or combined type drooling [2]. Third, make a clear diagnosis based on age, symptoms, relevant guidelines and auxiliary methods, and determine whether it is physiological or pathological drooling; 4. Assess and record the child's developmental age and dental age, evaluate the child's overall condition, and use appropriate and effective assessment tools to assess the severity of drooling. This study emphasizes that in addition to assessing the physical problems caused by drooling, it is also necessary to conduct a comprehensive assessment of the psychological state, social impairment, and quality of life of the child and their caregivers.

The international academic community has gradually shifted from relying solely on objective indicators to integrating caregiver self-report data, and is paying more and more attention to the subjective feedback of patients and their families [35]. Therefore, in addition to the above quantitative measurements, before formulating the best treatment plan, it is also necessary to consider the personal wishes and preferences of the child and their caregiver, combine the quantitative measurement indicators, the patient's self-reported outcome indicators and the caregiver's subjective opinions, and comprehensively consider them to further formulate treatment and management measures [18,27,30].

4.3. Adherence to therapeutic principles is a critical measure for effective management of drooling

Evidence 7–10 summarizes the treatment principles for drooling in children with cerebral palsy. Based on the literature retrieved so far, there are no clear guidelines or consensus on which intervention measures are the safest and most effective for children with different degrees of drooling. Therefore, when formulating clinical decision-making plans, multiple factors should be considered, including safety, efficacy, patient acceptance, patient and caregiver compliance with treatment measures, side effects, and quality of life [25]. Following the principle of "conservative treatment first, drug intervention second, and surgical treatment last", individualized treatment and management plans are developed and adjusted promptly based on monitoring and follow-up results. It is advocated to prioritize fewer invasive interventions, such as behavioral and physical therapy, followed by drug therapy [30]. Depending on the treatment effect, the dosage and intensity of treatment should be gradually increased as necessary, and finally, more invasive or side-effect-prone treatments such as botulinum toxin injection, surgical treatment, and radiotherapy should be considered.

Evidence 11–25 comprehensively summarizes various treatment modalities, including behavioral, physical, pharmacological, intradermal botulinum toxin injection, surgical, and radiation therapies, along with corresponding recommendations. Considering the complexity of the etiology and the individual differences in drooling, it is recommended that, based on the overall treatment principles, an individualized treatment plan combining multiple

treatment methods be considered. However, (e.g., Evidence 13 suggests integrating elastic therapy patches with oral training techniques, and Evidence 14 recommends combining orthodontic appliances with oral motor therapy), or combining physical therapy with pharmacotherapy, or pharmacotherapy with surgical intervention [2,18]. These approaches not only enhance treatment efficacy and reduce medication dosage but also facilitate the selection of minimally invasive surgical methods and avoid overtreatment. Intra-glandular injection of botulinum toxin is an important intervention method in the clinical treatment of drooling in cerebral palsy. It can directly act on the gland and inhibit glandular activity, thereby reducing saliva secretion [30]. Among many treatment methods, intraglandular injection of botulinum toxin has a clear therapeutic effect, long duration, relatively few complications, and wide applicability to a wide age range [23]. However, due to limited data in the literature, it is unclear whether this treatment is applicable to all children with cerebral palsy or neurodevelopmental disorders, and the operating procedures and dosages reported by various treatment centers lack uniformity and standardization [17]. Surgical procedures are invasive treatments. If other treatments cannot achieve the desired effect, surgical procedures may be considered as appropriate after strict evaluation of the indications, clarification of the expected effect of the surgery, and respect for the wishes of the child and their caregivers [25]. While this study summarized numerous treatment methods, it failed to provide a one-to-one correspondence between treatment methods and the severity of drooling. Therefore, it is difficult for physicians to standardize and homogenize their treatment decisions. It is hoped that future clinical studies will address this deficiency.

4.4. Dynamic follow-up after treatment is a critical safeguard to ensure therapeutic efficacy

To continuously assess the effectiveness of treatment measures, monitor adverse reactions, evaluate the improvement in the quality of life of children and their families, and assess long-term efficacy, Evidence 26–28 summarizes the best evidence for dynamic follow-up after treatment. As Orriëns LB et al. pointed out, controlling drooling requires “stepwise decision-making” [25]. Given that children with cerebral palsy are in a period of rapid development and considering the long-term nature of drooling treatment and the varying durations of effectiveness and risk profiles of different interventions, continuous dynamic follow-up after treatment is crucial to ensuring treatment effectiveness [21,36]. Physicians need to adjust the treatment plan in a timely and dynamic manner based on the follow-up results. Ultimately, by combining objective indicators such as the effectiveness of treatment with subjective indicators such as the needs of the child and caregivers through regular, structured reassessments, the treatment plan can be dynamically optimized, thereby promoting the goal of improving quality of life. Therefore, it is recommended to implement long-term dynamic management for children with cerebral palsy, and to carry out a cyclical process of “comprehensive assessment–professional intervention–reassessment–adjustment” by a multidisciplinary team.

5. Summary

This study summarizes the best evidence for the treatment and management of drooling in children with cerebral palsy, including 10 aspects of the entire process of drooling treatment and management, such as the establishment of a multidisciplinary team, comprehensive step-by-step assessment, treatment principles, treatment methods, and monitoring and follow-up. It can provide some reference for clinical practice. Medical staff can use appropriate evidence to carry out treatment based on the clinical situation, the patient’s condition, and the wishes of the child and his/her family, thereby improving the efficacy of treatment, reducing complications, and improving the quality

of life of children with cerebral palsy and their families.

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Establishment of Physiological Therapy: A New Health Preservation Strategy Based on the Quantum Decoherence Theory of Aging

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Abstract: *Objective:* To establish the theoretical system and technical specifications of Intentional Physiological Therapy (IPT), and explore its application value in anti-aging health preservation. *Methods:* Based on interdisciplinary research of quantum biology, neuroscience, aging biology and systems medicine, an intention-quantum-physiology coupling model was constructed by integrating microtubule quantum computing theory, mitochondrial quantum metabolism theory and biophoton communication mechanism; the technical system and evaluation standards of IPT were established through literature analysis, theoretical deduction and preliminary experimental verification. *Results:* (1) The quantum decoherence theory of aging was proposed, holding that aging is the gradual loss of quantum coherence at cell-tissue-system level driven by environmental perturbations and internal metabolic noise. (2) A four-level intention regulation model (molecular-gene, cell-tissue, organ-system, whole-integration) was established to realize multi-scale quantum state regulation. (3) The core technical system of IPT was designed, including quantum awareness training, mitochondrial intention regulation, biofield resonance and environment-assisted quantum ecology, forming a closed-loop regulation system. (4) Quantum optimization strategies for anti-aging were proposed for different age groups and physiological states. *Conclusion:* IPT provides a new quantum biological paradigm for anti-aging health preservation, breaking the limitations of traditional molecular biology research, with significant theoretical innovation, technical feasibility and broad application prospects, worthy of further in-depth research and clinical verification.

Keywords: Intentional physiology; Quantum biology; Anti-aging; Health preservation; Mitochondria; Quantum coherence; Biophotons

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1. Introduction

1.1. Research background

Population aging has become a global challenge in the 21st century. WHO statistics show that by 2050, the global population over 60 will reach 2.1 billion (22% of the total), and the over-80 population will exceed 400 million [1]. In China, the over-60 population reached 280 million (19.8%) by the end of 2023, and is expected to exceed 30% by 2035. Exploring effective anti-aging strategies is an urgent global health task. Traditional anti-aging research is based on the molecular biology paradigm, forming classical theories such as free radical, telomere, epigenetic clock and cellular senescence theories [2–4]. These theories have revealed partial molecular mechanisms and promoted the development of anti-aging technologies, but face fundamental dilemmas: they can only explain partial aging mechanisms, are difficult to restore youthful physiological functions, and most interventions target single molecular targets, lacking systematic regulation and easily causing side effects.

Meanwhile, psychosomatic medicine studies confirm that intentional activities (meditation, mindfulness, Qigong) can significantly regulate bodily physiological functions, with effects such as rapid onset and holistic regulation that cannot be fully explained by classical neuroendocrine-immune network mechanisms, suggesting a deeper intention-physiology regulatory mechanism [5–7]. In recent years, quantum biology breakthroughs have provided a new perspective. Quantum biology studies the application of quantum mechanics in biological systems, and key findings confirm that quantum effects exist in biological systems at room temperature: Engel et al. found quantum coherent energy transfer in photosynthetic FMO complexes in 2007; Liu et al. discovered quantum characteristics of mitochondrial “mitoflashes” in 2015; Kerskens et al. detected quantum entanglement signals in the human brain in 2022 [8–10]. These findings indicate that quantum effects may be the core mechanism of intention-physiology regulation, laying a foundation for new anti-aging strategies.

1.2. Research objectives and significance

This study aims to integrate the latest research results of multiple disciplines, establish a complete theoretical system and technical specifications of IPT, and clarify its anti-aging application value. Specific objectives include: proposing the quantum decoherence theory of aging, establishing an intention-quantum-physiology coupling model, designing the core technical system of IPT, exploring targeted anti-aging application strategies, and proposing future research directions.

The theoretical significance is reflected in three aspects: promoting the transformation of aging research from the molecular biology paradigm to the quantum system theory paradigm, establishing a connection between quantum biology and psychosomatic medicine, and providing a new theoretical basis for anti-aging technology development with the quantum decoherence theory of aging. The practical significance is equally prominent: developing a low-cost, non-invasive and systematic anti-aging technology easy to popularize, providing a new path for “healthy aging”, and promoting the integration of traditional health preservation culture and modern quantum biology technology to enrich the connotation of health preservation and boost the health industry development.

2. Theoretical basis

2.1. Core discoveries of quantum biology

2.1.1. Quantum effects in biological systems

Quantum biology research confirms that quantum phenomena (quantum tunneling, quantum coherence, quantum

entanglement, chiral-induced spin selection (CISS)) are widespread in biological systems and play a key role in life processes [11–15].

Quantum tunneling enables particles to pass through classical potential barriers, widely existing in enzyme catalysis, mitochondrial electron transport chains (ETC) and DNA charge transfer, significantly improving reaction efficiency [16]. Quantum coherence refers to the superposition state of quantum systems, the core of high-efficiency energy transfer in photosynthetic systems, and also plays an important role in protein folding and DNA replication [8,17]. Quantum entanglement is the non-local correlation between quantum systems, found in avian magnetoreception to achieve high-precision navigation [18,19]. The CISS effect of chiral molecules (DNA, proteins) filters electron spin, affecting DNA charge transfer and gene regulation, and participating in cell proliferation and differentiation [20,21].

2.1.2. Quantum biology of mitochondria

Mitochondria, as cellular energy centers, involve multiple quantum processes in their functions, which are the core of energy metabolism and functional regulation [9,22–25]. First, quantum tunneling in the ETC determines ATP production efficiency and reactive oxygen species (ROS) generation; electron leakage caused by reduced tunneling efficiency leads to excessive ROS and accelerated aging. Second, mitochondrial "mitoflashes" (quantized superoxide anion release) have obvious quantum characteristics, and their frequency peak can promote cell reprogramming through DNA demethylation [9,22]. Third, the quantized oscillation of mitochondrial membrane potential regulates enzyme activity, ATP/ROS production and cell fate [23]. In addition, the quantum metabolism theory holds that mitochondrial quantum state determines cellular metabolic and aging rates, and long-lived organisms maintain high mitochondrial quantum coherence through multiple ways, providing evidence for the quantum decoherence theory of aging [22,24,25].

2.2. Quantum theory of consciousness

2.2.1. Orch OR theory

Traditional neuroscience is difficult to explain the subjective nature and unity of consciousness. Penrose and Hameroff proposed the Orchestrated Objective Reduction (Orch OR) theory in 1996, holding that consciousness originates from quantum computing in neuronal microtubules; the quantum superposition state in microtubules generates conscious moments through objective reduction (OR) via quantum gravity effects; continuous OR events form human consciousness, with OR frequency synchronized with brain 40 Hz gamma waves [26–28]. Subsequent studies have found that microtubules can maintain quantum coherence at room temperature, supporting the Orch OR theory [27].

2.2.2. Experimental evidence of quantum entanglement in the brain

The existence of quantum effects in the brain is the key to supporting the Orch OR theory and the intention-quantum-physiology coupling model. In 2022, Kerskens and López Pérez detected proton spin correlation signals (quantum entanglement signals) in the human brain via MRI [10]. The signals exist in the awake state (mainly in the prefrontal and parietal cortices), disappear after anesthesia, and are enhanced during memory tasks. This is the first direct detection of quantum entanglement signals in the living human brain, providing strong experimental support for the quantum theory of consciousness. In addition, long-term meditation practitioners have higher brain quantum coherence and more stable gamma wave synchronization, confirming that intentional activities can

regulate the brain's quantum state [7].

2.3. Quantum decoherence theory of aging

Based on quantum biology and the quantum theory of consciousness, this study proposes the Quantum Decoherence Theory of Aging: the essence of aging is the gradual transformation of the living system from a quantum optimal state (high coherence, high entanglement, high efficiency) to a classical decoherent state (low coherence, low entanglement, low efficiency), driven by the cumulative damage of environmental perturbations (radiation, pollutants, stress) and internal metabolic noise (ROS, free radicals) on the quantum state of biological systems.

Aging quantum decoherence is a multi-level, progressive process involving four major mechanisms:

(1) Decreased mitochondrial quantum efficiency

Reduced ETC quantum tunneling efficiency leads to excessive ROS, forming a vicious circle of mitochondrial damage; irregular mitoflash frequency disrupts cell fate regulation and accelerates senescence.

(2) Broken cellular quantum communication

Reduced biophoton emission intensity and lost quantum coherence break intercellular quantum communication, leading to loss of cellular coordination, tissue function decline and age-related diseases.

(3) Solidification of epigenetic quantum states

Rigid DNA charge distribution leads to lost epigenetic quantum plasticity and reduced gene expression reversibility, causing abnormal expression of aging-related genes.

(4) Decoupling of system quantum entanglement

Weakened quantum correlation between organs and decoupled quantum entanglement lead to fragmented physiological rhythms, loss of systemic coordination and multiple age-related diseases.

Long-lived organisms (naked mole rats, turtles) maintain systemic quantum coherence by reducing ROS production, optimizing membrane lipid composition and maintaining epigenetic plasticity, confirming that maintaining quantum coherence is the key to delaying aging [29,30].

3. Mechanism of action of intentional physiological therapy

3.1. Intention-quantum-physiology coupling model

Based on the quantum decoherence theory of aging and the quantum theory of consciousness, a four-level intention-quantum-physiology coupling model is established, clarifying the quantum-level transmission path and regulatory mechanism of intention signals to realize multi-scale regulation of the body's quantum state. The four levels are closely coupled from top to bottom:

(1) Consciousness field level

Intentional focus regulates the quantum state of neuronal microtubules, enhances brain quantum coherence, and promotes biophoton emission; quantum signals (biophotons, neural oscillations) are transmitted to lower levels as intention carriers.

(2) Neuro-mitochondrial coupling level

Quantum signals regulate cellular calcium signaling; calcium ions, as second messengers, affect mitochondrial function, and mitochondrial quantum signals feedback regulate neuronal activity, forming two-way coupling.

(3) Mitochondrial quantum state level

The core of quantum regulation; intention signals improve ETC quantum tunneling efficiency, optimize mitoflash frequency, maintain mitochondrial quantum coherence, increase ATP production, reduce ROS generation, and regulate epigenetic states.

(4) Systemic physiological function level

The final effect of intention regulation; improved mitochondrial quantum efficiency and optimized epigenetic states promote energy metabolism, balance oxidation-reduction state, and regulate the aging process, improving overall physiological functions.

The model also includes three key coupling pathways for multi-channel transmission of intention signals: Neuro-Endocrine-Mitochondrial Axis (inhibiting HPA axis overactivation to protect mitochondria), Autonomic Nerve-Mitochondrial Axis (enhancing vagal tone to promote mitochondrial biogenesis), and Quantum-Biophoton Pathway (enhancing biophoton emission to realize rapid holistic quantum regulation).

3.2. Four-level intention regulation mechanism

Based on the coupling model, a four-level intention regulation mechanism is established to realize multi-scale, precise regulation of the body's quantum state, providing a theoretical basis for the IPT technical system design.

3.2.1. Molecular-gene level: Quantum epigenetic regulation

The core is to regulate gene expression by affecting the quantum state of DNA and epigenetic enzymes, delaying aging through three mechanisms: quantization of DNA charge transfer (biophotons regulate DNA epigenetic state), spin selectivity regulation (intention adjusts DNA electron spin to affect epigenetic enzyme activity), and mitochondrial-nuclear quantum communication (quantized ROS signals regulate nuclear gene expression) [21]. Health preservation applications include regulating telomerase activity, optimizing aging-related gene expression and slowing the epigenetic clock; preliminary experiments show 8 weeks of IPT training increases telomerase activity by 30% and slows the epigenetic clock by 2–3 years.

3.2.2. Cell-tissue level: Mitochondrial quantum state management

The core is to maintain mitochondrial quantum coherence, improve cell function and promote tissue repair through: mitoflash frequency regulation (optimizing frequency to promote cell reprogramming), mitochondrial fusion-fission balance maintenance (promoting mitochondrial network formation) and intercellular quantum communication enhancement (strengthening biophoton emission) [9]. Health preservation applications include maintaining stem cell function, promoting tissue repair and reversing cellular aging; preliminary clinical observations show IPT training increases stem cell numbers by 25%.

3.2.3. Organ-system level: Autonomic nerve quantum balance

The core is to maintain inter-organ quantum coherence and optimize system functions through: the vagus nerve-mitochondrial axis (enhancing parasympathetic tone to improve mitochondrial quantum efficiency), HPA axis quantum rhythm optimization (synchronizing with circadian rhythm to reduce cortisol levels) and cardiovascular-respiratory coupling enhancement (synchronizing HRV and respiratory rhythm to improve cardiovascular function). Health preservation applications include optimizing cardiovascular function, maintaining metabolic homeostasis and protecting nerve function; 12 weeks of IPT training increases HRV (RMSSD) by 30% and

reduces blood pressure by 10–15 mmHg.

3.2.4. Whole-integration level: Unity of consciousness field and biofield

The core is to maintain systemic quantum coherence and achieve physical and mental harmony through: consciousness field quantum effects (regulating quantum coherence to synchronize the biofield), biofield coherence enhancement (strengthening heart-brain electromagnetic field quantum entanglement) and environment-system resonance (synchronizing the body's quantum state with the natural environment) [10]. Health preservation applications include systemic rejuvenation, extending healthy lifespan and achieving physical and mental harmony; long-term IPT practitioners have a comprehensive physiological age 15–20 years younger than their actual age.

4. Technical system of intentional physiological therapy

4.1. Core technical modules

Based on the four-level intention regulation mechanism, the core technical system of IPT is designed, including **four modules** that correspond to different regulation levels and form a complete closed-loop system (**Table 1**). Each module has clear operation steps and evaluation indicators to ensure training standardization and effectiveness.

Table 1. Core technical modules of intentional physiological therapy

Module	Technical content	Action level	Health preservation goal
Quantum awareness training	Quantum body scan, quantized breathing (0.1 Hz), HRV biofeedback, quantum mindfulness	Sensory-Perceptual Level (Coupling Model Level 4)	Enhance interoception, optimize autonomic nerve balance, improve brain quantum coherence
Mitochondrial intention regulation	Mitochondrial visualization, energy metabolism optimization, grounding integration, near-infrared phototherapy assistance	Cell-Tissue Level (Coupling Model Level 2/3)	Restore mitochondrial quantum efficiency, optimize mitoflash frequency, delay cellular aging
Biofield resonance	Group synchronous meditation, Schumann resonance synchronization, heart-brain coupling training	Organ-System Level (Coupling Model Level 3/4)	Enhance inter-organ quantum coordination, optimize biofield coherence, improve autonomic and cardiovascular function

4.2. Standardized operation procedures

To ensure IPT operability and reproducibility, standardized operation procedures are formulated, including a basic protocol (8-week introductory course) for the general public and an advanced protocol (systemic rejuvenation) for those needing aging reversal.

4.2.1. Basic protocol (8-week introductory course)

Divided into 4 stages (2 weeks each), 20–30 minutes per session, twice a day:

(1) Weeks 1–2 (Quantum awareness establishment)
Core training of quantum body scan, auxiliary HRV biofeedback; goal: establish quantum state perception ability, HRV (RMSSD) increased by 20%.

(2) Weeks 3–4 (Quantized breathing)

Core training of 0.1 Hz resonant breathing (4 s inhalation-4 s breath holding-6s exhalation), auxiliary grounding integration; goal: master quantized breathing, HRV (RMSSD) increased by an additional 10%.

(3) Weeks 5–6 (Mitochondrial visualization)

Core training of mitochondrial visualization, auxiliary near-infrared phototherapy; goal: master visualization methods, mitoflash frequency returns to 1–3 times per minute [9].

(4) Weeks 7–8 (Integration and autonomy)

Unassisted autonomous training integrating previous content; goal: enter the target quantum state in < 5 minutes and maintain for > 20 minutes, formulate personalized long-term plans.

4.2.2. Advanced protocol (systemic rejuvenation)

Based on the basic protocol with increased intensity and difficulty, divided into 3 modules (4–6 weeks each), 45–90 minutes per session, 4–5 times a week:

(1) Quantum optimization of metabolism

Intermittent fasting combined with deep meditation, auxiliary ketogenic diet intention support and mitochondrial nutrient supplementation; goal: reduce body fat rate by 5–10%, increase ATP production efficiency by 20%.

(2) Epigenetic reprogramming

Deep meditation combined with theta frequency sound waves, auxiliary group synchronous meditation; goal: slow the epigenetic clock by 5–10 years, regulate anti-aging/pro-aging gene expression [4].

(3) Restoration of system resonance

Daily activities in a Schumann resonance environment, auxiliary natural light cycle adherence and seasonal retreats; goal: enhance inter-organ quantum entanglement, comprehensive physiological age 10–15 years younger than actual age.

4.3. Configuration of environment-assisted quantum ecology

Environment-assisted quantum ecology is an important part of IPT, creating a supportive quantum environment to enhance training effects. The standard configuration includes four optimized environmental factors, with basic requirements and personalized adjustment principles:

(1) Sound wave field

Pink noise (30–40 dB) as background, matching binaural beats (theta wave for basic protocol, theta/gamma wave alternation for advanced protocol) with sound pressure 10–15 dB lower than background.

(2) Magnetic field

Schumann resonance generator (7.83 Hz, 0.1–0.5 μT) and PEMF (1–10 Hz, 10–50 μT); PEMF is used for targeted irradiation of major organs.

(3) Light wave field

Full-spectrum dynamic lighting (color temperature changing with natural light) and near-infrared PBM (800–850 nm, 10–20 mW/cm^2); PBM for targeted irradiation of aging-prone organs in the advanced protocol.

(4) Energy field

Negative ion environment (1000–5000 ions/cm^3) and living plant wall (≥ 20% of training room area, high biophoton emission plants) to maintain 50–60% relative humidity.

4.4. Evaluation standards of IPT training effect

A multi-level evaluation system covering quantum, physiological and subjective experience indicators is established, with evaluations at baseline, intermediate and final stages to objectively assess training effects:

(1) Quantum level indicators (Core)

Brain quantum coherence (gamma wave synchronization, quantum entanglement signal intensity), mitochondrial quantum efficiency (ETC tunneling efficiency, mitoflash frequency) and biofield coherence (heart-brain electromagnetic field coherence, biophoton emission intensity), with clear percentage increase standards for effective training [9,10,22].

(2) Physiological level indicators (Auxiliary)

Autonomic nervous system indicators (HRV), metabolic indicators (blood glucose, blood lipid), anti-aging indicators (telomere length, epigenetic clock) and organ function indicators (cardiovascular, immune, nerve function), with specific improvement standards for each indicator [3,4].

(3) Subjective experience indicators

Physical comfort, mental state and quantum awareness, scored on a 10-point scale with an average increase of ≥ 3–4 points for effective training.

The comprehensive evaluation is based on the total effective rate (≥ 70% for effective, ≥ 85% for significantly effective, < 70% for ineffective); the training plan is adjusted for ineffective training according to individual differences.

4.5. Safety specifications and contraindications

IPT is a non-invasive, low-risk therapy, and strict safety specifications and contraindications are formulated to ensure practitioner safety:

(1) Safety specifications

Ensure training environment safety (air quality, temperature, humidity), gradual increase of training intensity, professional operation of auxiliary equipment, and 5–10 minutes of post-training relaxation; stop training immediately for abnormal physiological indicators.

(2) Contraindications

IPT is strictly prohibited for people with severe cardiovascular diseases, severe mental diseases, implanted medical devices, special groups (pregnant women in the first 3 months, minors under 16, severe liver/kidney dysfunction) and acute diseases; mild chronic disease patients can receive training under professional guidance with a pre-training physical examination.

5. Application strategies of intentional physiological therapy in anti-aging health preservation

Based on the quantum decoherence theory of aging, coupling mechanism and standardized IPT technical system, targeted application strategies are formulated for different age groups, physiological states and health preservation needs, with the core principle of “maintaining quantum coherence, delaying quantum decoherence, realizing systemic rejuvenation”.

5.1. Targeted application strategies for different age groups

The human body's quantum state shows obvious age-related changes, and IPT strategies focus on different regulation priorities and training intensities for different age groups:

(1) Young people (18–35 Years Old)

Core goal is quantum state maintenance and potential development; adopt a simplified basic protocol (20–30 minutes, 3–4 times a week), simplified environment configuration, focus on enhancing quantum awareness and autonomic nerve balance; evaluation focuses on quantum and subjective experience indicators. The value lies in preventing premature aging and improving work efficiency.

(2) Middle-Aged People (36–59 Years Old)

Core goal is quantum decoherence intervention and function restoration; adopt the complete basic protocol combined with the metabolic quantum optimization module (30–45 minutes, 4–5 times a week), standard environment configuration, focus on mitochondrial quantum state management and autonomic nerve balance; comprehensive evaluation of quantum, physiological and subjective experience indicators. As the key intervention group, IPT can delay age-related diseases and lay a foundation for healthy aging [2–4].

(3) Elderly people (60 Years Old and Above)

Core goal is systemic quantum resonance restoration and healthy aging; adopt a personalized adjusted basic protocol (reduced intensity, 20–30 minutes, 3–4 times a week), optimized environment configuration (focus on safety and comfort), focus on the unity of consciousness field and biofield; evaluation focuses on physiological and subjective experience indicators with real-time safety monitoring. IPT can improve the elderly's physical and mental state and reduce chronic disease burden [5,7].

5.2. Integration of IPT and traditional health preservation methods

Traditional Chinese health preservation methods (Qigong, Tai chi, traditional Chinese medicine health preservation) have core concepts consistent with IPT (maintaining systemic quantum coherence, physical and mental harmony). Their integration can complement each other and enhance anti-aging effects:

(1) Integration with Qigong and Tai Chi

Add quantum awareness training and mitochondrial visualization to Qigong/Tai chi movements; Qigong/Tai chi promotes quantum energy flow circulation, while IPT enhances quantum coherence to improve the efficiency of "intention leading Qi"; configure environment-assisted quantum ecology in practice to enhance the effect of "unity of man and nature" [5–7].

(2) Integration with traditional Chinese medicine health preservation

Adjust IPT training plans and environment configuration according to TCM constitution classification; combine IPT with TCM regimens (diet therapy, meridian massage); use TCM syndrome differentiation to evaluate IPT effects, forming a comprehensive evaluation system with quantum and physiological indicators.

5.3. Promotion and popularization paths of IPT

To promote the wide application of IPT, three-level promotion and popularization paths are proposed, combining professional training, home application and public health services to realize IPT standardization, popularization and industrialization:

(1) Professional training system construction

Formulate standardized training syllabuses and assessment standards, establish professional training institutions (offline + online), and build a national IPT professional certification system to ensure service standardization and professionalism.

(2) Home-based IPT application promotion

Develop portable auxiliary equipment (Schumann resonance generators, HRV biofeedback bracelets), build online training platforms (APP, WeChat mini-program) with courses and effect tracking, and launch popular science content to improve public awareness and acceptance.

(3) Integration into public health services

Set up IPT training rooms in community health service centers, promote IPT in nursing homes, and cooperate with health departments to carry out anti-aging public health projects, providing data support for IPT popularization [1].

6. Discussion and future research directions

6.1. Discussion

This study establishes the theoretical system and technical specifications of IPT based on the quantum decoherence theory of aging, breaking the limitations of traditional molecular biology anti-aging research and providing a new quantum biological paradigm [2–4]. Compared with traditional anti-aging interventions, IPT has three advantages: holistic and systematic regulation (multi-level quantum state regulation), non-invasive and low-risk (no drug side effects, suitable for long-term use), and interactive and sustainable (improving the body's quantum plasticity and self-regulation ability).

The theoretical innovation of this study is proposing the quantum decoherence theory of aging, redefining the essence of aging, and establishing the intention-quantum-physiology coupling model to clarify the quantum biological mechanism of intention regulating physiology [8–10,22]. The technical innovation is designing the standardized IPT technical system with core modules, operation protocols, environment configuration, evaluation standards and safety specifications, ensuring IPT operability and reproducibility.

However, the study has limitations: insufficient preliminary experimental verification with small sample sizes, complex and expensive quantum level indicator detection methods, and an incompletely clear mechanism of intention regulating the body's quantum state, all of which need further research [10,22].

6.2. Future research directions

Based on the research results and limitations, the following future research directions are proposed:

(1) Large-scale clinical verification

Conduct large-scale randomized controlled trials and long-term follow-up studies to verify IPT effectiveness and safety, providing clinical evidence for popularization.

(2) Improvement of quantum detection technology

Develop simple, low-cost portable quantum detection equipment to realize rapid detection of quantum level indicators and promote evaluation popularization [10,25].

(3) In-depth research on mechanism

Use advanced technologies (single-molecule quantum imaging, transcriptomics) to study the specific

mechanism of intention regulating the quantum state, especially quantum epigenetic regulation and mitochondrial quantum state management [4,9,21,22].

(4) Optimization of IPT technical system

Optimize technical modules and protocols based on clinical and mechanism research, develop personalized training plans and new environmental auxiliary equipment.

(5) Industrialization development

Integrate IPT with health care, elderly care and sports industries, develop a series of products and services to promote research result transformation.

(6) International cooperation and exchange

Strengthen cooperation with foreign research institutions, introduce advanced technologies and concepts, and promote the global development and application of IPT [8,10,26].

7. Conclusion

This study integrates the latest research results of quantum biology, neuroscience, aging biology and psychosomatic medicine, proposes the quantum decoherence theory of aging, establishes the intention-quantum-physiology coupling model, and designs the standardized technical system and application strategies of IPT [2–15,26–30]. The research results show that IPT is a new anti-aging health preservation strategy with significant theoretical innovation, technical feasibility and broad application prospects.

IPT breaks through the limitations of traditional molecular biology anti-aging research, takes maintaining the body's quantum coherence as the core, realizes multi-scale, systematic regulation of the quantum state through intention regulation and environment assistance, effectively delaying quantum decoherence, restoring mitochondrial function, optimizing organ function and achieving anti-aging effects [2–4,9,22–25]. Targeted application strategies for different age groups and integration with traditional health preservation methods further enhance IPT practicality and popularization.

Despite existing limitations, with the in-depth development of quantum biology and continuous optimization of IPT technology, IPT is expected to become an important anti-aging health preservation method, benefiting the general public, promoting the health industry development and providing a new path for global healthy aging [1].

Disclosure statement

The authors declare no conflict of interest.

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Advances in Mechanisms and Clinical Applications of Lasers with Different Wavelengths in Medicine

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Abstract: Since its inception, laser technology has undergone a leapfrog development from fundamental exploration to extensive clinical applications. In its early stages, lasers were mainly used for simple tissue cutting. With continuous technological innovation, their clinical value in precision therapy and minimally invasive intervention has become increasingly prominent. Lasers have evolved into an indispensable tool for the treatment of numerous diseases, driving a paradigm shift in diagnosis and treatment within the medical field. Lasers of different wavelengths exhibit significant differences in penetration depth and absorption characteristics within biological tissues. This wavelength selectivity enables lasers to act precisely on target tissues while minimizing damage to surrounding normal tissues. For instance, specific wavelengths can be selectively absorbed by chromophores such as melanin and hemoglobin, thereby achieving precise treatment of related diseases. This constitutes the fundamental mechanism underlying the precision of medical lasers. This review aims to systematically summarize recent advances in the working principles, expanded clinical applications, and cutting-edge research trends of various wavelengths of lasers in medicine. It is intended to provide comprehensive and up-to-date references for researchers and clinicians in related fields, and to promote the further development and application of medical laser technology.

Keywords: Photothermal effect; Tissue optics; Absorption coefficient

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1. Introduction

Lasers with different wavelengths exhibit diverse mechanisms of action and clinical application potentials, due to their differences in tissue penetration depth, absorption properties, and photothermal, photochemical, or

photomechanical effects. Low-intensity lasers in the visible to near-infrared range can regulate cellular redox status, activate signaling pathways, and promote tissue repair and anti-inflammatory responses. In contrast, high-energy mid- and far-infrared lasers mainly rely on thermal effects to achieve tissue ablation, coagulation, or remodeling, and are widely used in surgery, skin scar treatment, and urinary calculus management. With the development of precision medicine, the integration of intelligent optical systems and novel laser sources (such as ultrashort-pulse lasers and quantum cascade lasers) has further improved the targeting and safety of treatments. In recent years, the emergence of advanced technologies, including fractional lasers, transcranial photobiomodulation, and additive manufacturing combined with laser navigation, has promoted the in-depth exploration of lasers in neurological rehabilitation, tissue repair, and minimally invasive interventions. Therefore, systematically clarifying the mechanisms underlying the relationship between laser wavelength and biological effects, and summarizing the translational progress in multidisciplinary clinical practice, is of great significance for optimizing treatment strategies and expanding application boundaries.

2. Classification and basic mechanisms of lasers

2.1. Selective photothermolysis

Lasers of specific wavelengths can be selectively absorbed by chromophores in target tissues, such as melanin and hemoglobin [1]. The absorbed energy is converted into heat, which causes coagulation, vaporization, or necrosis of target tissues. Since surrounding normal tissues absorb little laser energy, they are minimally damaged.

2.2. Photomechanical/photoacoustic effects (targeted photolysis mechanism of picosecond lasers)

Picosecond lasers have an extremely short pulse duration and can release high energy in a very short time, generating strong photomechanical shock waves [2]. Such shock waves mechanically fragment target substances such as pigment particles. The fragmented particles are then phagocytosed and cleared by phagocytes in the body to achieve therapeutic effects. Meanwhile, laser energy also induces photoacoustic effects and generates ultrasonic waves, which can be used for tissue imaging and disease diagnosis [3].

2.3. Thermal coagulation and vaporization effect

Mid-infrared lasers have relatively long wavelengths and shallow penetration depth in tissues, but exhibit strong thermal effects. When laser energy is applied to tissues, the tissue temperature rises rapidly, leading to thermal coagulation and subsequent scar tissue formation, which achieves tissue repair and remodeling [4].

2.4. Photobiomodulation effect

Low-power lasers have low energy and do not cause obvious thermal damage to tissues. However, they can affect cell metabolism, proliferation, and differentiation through photobiomodulation [5]. They can activate multiple intracellular enzyme systems, promote the release of cytokines, regulate inflammatory responses, and accelerate tissue repair and regeneration. They show important application value in the treatment of inflammatory diseases and the repair of tissue injuries.

3. Working principles and clinical applications of lasers at various wavelength bands

Ultraviolet lasers (100–400 nm) have high photon energy and can break molecular bonds in tissue cells, leading to photochemical ablation [6]. They are clinically used in corneal refractive surgery (PRK, LASIK assistance) and pretreatment for epidermal grafting in vitiligo. In corneal refractive surgery, photorefractive keratectomy (PRK) uses ultraviolet lasers to directly ablate the corneal anterior limiting lamina and superficial stroma, thereby changing corneal curvature to correct myopia, hyperopia, and astigmatism [7]. Recent studies have explored the mechanism of skin in-situ regeneration and repair mediated by ultraviolet lasers. It has been found that ultraviolet lasers can activate skin stem cells, promote their proliferation and differentiation, and regulate cytokine secretion to accelerate skin tissue regeneration and repair [8]. This discovery provides a new theoretical basis for the application of ultraviolet lasers in skin injury repair and is expected to support the development of more effective treatments.

Visible-wavelength lasers (400–760 nm) exhibit strong absorption by chromophores such as hemoglobin and melanin. When laser energy is applied to tissue, hemoglobin and superficial melanin selectively absorb laser energy and convert it into heat. As a result, the diseased tissue is damaged, while the surrounding normal tissue is minimally injured [9]. Visible-wavelength lasers include argon lasers, copper vapor lasers, ruby lasers, and others. Argon laser energy is selectively absorbed by hemoglobin in capillaries, leading to capillary coagulation and occlusion. It can also act on blood vessels and inflamed tissue at the lesion site to reduce inflammation, and is used in the treatment of telangiectasia and rosacea [10]. Copper vapor lasers can activate photosensitizers to generate cytotoxic reactive oxygen species, which destroy vascular endothelial cells in the lesion, thus achieving a therapeutic effect on port-wine stains [11]. The heat generated by ruby lasers breaks down pigment granules in the epidermis, which are then removed by phagocytes. This laser is used to treat epidermal pigmentary diseases such as freckles and café-au-lait spots. Meanwhile, the laser energy can also target melanin in hair follicles and destroy follicular tissue to achieve permanent hair removal.

Near-infrared lasers (760–2500 nm) have relatively long wavelengths and deeper penetration depth in tissues, allowing them to reach deep dermal and even subcutaneous tissues [12]. They can also induce photoacoustic effects, which help clinicians evaluate the status of diseased tissues; the mechanical force generated by photoacoustic effects can also disrupt abnormal tissues to a certain extent, achieving synergistic therapeutic outcomes with the photothermal effects of lasers. Common near-infrared lasers include alexandrite lasers, Nd:YAG lasers, and picosecond lasers [13]. Alexandrite lasers can penetrate into the dermis and be selectively absorbed by melanin, and are mainly used for the treatment of nevus of Ota and dark tattoo removal [14]. Nd:YAG lasers target deep vascular and pigmented tissues; after the energy is absorbed by hemoglobin in blood vessels, thermal energy is produced to coagulate and occlude vessels, so Nd:YAG lasers are applied in the treatment of hemangiomas and can also improve pigmented lesions. Picosecond lasers have an extremely short pulse width and release high energy in a short time, generating strong photomechanical shock waves that effectively break down pigment particles, leading to significant efficacy in the treatment of freckles and melasma; picosecond lasers can also stimulate the regeneration and rearrangement of collagen, and are used for scar repair and facial rejuvenation [15,16].

Mid-infrared lasers (2500 nm–1 mm) have long wavelengths and strong water absorption. When laser energy is applied to tissue, water molecules in the tissue absorb a large amount of laser energy, which is rapidly converted into heat, leading to an increase in tissue temperature [17]. Such thermal energy can induce tissue thermal coagulation, vaporization, or thermal remodeling. Clinical applications mainly include erbium lasers and carbon dioxide lasers. The 2940 nm erbium laser exhibits extremely strong water absorption and can vaporize water

molecules in the superficial tissue within a very short time, allowing precise skin resurfacing and improving skin roughness, wrinkles, or skin scars [18]. The 10600 nm carbon dioxide laser causes tissue coagulation and vaporization through thermal effects, and simultaneously stimulates the regeneration and rearrangement of dermal collagen, achieving tissue repair and remodeling. It is used for the excision of benign neoplasms and the treatment of skin ulcers.

Other special-wavelength lasers include 980 nm diode lasers and 830 nm low-power lasers. The 980 nm diode laser shows good tissue penetration and selective absorption by hemoglobin. In the treatment of vascular proliferative diseases such as strawberry hemangioma and port-wine stain, the 980 nm diode laser causes coagulation and occlusion of pathological blood vessels through thermal coagulation, thus inhibiting vascular proliferation and achieving therapeutic effects. The 830 nm low-power laser can inhibit the release of inflammatory factors such as tumor necrosis factor-α and interleukin-6, and reduce inflammatory responses. It also activates the endogenous analgesic system and promotes the release of analgesic substances such as opioid peptides to relieve pain, so it is used for the treatment of postherpetic neuralgia.

4. Latest advances in lasers across disciplines

4.1. Photodynamic and low-level photobiomodulation therapy

In recent years, based on the penetration characteristics of lasers with different wavelengths in biological tissues and their interaction mechanisms with cellular photoreceptors, low-level photobiomodulation therapy (PBM) has gradually become a promising non-invasive treatment in the medical field. PBM involves the absorption of specific red and near-infrared light by mitochondrial cytochrome c oxidase, triggering a cascade of biological effects, regulating reactive oxygen species levels, ATP synthesis, and signal transduction pathways, and ultimately affecting cell proliferation, anti-inflammation, and tissue repair processes [19]. Dompe et al. described the molecular mechanisms of PBM and confirmed that the activation of redox-sensitive pathways is crucial for tissue repair. Near-infrared low-level lasers can significantly promote cell proliferation by regulating redox-sensitive signaling pathways, providing theoretical support for wound healing and regenerative medicine. Although the pro-repair effects of PBM have been verified, inappropriate parameter settings may cause thermal damage or ineffective intervention. Dosage and wavelength must be strictly controlled in clinical applications. The efficacy of PBM is not universal, and precise regulation is required according to individual differences. PBM is applied in neurocognition and pain management. PBM may alleviate neurodegenerative diseases by enhancing mitochondrial function in the brain. PBM has significant analgesic effects, and its mechanisms involve the inhibition of inflammatory factor release and the regulation of neuronal excitability.

4.2. Applications of lasers in skin and scar treatment

With the rapid development of optoelectronic technology, lasers with different wavelengths have become an important research direction in medical aesthetics and wound repair for skin tissue regeneration and scar treatment. Various lasers achieve precise intervention in collagen remodeling, microcirculation reconstruction, and inflammation regulation in scar tissue through selective photothermolysis, photomechanical effects, and photobiomodulation [20]. From non-ablative fractional lasers to high-energy carbon dioxide lasers, the optimized combination of wavelength, pulse width, and energy density has significantly improved the safety and efficacy of treatment. Numerous studies have shown that lasers with different wavelengths can effectively regulate key

pathological processes in scar tissue, including collagen remodeling, angiogenesis, and inflammatory responses, via selective photothermolysis or photomechanical effects. Especially in the treatment of hypertrophic scars and contracture scars, fractional carbon dioxide lasers exhibit prominent clinical advantages by promoting epidermal regeneration and stimulating orderly dermal repair due to their micro-ablative properties [21]. The mechanism of laser therapy for scars not only relies on the wound healing cascade induced by thermal injury but also involves the molecular regulation of signaling pathways such as TGF-β/Smad and the phenotypic transformation of fibroblasts [22].

4.3. Laser technologies in ophthalmology and minimally invasive interventions

From photocoagulation for retinal diseases to endovascular plaque ablation, lasers have improved the accuracy and safety of surgery and promoted the development of intelligent optical assistance systems [23]. The selection of laser wavelengths directly affects the interaction mechanism between lasers and biological tissues as well as the clinical efficacy. Micropulse lasers are widely used in the treatment of chronic retinal diseases such as diabetic macular edema and central serous chorioretinopathy due to their controllable thermal effects and selective action on the retinal pigment epithelium, avoiding photocoagulation scars and visual field defects caused by traditional continuous-wave lasers [24,25]. Micropulse lasers achieve subthreshold photodamage through intermittent energy delivery, activate retinal repair mechanisms while preserving the function of photoreceptors, and significantly expand the therapeutic safety window [25]. In minimally invasive interventional therapy, laser technology has been gradually integrated with intelligent optical imaging, navigation and feedback systems, improving ablation accuracy and intraoperative evaluation capability. Laser ablation systems based on specific wavelengths (such as 1470 nm or 1940 nm) combined with fiber-optic sensing and artificial intelligence algorithms allow precise control of thermal damage in endovascular or solid tumor interventions, reducing collateral damage to surrounding healthy tissues.

4.4. Applications of lasers in urology, surgical operations and other medical fields

In the field of urology, lasers have become one of the core methods for stone treatment due to precise energy delivery and controllable thermal effects. Liang et al. reported that holmium laser under ureteroscopy can effectively fragment stones, but the risk of local tissue damage caused by heat accumulation should be noted [26]. Taratkin et al. further compared the stone fragmentation mechanisms of Ho:YAG and thulium fiber lasers in different medium environments, and pointed out that wavelength and pulse characteristics significantly affect ablation efficiency and thermal diffusion range. Pulsed dye lasers and copper vapor lasers achieve selective photothermal destruction of lesions by matching hemoglobin with their specific absorption spectra, while protecting surrounding tissues to the maximum extent. Overall, lasers with different wavelengths exhibit highly specialized clinical efficacy in urological lithotripsy, precision surgery, wound repair, vascular therapy and other aspects due to their different interaction mechanisms with biological tissues.

4.5. Advances in the integration of emerging optical technologies and multimodal diagnosis and treatment

From the visible and near-infrared to mid-infrared and even terahertz bands, the penetration depth, selective absorption, and photochemical effects of lasers have been systematically applied in many clinical fields, including tumor ablation, skin repair, neural regulation, and chronic disease management. With the development of intelligent imaging guidance, combined photodynamic and photothermal therapy, and multifunctional nanoprobes,

optical diagnosis and treatment are evolving toward real-time feedback, personalized intervention, and minimally invasive high efficiency. This process has promoted the technological upgrading of traditional laser devices and provided new theoretical foundations and practical approaches for integrated medical solutions across scales and with multiple parameters. Intelligent precision optical diagnosis and treatment technologies, by integrating wavelength-tunable lasers, real-time imaging, and feedback systems, have significantly improved the targeting and safety of treatment. In photodynamic therapy, the combination of new photosensitizers and specific-wavelength lasers has enhanced the selective killing efficiency of tumor cells and extended its applications in anti-infection and immunoregulation. Meanwhile, short-wave infrared ultrafast fiber laser systems have offered new possibilities for noninvasive intervention in deep tissues due to their large penetration depth and low tissue scattering. In skin aesthetics, the differential effects of lasers with different wavelengths on pigment, blood vessels, and collagen have been widely used, but no unified standards have been established for personalized parameter setting.

5. Conclusion

This review systematically summarizes the research advances in the mechanisms of action and clinical applications of lasers with different wavelengths in the medical field. Lasers of varying wavelengths exhibit distinct interaction modes with biological tissues, which mainly depend on their penetration depth, absorption characteristics, and thermal effect controllability—these differences determine their unique advantages and application scopes in clinical practice. Specifically, short-wavelength lasers are characterized by strong surface absorption, making them suitable for superficial tissue treatment such as skin repair and superficial tumor ablation; mid-wavelength lasers, represented by Ho:YAG lasers, have moderate penetration depth and controllable thermal effects, and are widely used in urological lithotripsy and minimally invasive surgery; long-wavelength lasers, including near-infrared and terahertz lasers, possess deep tissue penetration and low scattering properties, providing new approaches for deep tumor diagnosis and noninvasive intervention.

In clinical applications, lasers with different wavelengths have been maturely applied in multiple disciplines such as urology, dermatology, oncology, and neurosurgery, significantly improving the efficacy of disease treatment, reducing trauma, and promoting patient recovery. With the continuous development of related technologies, the combination of lasers with intelligent imaging guidance, nanomaterials, and synergistic therapy has further optimized their targeting and safety, overcoming the limitations of traditional laser treatment such as tissue damage caused by heat accumulation.

However, there are still some challenges in the clinical application of lasers of different wavelengths: the standardized setting of individual treatment parameters has not been fully established, the long-term safety of some new laser technologies needs to be further verified, and the cost of high-performance laser equipment limits their popularization. In the future, with in-depth research on the interaction mechanisms between lasers and biological tissues, and the continuous innovation of laser equipment and auxiliary technologies, lasers of different wavelengths will show broader application prospects in personalized treatment, precise minimally invasive intervention, and chronic disease management, bringing new breakthroughs to the development of modern medicine.

Disclosure statement

The authors declare no conflict of interest.

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Clinical Efficacy of Xiaochengqi Decoction Enema Combined with Conventional Therapy in Patients with Acute Simple Intestinal Obstruction

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Abstract: *Objective*: To evaluate the clinical efficacy of Xiaochengqi Decoction enema in the treatment of acute simple intestinal obstruction and to compare its effects with those of Gastrografin and soap water enema. Methods: This study was designed as a prospective randomized controlled study. A total of 150 patients diagnosed with acute simple intestinal obstruction and admitted to the Emergency Department of Linfen People's Hospital between September 2023 and August 2025 were enrolled. Patients were randomly assigned into the Xiaochengqi Decoction group, the Gastrografin group, and the soap water group, with 50 patients in each group. All groups received conventional conservative management, including fasting, continuous gastrointestinal decompression, fluid resuscitation, and correction of water–electrolyte and acid–base imbalances. In addition, patients in the Xiaochengqi Decoction group received modified Xiaochengqi Decoction retention enema, those in the Gastrografin group received 76% Gastrografin via nasogastric tube, and those in the soap water group received soap water enema. Clinical efficacy, symptom relief time, length of hospital stays, and imaging improvement were compared among the three groups. *Results*: No statistically significant differences were observed among the three groups in baseline characteristics ($p > 0.05$). No statistically significant difference in overall clinical efficacy was observed among the groups ($\chi^2 = 6.036$, $P = 0.196$). The total effective rate was highest in the Xiaochengqi Decoction group (90.0%), followed by the Gastrografin group (86.0%) and the soap water group (76.0%). Significant differences were also identified in abdominal pain relief time, time to first flatus, time to first defecation, and length of hospital stay (all $p < 0.001$), with the shortest durations observed in the Xiaochengqi Decoction group. Imaging improvement rates differed significantly among groups ($\chi^2 = 11.836$, $P = 0.019$), with the highest rate in the Xiaochengqi Decoction group (98.0%). *Conclusion*: Xiaochengqi Decoction enema, when combined with conventional conservative therapy, may improve clinical outcomes in patients with acute simple intestinal obstruction, promote recovery of bowel function, and reduce hospital stay, demonstrating favorable clinical applicability.

Keywords: Xiaochengqi decoction; Simple intestinal obstruction; Enema therapy; Emergency medicine; Clinical efficacy

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1. Introduction

Acute simple intestinal obstruction is a common clinical condition encountered in emergency departments and represents an important subtype of mechanical intestinal obstruction [1]. It is characterized by impaired intestinal transit without evidence of compromised bowel wall perfusion [2]. Patients typically present with abdominal pain, abdominal distension, nausea, vomiting, and cessation of flatus or defecation. If not managed appropriately, the condition may progress to strangulated obstruction or bowel necrosis, which can lead to severe morbidity and mortality [3].

Conservative management remains the primary therapeutic strategy for acute simple intestinal obstruction and generally includes fasting, gastrointestinal decompression, fluid resuscitation, and correction of water–electrolyte disturbances [4]. Enema therapy is frequently used as an adjunctive intervention to relieve intraluminal pressure and facilitate intestinal decompression. Traditional soap water enema mainly exerts a lubricating effect and may provide limited therapeutic benefit. Gastrografin, a hyperosmolar water-soluble contrast agent, has been reported to promote fluid shifts into the intestinal lumen and stimulate bowel motility; however, its therapeutic efficacy in emergency settings remains controversial [5].

Xiaochengqi Decoction, a classical traditional Chinese medicine formulation, has been widely used for gastrointestinal disorders and is believed to exert regulatory effects on intestinal motility [6,7]. In recent years, herbal retention enema has gained increasing attention as a complementary approach in the management of intestinal obstruction, yet comparative clinical evidence remains insufficient. Therefore, the present study employed a randomized controlled design to evaluate the clinical efficacy of Xiaochengqi Decoction enema and to compare its effects with those of Gastrografin and soap water enema.

2. Methods

2.1. Study population

A total of 150 patients diagnosed with acute simple intestinal obstruction and admitted to the Emergency Department of Linfen People's Hospital between September 2023 and August 2025 were enrolled in this study. All patients met the diagnostic criteria for acute simple intestinal obstruction, including abdominal pain, abdominal distension, and cessation of flatus or defecation, without signs of peritoneal irritation on physical examination [8]. Abdominal radiography demonstrated the presence of air–fluid levels. All participants provided written informed consent prior to inclusion.

2.2. Randomization and grouping

Patients were randomly assigned using a random number table into three groups: the Xiaochengqi Decoction group, the Gastrografin group, and the soap water group, with 50 patients in each group. No statistically significant differences were observed among the groups with respect to baseline characteristics, including age, sex, disease duration, and abdominal pain visual analogue scale (VAS) scores ($p > 0.05$).

2.3. Treatment protocol

All patients received conventional conservative management upon admission, including fasting, continuous gastrointestinal decompression, fluid resuscitation, and correction of water–electrolyte disturbances. In addition, group-specific interventions were administered as follows:

(1) Xiaochengqi Decoction group
Modified Xiaochengqi Decoction retention enema twice daily;
(2) Gastrografin group
Administration of 76% Gastrografin (100 mL) via nasogastric tube twice daily;
(3) Soap water group
Soap water enema (700 mL) twice daily

Patients were treated and observed for up to 10 days or until clinical resolution of obstruction. Clinical efficacy, abdominal pain relief time, time to first flatus, time to first defecation, length of hospital stay, and imaging improvement were recorded and analyzed. Clinical outcomes were categorized as cured, improved, or ineffective. Cured was defined as complete resolution of abdominal symptoms with disappearance of air–fluid levels on imaging; Improved was defined as partial symptom relief with radiological improvement; Ineffective indicated no clinical improvement or clinical deterioration requiring surgical intervention. The total effective rate was calculated as:

Total effective rate = (cured + improved cases) / total cases × 100%.

2.4. Statistical analysis

Statistical analyses were performed using SPSS version 27.0. Normally distributed continuous variables are presented as mean ± standard deviation (SD), with overall intergroup comparisons conducted using one-way analysis of variance (ANOVA), and pairwise post-hoc comparisons were performed via the Bonferroni test.Non-normally distributed continuous variables are expressed as median (interquartile range), and the Kruskal-Wallis (KW) H test was adopted for overall between-group comparisons. Categorical variables were analyzed using the chi-square (χ^2) test. Values marked with distinct lowercase superscript letters (a, b, c) within the same row denote statistically significant intergroup differences after Bonferroni pairwise comparison. A two-tailed P value < 0.05 was considered statistically significant.

3. Results

3.1. Baseline characteristics

No statistically significant differences were observed among the
age, sex distribution, disease duration, and abdominal pain severity (all $p > 0.05$), indicating that the groups were comparable at baseline (**Table 1**).

Table 1. Comparison of baseline characteristics among the three groups

Variables	Xiaochengqi Decoction group (n = 50)	Gastrografin group (n = 50)	Soap water group (n = 50)	F/χ^2 value	p value
Age (years)	53.6 ± 11.2	55.1 ± 10.8	54.3 ± 12.1	0.217	0.805
Sex (male/female)	28/22	26/24	29/21	0.378	0.828
Disease duration (h)	19.2 ± 6.8	20.5 ± 7.4	18.9 ± 6.5	0.790	0.456
Abdominal pain VAS score	8 (7, 8)	8 (7, 9)	8 (7, 8)	1.023	0.600

Note: Continuous variables are presented as mean ± standard deviation (SD) and were compared using one-way analysis of variance (ANOVA). Categorical variables were compared using the chi-square (χ^2) test. A p value < 0.05 was considered statistically significant.

3.2. Clinical efficacy

No statistically significant difference in clinical efficacy distribution was observed among the three groups (χ^2 =6.036, P = 0.196). Overall, the Xiaochengqi Decoction group demonstrated the highest therapeutic response , followed by the Gastrografin group and the soap water group. Detailed results are presented in **Table 2**, and comparisons of total effective rates are shown in **Figure 1**.

Table 2. Comparison of clinical efficacy among the three groups

Groups	Cured	Improved	Ineffective	Total effective rate
Xiaochengqi Decoction group (n = 50)	33 (66.0%)	12 (24.0%)	5 (10.0%)	45 (90.0%)
Gastrografin group (n = 50)	29 (58.0%)	14 (28.0%)	7 (14.0%)	43 (86.0%)
Soap water group (n = 50)	22 (44.0%)	16 (32.0%)	12 (24.0%)	38 (76.0%)

Note: Total effective rate = (cured + improved cases) / total cases×100%. Group comparisons were performed using the chi-square (χ^2) test.

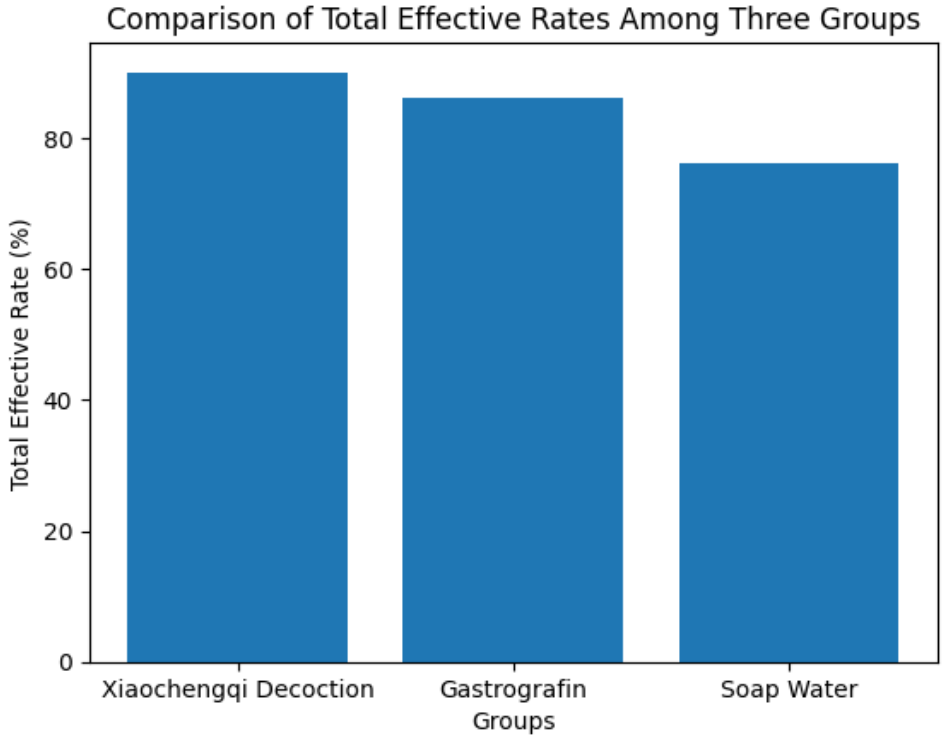


Figure 1. Comparison of total effective rates among the three groups.

Note: Total effective rate = (cured + improved cases)/total cases × 100%. The difference among groups was not statistically significant (χ^2 = 6.036, P = 0.196).

3.3. Symptom relief and hospital stay

One-way analysis of variance (ANOVA) revealed statistically significant differences among the three groups in abdominal pain relief time, time to first flatus, time to first defecation, and length of hospital stay (all $p < 0.001$). Overall, the Xiaochengqi Decoction group exhibited the shortest durations, followed by the Gastrografin group and the soap water group (**Table 3**). The distribution of abdominal pain relief time is illustrated in **Figure 2**.

Table 3. Comparison of symptom relief time and length of hospital stay among the three groups

Variables	Xiaochengqi Decoction group	Gastrografin group	Soap water group	*F* value	*p* value
Abdominal pain relief time (h)	12.8 ± 4.5[a]	18.5 ± 5.3[b]	25.1 ± 7.2[c]	54.416	< 0.001
Time to first flatus (h)	18.5 ± 5.2[a]	25.2 ± 6.5[b]	31.8 ± 8.4[c]	48.682	< 0.001
Time to first defecation (h)	27.1 ± 7.3[a]	35.4 ± 8.9[b]	42.6 ± 10.7[c]	36.527	< 0.001
Length of hospital stay (d)	5.5 ± 1.4[a]	6.9 ± 1.7[b]	7.8 ± 2.0[c]	25.619	< 0.001
Abdominal distension score on Day 2	4 (3, 4)	4 (3, 5)	4 (4, 5)	5.744	0.057

Note: Normally distributed continuous variables were expressed as mean ± standard deviation, with intergroup overall comparisons conducted by one-way analysis of variance (ANOVA), and pairwise post-hoc comparisons were performed using the Bonferroni method; non-normally distributed continuous variables were presented as median (interquartile range) , and the Kruskal-Wallis (KW) H test was used for between-group overall comparisons. A two-tailed *P* value < 0.05 indicated statistically significant difference. Values with different lowercase superscript letters (a, b, c) in the same row were significantly different after pairwise Bonferroni comparison.

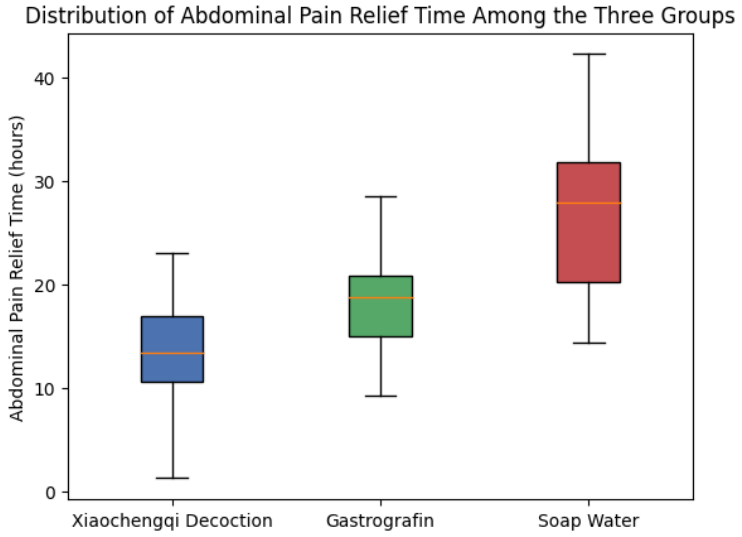


Figure 2. Distribution of abdominal pain relief time among the three groups.

Note: Data are presented as mean ± standard deviation. Differences among groups were statistically significant ($p < 0.001$).

3.4. Imaging outcomes

A statistically significant difference in imaging improvement was observed among the three groups ($\chi^2 = 11.836$, $P = 0.019$). The Xiaochengqi Decoction group demonstrated the highest imaging improvement rate, followed by the Gastrografin group and the soap water group (**Table 4** and **Figure 3**).

Table 4. Comparison of imaging improvement among the three groups

Groups	Disappearance of air–fluid levels	Reduction of air–fluid levels	No change or worsening	Improvement rate
Xiaochengqi Decoction group (n = 50)	33 (66.0%)	16 (32.0%)	1 (2.0%)	49 (98.0%)
Gastrografin group (n = 50)	29 (58.0%)	15 (30.0%)	6 (12.0%)	44 (88.0%)
Soap water group (n = 50)	22 (44.0%)	16 (32.0%)	12 (24.0%)	38 (76.0%)

Note: Improvement rate = (disappearance + reduction of air–fluid levels)/total cases × 100%. Group comparisons were performed using the chi-square (χ^2) test.

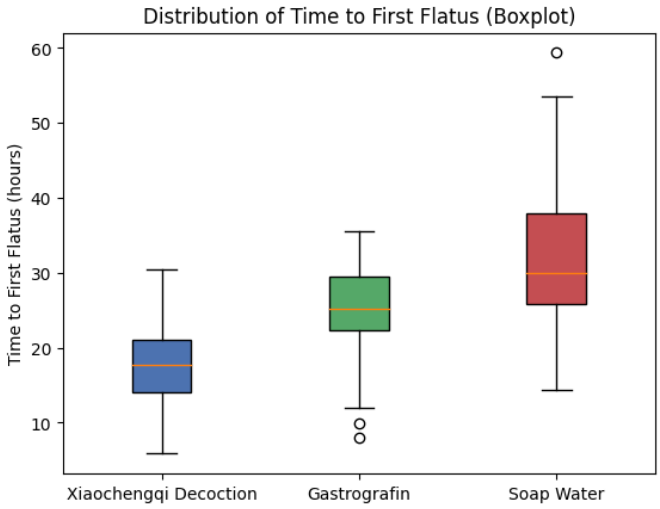


Figure 3. Distribution of time to first flatus among the three groups.

Note: Data are presented as mean ± standard deviation. Differences among groups were statistically significant ($p < 0.001$).

4. Discussion

Acute simple intestinal obstruction is a frequently encountered condition in emergency departments. Its key pathophysiological characteristic is impaired intestinal transit without evident compromise of bowel wall perfusion. Early and appropriate conservative management is therefore essential, as many patients may achieve favorable outcomes without surgical intervention [3]. The identification of safe and effective adjunctive therapies remains clinically important.

In the present randomized controlled study, three commonly used therapeutic approaches were compared: Xiaochengqi Decoction retention enema, Gastrografin administration, and soap water enema. Baseline characteristics were comparable among the groups, supporting the validity of subsequent efficacy comparisons.

With respect to overall clinical efficacy, the Xiaochengqi Decoction group exhibited the numerically highest response rate. Soap water enema, although traditionally used, primarily provides lubrication and mechanical stimulation and may exert limited influence on intestinal motility. Gastrografin, a hyperosmolar water -soluble contrast agent, has been reported to promote intraluminal fluid shifts and stimulate bowel activity through osmotic mechanisms [5,9]. However, its therapeutic role remains debated, with varying results reported across studies [9,10]. The findings of the present study suggest a trend indicate that the efficacy of Gastrografin was intermediate between Xiaochengqi Decoction enema and soap water enema, which is broadly consistent with previous clinical observations [4].

Time-related clinical outcomes are particularly relevant in the management of intestinal obstruction. In this study, abdominal pain relief time, time to first flatus, and time to first defecation were shorter in the Xiaochengqi Decoction group. Time to first flatus is widely regarded as an objective indicator of bowel function recovery, and reductions in this parameter may reflect improved gastrointestinal motility [11,12]. The favorable outcomes observed in the herbal enema group may be related to the combined pharmacological properties of its components. Pharmacological studies suggest that Xiaochengqi Decoction may influence gastrointestinal motility and intestinal function [6]. The potential synergistic effects of its constituent herbs may contribute to the restoration of bowel transit, although the precise mechanisms require further investigation.

From a modern clinical perspective, the pathogenesis of simple intestinal obstruction involves not

only mechanical factors but also bowel wall edema, inflammatory responses, and motility disturbances [13]. Interventions targeting a single mechanism may therefore provide incomplete therapeutic effects. Herbal retention enema, through its potential multimodal actions, may offer complementary benefits within conservative treatment strategies [6].

Length of hospital stay represents an important clinical and economic outcome [14]. Patients in the Xiaochengqi Decoction group exhibited shorter hospitalization durations, suggesting potential advantages in recovery efficiency and healthcare resource utilization. For emergency patients, earlier symptom resolution and reduced hospital stay are of practical clinical relevance [14].

Imaging outcomes further supported the clinical findings. The highest rate of improvement in air–fluid levels was observed in the Xiaochengqi Decoction group. Imaging assessments provide relatively objective evidence of treatment response, and the concordance between radiological and clinical outcomes strengthens the interpretation of the results [1].

Several limitations should be acknowledged. This was a single-center study with a relatively limited sample size. Long-term outcomes, including recurrence rates, were not evaluated. Additionally, subgroup analyses based on etiology were not performed. Future multicenter studies with extended follow-up are warranted. Overall, Xiaochengqi Decoction retention enema, when combined with conventional conservative therapy, was associated with favorable clinical outcomes in patients with acute simple intestinal obstruction, particularly in promoting bowel function recovery and reducing hospital stay.

5. Conclusion

The findings of this study suggest that Xiaochengqi Decoction enema, when combined with conventional conservative management, may improve clinical outcomes in patients with acute simple intestinal obstruction. This approach was associated with enhanced recovery of bowel function, shorter abdominal pain relief time, and improved imaging findings. Compared with Gastrografin and soap water enema, Xiaochengqi Decoction enema demonstrated favorable trends across multiple clinical parameters, indicating its potential clinical applicability.

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Research Progress of Appropriate Traditional Chinese Medicine Nursing Techniques for Postpartum Urinary Retention

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Abstract: This review summarizes the definition and classification, etiology and pathogenesis of postpartum urinary retention, as well as the application of Traditional Chinese Medicine (TCM) nursing techniques in its prevention and treatment. It also identifies the limitations and prospects of TCM nursing techniques in managing postpartum urinary retention, aiming to provide a reference for the clinical application and future research of TCM nursing techniques regarding this condition.

Keywords: Traditional Chinese Medicine (TCM) nursing; Postpartum urinary retention; Review

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1. Introduction

Postpartum urinary retention (PUR) refers to the condition where a parturient experiences bladder distension with incomplete voiding or residual urine volume > 100 mL within 6 to 8 hours after vaginal delivery [1]. As a common obstetric complication, it predominantly affects primiparas, particularly in cases of prolonged labor or surgical delivery [2]. The incidence of PUR varies by delivery method in China. The normal incidence is approximately 12%, while forceps-assisted delivery may result in 25–30% retention. Cesarean section, as a surgical delivery method, also shows relatively high postoperative retention rates, though specific values differ based on study design and sample size [3]. Internationally, the incidence ranges from 1.7% to 17.9% [4]. PUR not only causes lower abdominal distension and discomfort, impairs uterine contraction, and may lead to postpartum hemorrhage, but prolonged retention can also trigger urinary tract infections, pyelonephritis, and urinary incontinence, significantly compromising maternal recovery and quality of life [5]. The etiology of PUR is complex, with studies indicating strong associations between PUR and epidural analgesia, forceps delivery, perineal edema, episiotomy, and second-degree perineal tear [6]. Conventional nursing interventions for postpartum urinary retention, such as

catheterization and medication, are associated with high risks of infection and significant side effects. In recent years, Traditional Chinese Medicine (TCM) nursing techniques, including acupoint massage and acupoint application, have demonstrated advantages in terms of simplicity, safety, and efficacy in the prevention and treatment of this condition, offering new perspectives for clinical practice.

2. Etiology, pathogenesis, and pattern differentiation of postpartum urinary retention

In Traditional Chinese Medicine, urinary retention (Longbi) is attributed to bladder dysfunction of Qi transformation, involving the kidneys, triple burner, lungs, and spleen, and treated based on deficiency–excess differentiation [7]. Urinary retention is related to multiple factors, with main causes including:

(1) Postpartum Qi and blood deficiency, lung and spleen impairment, and water retention in the bladder;
(2) Kidney Qi deficiency, leading to water retention in the bladder;
(3) Postpartum retained lochia or cesarean section causing blood stasis;
(4) Liver Qi stagnation, leading to water retention.

This condition is characterized by a deficiency of Qi and blood as the root, and Qi stagnation and blood stasis as the manifestations [8]. The main diagnostic patterns of postpartum urinary retention include Qi deficiency syndrome, kidney deficiency syndrome, Qi stagnation syndrome, and blood stasis syndrome [9].

3. Application of traditional Chinese medicine nursing techniques in postpartum urinary retention

3.1. Moxibustion

Moxibustion refers to the application of warm thermal stimulation generated by burning moxa to specific acupoints, aiming to activate meridian Qi and regulate physiological functions. Clinically, commonly selected acupoints include Shenque (CV8), Guanyuan (CV4), and Zusanli (ST36). Xu Min applied warm moxibustion to Qihai (CV6), Zhongji (CV3), and Guanyuan (CV4) via a moxibustion box for 20 minutes, demonstrating a higher clinical total effective rate for urinary retention compared to the conventional nursing group [10]. Chen Huayun employed ginger-separated moxibustion, selecting Guanyuan (CV4) and bilateral Guilai (ST29) points, achieving a higher treatment efficacy for urinary retention compared to the control group (physical therapy combined with neostigmine injection) [11]. These findings indicate that moxibustion can improve symptoms and prognosis of postpartum urinary retention to some extent, but its therapeutic effects on patients with different delivery methods require further exploration.

3.2. Acupressure points

Acupressure refers to the application of various techniques to stimulate specific acupoints or body regions in patients, which has therapeutic effects of unblocking obstructions, dredging meridians, regulating bodily functions, and balancing Yin and Yang [12]. Multiple studies have confirmed the significant clinical efficacy of acupoint massage in treating postpartum urinary retention (PUR) [13,14]. Commonly used acupoints include Shuidao (ST28), Guanyuan (CV4), Sanyinjiao (SP6), Zhongji (CV3), and Qihai (CV6). In a study by Zhang Jun, the control group received conventional Western medical care, while the observation group received a combination of traditional Chinese abdominal massage and acupoint massage [13]. The observation group underwent horizontal rubbing of the

lower abdomen below the navel and gentle to firm pressure on Guanyuan (CV4), Zhongji (CV3), and Sanyinjiao (SP6). Results showed that the incidence of urinary retention in the observation group was significantly lower than that in the control group within 2–8 hours postpartum. Yin Xiaoqing found that Shuidao (ST28) acupoint massage could shorten the first urination time in primiparous and parous women, reduce postpartum urinary retention volume, lower the incidence of urinary retention, and enhance the comfort of the first urination in both groups [14].

3.3. Acupoint injection therapy

Acupoint Injection Therapy refers to the administration of small doses of medication into specific acupoints to achieve a synergistic effect of drug and acupoint compatibility. Commonly selected acupoints include Zusanli (ST36), Qihai (CV6), Zhongji (CV3), Guanyuan (CV4), and Sanyinjiao (SP6) [15–17]. Research by Hong Biqi demonstrated that Acupoint Injection Therapy is more effective than intramuscular injection, body needle acupuncture, and induced micturition in treating postpartum urinary retention [16]. Acupoint Injection Therapy can effectively reduce residual urine volume and shorten the time to first micturition. It exerts benign stimulation on acupoints, promotes the dispersion of meridian Qi and blood, and enhances the recovery of vital energy, thereby improving dysuria. Ji Hongyu used neostigmine for Acupoint Injection Therapy at Qihai (CV6), Zhongji (CV3), and Guanyuan (CV4), achieving a higher efficacy rate in treating postpartum urinary retention compared to acupuncture [17].

3.4. Auricular acupressure

Auricular therapy is grounded in meridian theory, which proposes that the twelve meridians connect with the ear and internal organs, thereby regulating Qi and promoting circulation. Clinical studies have reported that application of Vaccaria seeds to points such as Kidney (CO10), Bladder (CO14), Lung (CO12), Liver (CO12), Spleen (CO13), Triple Burner (CO17), Sympathetic (AH6a), Shenmen (TF4), and Subcortex (AT4) may benefit patients with dysuria and functional urinary retention.Xie Juhong implemented auricular acupoint compression therapy based on traditional low-frequency pulse electrical stimulation, selecting five auricular points on both ears: Kidney (CO10), Bladder (CO14), Urethra (HX1), External Genitalia (HX2), and Subcortical (AT4). The total effective rate of treatment was 100%, significantly higher than 78.26% in the traditional intervention group [18]. Liu Wen randomized 120 postpartum patients with urinary retention into two groups [19]. Auricular acupressure at Kidney (CO10), Shenmen (TF4), Bladder (CO14), and Triple Burner (CO17) achieved a 95.00% total effective rate, higher than 75.00% in controls, demonstrating superior efficacy over routine care.

3.5. Acupoint application

Acupoint application is a method of applying medicinal materials, in which traditional Chinese herbs are crushed and prepared, then applied to specific acupoints to enhance therapeutic effects via meridian-organ pathways. Research shows that the commonly used acupoints for treating postpartum urinary retention include Shenque (CV8) and Guanyuan (CV4), with commonly applied herbs such as ginger, *Allium fistulosum L*. (Congbai), *Astragalus membranaceus* (Huangqi), and talc powder (Huashi) [20]. Zeng Li enrolled 60 patients with postpartum urinary retention, dividing them into an intervention group (acupoint application combined with low-frequency pulse electrotherapy) and a control group (electrotherapy alone) [21]. The intervention group received herbal acupoint application at Zusanli (ST36), Zhongji (CV3), Guanyuan (CV4), Sanyinjiao (SP6), Qihai (CV6), and Qugu (CV2) in addition to electrotherapy. After treatment, the intervention group demonstrated shorter urination time, higher voiding success, and a total effective rate of 96.67%, compared with 66.67% in the control group, indicating that

acupoint application combined with electrotherapy may enhance clinical outcomes in postpartum urinary retention.

3.6. Combination therapy

Combination therapy integrates multiple traditional Chinese nursing techniques to enhance therapeutic efficacy. Guo Fengqin improved postpartum urinary retention by combining acupoint massage at bilateral Shuidao (ST28) points, acupoint application, and moxibustion, resulting in earlier first voiding, increased urine output, reduced residual urine, and improved initial voiding comfort [22]. Zhang Yi enrolled 200 patients after vaginal delivery; the observation group received Acupoint Injection Therapy combined with moxibustion, achieving a treatment efficacy rate of 98.0%, higher than 82.0% in the control group, along with shorter spontaneous urination recovery and lower residual urine [15]. Li Chenjie randomized 150 postpartum women after labor analgesia into combination therapy, auricular acupressure, and acupoint massage groups [23]. The combination therapy group showed higher rates of spontaneous urination and lower postpartum urinary retention, residual urine, and catheterization rates ($p < 0.05$). These findings suggest that integrating multiple TCM nursing techniques may provide more effective and efficient management of postpartum urinary retention.

4. Summary

Traditional Chinese Medicine (TCM) nursing techniques provide novel approaches for preventing and treating postpartum urinary retention. By regulating Qi and blood and promoting meridian circulation, they can enhance bladder function, reduce urinary retention, and improve maternal quality of life. Limitations remain, including small sample sizes, variable methodological quality, and unclear mechanisms of action. Future research should focus on multicenter, large-sample randomized trials to provide more robust evidence, particularly regarding whether different TCM techniques produce varying outcomes for mothers with different delivery methods. Integration with modern nursing approaches is a key future direction. In summary, TCM nursing techniques hold broad clinical potential for postpartum urinary retention, but ongoing investigation and innovation are essential to facilitate their widespread and sustainable application, ultimately benefiting maternal health.

Disclosure statement

The authors declare no conflict of interest.

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Research Progress on Functional Assessment of Non-specific Low Back Pain

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Abstract: Nonspecific low back pain (NLBP) is a prevalent condition in daily life with a notably high recurrence rate. It is particularly common among athletes, especially those involved in sports such as weightlifting and ice hockey. Assessment is crucial both before and after rehabilitation therapy for NLBP to evaluate its effectiveness. Functional assessment, as a common evaluation method, plays a significant role in understanding patients' functional impairments and quality of life, as well as guiding rehabilitation interventions and assessing treatment outcomes. There are numerous tools available for assessing NLBP. This paper summarizes recent domestic and international literature on nonspecific low back pain.

Keywords: Nonspecific low back pain; Functional assessment; Pain; Functional impairment

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1. Introduction

Low back pain refers to pain and discomfort located above the 12th rib and below the gluteal fold. It is the leading cause of global disability, with a lifetime prevalence rate as high as 84% [1–3]. Nonspecific low back pain (NLBP) is defined as low back pain that cannot be attributed to identifiable, known specific pathologies, involving neither nociceptor activation nor somatosensory nervous system damage or disease [1,4]. It accounts for up to 85% of all low back pain cases [5]. Each year, 5% to 10% of the workforce is absent due to low back pain, with most absences lasting less than seven days [6]. Additionally, the total wealth of individuals with low back pain is reduced by 87% compared to healthy individuals [7]. Low back pain not only affects personal wealth accumulation and quality of life but also imposes direct medical burdens and indirect social losses [7,8]. NLBP has a high prevalence rate, affecting individuals of all ages and posing a risk to nearly everyone, with almost everyone experiencing episodes of back pain [2]. This condition initially manifests as acute and subacute back pain and later progresses to chronic low back pain with high disability rates [2]. During the acute, subacute, and chronic phases of low back pain, clinicians use functional assessments to evaluate the degree of functional impairment, guide clinical rehabilitation

decision-making, and determine the effectiveness of various rehabilitation methods. Currently, there are numerous tools available for assessing the functional status of low back pain both domestically and internationally. This paper summarizes the introductions, reliability and validity, advantages, and disadvantages of functional assessment scales or questionnaires for low back pain based on domestic and international literature, providing a theoretical basis for future functional assessments.

2. Pain

2.1. Numeric pain rating scale

2.1.1. Introduction

The Numeric Pain Rating Scale (NPRS) requires patients to rate their pain on a scale from 0 to 10 (an 11-point scale) [9]. Pain intensity ranges from 0 (no pain) to 10 (extremely severe pain). The verbal NPRS asks patients to verbally state their pain intensity on a scale of 0–10. The minimal important difference for the NPRS is 2/10 or 30% of the baseline score [10].

2.1.2. Reliability and validity

The paper and electronic versions of the NPRS exhibit poor reliability (ICC = 0.49; 95% CI: 0.31, 0.64) among individuals with chronic lower back pain, and there is a lack of moderate- to high-quality literature evidence regarding its validity [11,12].

2.1.3. Advantages and disadvantages

This scale is suitable for a wide range of populations (e.g., elderly patients, patients with significant motor difficulties), easy to administer and score, simple, and relatively consistent [9].

2.2. Visual analogue scale

2.2.1. Introduction

The Visual Analogue Scale (VAS) consists of a line, typically 10 cm long, with one end marked as pain-free (0 mm) and the other end marked as extreme pain (100 mm) [9]. Patients are asked to indicate the point along the line that best represents their pain intensity. The patient's pain intensity score is the distance from the pain-free end to the marked point. The minimal important difference for the VAS is 15 percentage points or 30% of the baseline score [10].

2.2.2. Reliability and validity

The VAS demonstrates reliability and responsiveness in assessing individuals with chronic lower back pain, but there is a lack of moderate- to high-quality research evidence regarding its validity [12,13].

2.2.3. Advantages and disadvantages

This scale is a graphical scale that only assesses pain intensity and requires verbal expression, making it unsuitable for patients with motor or cognitive impairments [9].

2.3. McGill pain questionnaire

2.3.1. Introduction

The McGill Pain Questionnaire (MPQ) primarily consists of three categories of textual descriptions, including sensory, affective, and evaluative aspects, through which patients describe their subjective pain experiences [14]. The questionnaire includes four sections: pain location, pain descriptors, pain changes over time, and pain intensity, including a body pain distribution diagram. Pain descriptors summarize all items across the three dimensions. The sensory score ranges from 1 to 42, the affective score ranges from 1 to 14, and the evaluative score ranges from 1 to 5.

2.3.2. Reliability and validity

The MPQ is an assessment tool with good reliability, validity, and responsiveness, and it is extremely sensitive to changes in outcomes caused by interventions [15].

2.3.3. Advantages and disadvantages

The MPQ includes the additional advantage of nociceptive and neuropathic items in the sensory pain dimension, making it useful for assessing neuropathic lower back pain. It is comprehensive and easy to administer but time-consuming [15].

3. Common functional impairment questionnaires for low back pain

3.1. Oswestry disability index (ODI)

3.1.1. Introduction

The Oswestry Disability Index (ODI) was initially proposed by Fairbank et al. and has since been translated into various languages, with revisions and validations conducted in different countries [16–18]. The ODI comprises 10 items, one related to pain and nine related to daily living abilities, with each item scored from 0 to 5 (lifting, walking, social life, personal care, sitting, standing, sleeping, traveling, sexual life). The total score is derived by multiplying the sum of these scores by 50%, ranging from 0 to 100%. A higher score indicates a greater degree of functional impairment.

3.1.2. Reliability and validity

The revised ODI demonstrates the strongest correlation with the physical functioning and bodily pain subscales of the Short Form 36 (SF-36), with coefficients exceeding the 0.4–0.6 range [19]. The reliability and validity of the simplified Chinese version of the ODI for assessing low back pain in mainland China have been validated, showing significant correlations with eight subscales of the SF-36 ($r = 0.25–0.78$, $p \leq 0.001$), particularly in physical functioning ($r = 0.78$, $p < 0.001$), and a moderate correlation with the Visual Analog Scale (VAS) ($r = 0.69$, $p < 0.001$) [17].

3.1.3. Advantages and disadvantages

The ODI is a self-reported impairment questionnaire considered the “gold standard” for measuring functional outcomes of the lower back in clinical and research settings [20]. It is suitable for patients with mild to moderate functional impairment and those with persistent severe functional impairment due to low back pain [21]. According

to Dr. Brodke's report, a drawback of the ODI is its poor ability in unidimensional assessment [22]. The ODI's item structure evaluates different domains, such as pain and sleep, making it difficult for clinicians to clearly identify which domain is being measured and which domain influences changes in the ODI. Additionally, the ODI is not suitable for stratifying individuals with relatively high functional levels (i.e., low disability patients), potentially yielding poor test results when clinicians examine a diverse patient population.

3.2. Roland-Morris disability questionnaire (RMDQ)

3.2.1. Introduction

The Roland-Morris Disability Questionnaire (RMDQ) was first proposed by Roland and Morris in 1983 [23]. The original 24-item measure has been culturally adapted or translated and shortened to 18-item and 23-item versions for use in other countries [18]. The RMDQ consists of 24 self-reported items concerning patients' perceptions of low back pain and related functional impairments. These include 15 items on physical ability/activity, 3 on sleep/rest, 2 on psychosocial aspects, 2 on household management, 1 on eating, and 1 on pain frequency. Patients can report their current pain using a pain rating scale. Patients respond with "yes" or "no" (scored as 1 or 0, respectively), resulting in scores ranging from 0 (no disability) to 24 (maximum disability). Scores from 0 to 24 are then converted to percentage scores.

3.2.2. Reliability and validity

Both the paper and electronic versions of the RMDQ demonstrate good reliability (ICC = 0.85; 95% CI: 0.77, 0.90) [11]. The RMDQ also exhibits good validity, responsiveness, with a minimal important difference of 5/24 or 30% of the baseline score [10,13,24].

3.2.3. Advantages and disadvantages

The RMDQ is a self-reported outcome measurement tool with good psychometric properties and ease of administration [23,25]. It is suitable for assessing patients with mild functional impairment due to low back pain [21]. The questionnaire is relatively simple, with patients completing it in approximately 5 minutes, and responses are independent of age, gender, or social class [25]. According to Wang Xueqiang et al., the RMDQ has limitations in evaluating functional impairments caused by low back pain, particularly in assessing pain severity, mental health, and social well-being [26].

3.3. Quebec back pain disability scale (QBPDS)

3.3.1. Introduction

The Quebec Back Pain Disability Scale (QBPDS) questionnaire assesses how pain affects the daily lives of patients with low back pain. The questionnaire consists of 20 items related to functional impairments in basic daily activities, including sleeping, sitting/standing, walking, exercising, bending, and lifting heavy objects. Each activity is scored from 0 (no difficulty) to 5 (unable to perform). Responses to these 20 questions use a 6-point numerical rating scale indicating difficulty levels (0 points, "not difficult at all"; 1 point, "not difficult"; 2 points, "somewhat difficult"; 3 points, "quite difficult"; 4 points, "very difficult"; 5 points, "unable to do"). The QBPDS includes more content related to upper limb activities (pulling/pushing, throwing/catching, reaching) than other scales. If more than 50% of the 20 questions are answered, the QBPDS score (and scores for QBPDS subscales) is calculated. The proportional recalculation method involves dividing the raw total score by the highest possible

score (after considering missing answers) and multiplying by 100. The total score is the sum of all items, ranging from 0 (no disability) to 100 (maximum disability). The minimal detectable change for the QBPDS is 15 points, with a minimal important difference of 20 percentage points or 30% of the baseline score [10,27].

3.3.2. Reliability and validity

After cultural adaptation and translation, the QBPDS demonstrates good reliability, validity, and responsiveness [28–30]. The QBPDS shows moderate correlations with the physical functioning and bodily pain subscales of the SF-36 (-0.5–0.64) [19].

3.3.3. Advantages and disadvantages

The QBPDS is also a psychometrically sound tool for assessing functional impairments due to low back pain, utilizing a self-reported testing method. However, it is not widely used and only evaluates disability levels and sleep quality [15].

4. Summary

The objective of functional assessment for non-specific low back pain (NLBP) is to obtain highly correlated and responsive results using assessment tools with high reliability and validity, while minimizing patient discomfort. This is crucial for evaluating individuals in acute, subacute, and chronic stages. For pain assessment, the most commonly used tools globally are the Numeric Pain Rating Scale (NPRS), Visual Analog Scale (VAS), and McGill Pain Questionnaire (MPQ). No single scale can evaluate all populations effectively. NPRS and VAS are often regarded as the "gold standards" for pain assessment in both research and clinical settings [13]. Among them, NPRS is the most widely used, but it exhibits poor reliability for assessing chronic low back pain. VAS is also widely used, second only to NPRS, but it is not suitable for patients with motor or cognitive impairments. NPRS and VAS are unidimensional measurement tools, whereas MPQ is multidimensional, describing subjective pain experiences from sensory, affective, and evaluative perspectives. Although MPQ provides comprehensive evaluations, it is time-consuming and less widely used than NPRS and VAS. For assessing the degree of functional impairment due to low back pain, the Orthopaedic Section of the American Physical Therapy Association recommends the Oswestry Disability Index (ODI) and Roland-Morris Disability Questionnaire (RMDQ). These tools are effective in identifying baseline levels related to pain, function, and impairment in low back pain patients and can monitor changes during treatment [25]. ODI, widely regarded as the "gold standard" for measuring functional outcomes in clinical and research settings for low back pain, is extensively used but has limited ability to assess the impact of specific dimensions on patients [20]. It is suitable only for patients with mild to moderate functional impairments or persistent severe functional impairments. Compared to RMDQ, ODI demonstrates better test-retest reliability and smaller measurement errors in assessing physical function in NLBP [24]. RMDQ is also widely used, second only to ODI, and is a commonly employed tool for evaluating the degree of functional impairment in low back pain. However, it has limitations in assessing pain intensity, mental health, and social well-being, and is more suitable for evaluating patients with mild functional impairments. Both RMDQ and ODI exhibit good construct validity and reliability, as well as short responsiveness, and are often used in conjunction with quality-of-life assessment tools (e.g., SF-36). Compared to RMDQ and ODI, the Quebec Back Pain Disability Scale (QBPDS) is less widely used and assesses only functional impairment and sleep quality.

In summary, when selecting scales or questionnaires to assess pain or functional impairment in low back pain patients, clinicians or therapists should consider the content, reliability, validity, advantages, disadvantages, and applicability of the tools. They should make reasonable use of these tools based on the specific conditions of patients. If necessary, these scales or questionnaires can be used in combination to comprehensively evaluate patients' functional status from multiple dimensions.

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Research Progress on Ferroptosis in Ischemic Cardiomyopathy

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Abstract: Ischemic cardiomyopathy (ICM) is the terminal manifestation of long-term myocardial ischemia, necrosis, and fibrosis caused by coronary artery disease, and its pathogenesis involves multiple modes of cell death. In recent years, the role of ferroptosis as an iron dependent, lipid peroxidation driven regulatory form of cell death in ICM has gradually been revealed. This article systematically reviews the molecular mechanisms of ferroptosis and its role in the occurrence and development of ICM, and explores potential therapeutic strategies targeting ferroptosis, aiming to provide new ideas for the prevention and treatment of ICM.

Keywords: Ferroptosis; Ischemic cardiomyopathy; Regulatory mechanism; Targeted therapy

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1. Introduction

Ischemic cardiomyopathy (ICM) is a common cardiovascular disease caused by long-term chronic myocardial ischemia due to coronary atherosclerosis [1]. At present, the clinical diagnostic criteria for ICM mainly include the presence of severe coronary artery disease with left ventricular dysfunction, and at least one of the following characteristics must be met.

(1) Previous history of revascularization or acute myocardial infarction (AMI);
(2) The degree of stenosis in the left main trunk or left anterior descending branch is greater than 75%;
(3) Two or more major coronary arteries have a lumen stenosis of > 75% [2].

Moreover, ICM often presents with serious complications such as arrhythmia, embolism, and heart failure, which to some extent imposes a heavy disease burden on patients and society [3]. Its pathological and physiological mechanisms involve a series of metabolic, neurohumoral, and inflammatory factors, specifically manifested as myocardial cell hypertrophy, interstitial fibrosis, oxidative stress injury, calcium homeostasis imbalance, and various forms of programmed cell death [4]. Therefore, understanding the

etiology and pathogenesis of ICM is of great significance for guiding clinical treatment and improving patient prognosis. In recent years, studies have shown that ferroptosis is involved in pathological and physiological processes such as myocardial infarction and myocardial ischemia-reperfusion injury (MIRI), both of which may lead to the development of fibrosis, suggesting that ferroptosis may play an important role in the pathogenesis of chronic ischemia hypoxia induced ICM [5]. This article focuses on the molecular mechanisms and potential therapeutic significance of ferroptosis in the occurrence and development of ICM.

2. Iron death

2.1. Overview of iron death

Iron dependent non apoptotic cell programmed cell death is a novel form of cell death that is dependent on iron, first discovered by Dixon et al. [6]. It is completely different from traditional cell apoptosis, necrosis, and autophagy, and is an iron dependent, lipid peroxidation mediated cell death mode [7]. In terms of morphology, the characteristics of ferroptosis are reflected in mitochondrial shrinkage (shrinking), increased mitochondrial membrane density, reduced or absent cristae, and rupture of the outer mitochondrial membrane [8]. In terms of biochemistry, the characteristics of iron death are reflected in iron accumulation and lipid peroxidation [9]. The mechanisms that cause ferroptosis mainly include three classic mechanisms: dysregulation of iron ion metabolism, redox disorders, and lipid peroxidation. Other factors such as coenzyme Q10, ferritin autophagy, lipid autophagy, and mitochondrial metabolic disorders can also regulate the process of ferroptosis [10].

2.2. Molecular mechanism of ferroptosis

2.2.1. Iron metabolism and iron death

Iron, as an essential trace element for the human body, plays a dual role in maintaining physiological functions of the heart: it is both indispensable and potentially toxic. Studies have shown that both iron deficiency and iron overload can have toxic effects on the heart, impair normal heart function, and induce various cardiovascular diseases. Therefore, maintaining iron homeostasis is crucial for the normal physiological activity of myocardial cells. Under physiological conditions, cellular iron uptake is mainly regulated by the plasma membrane protein transferrin receptor 1 (TFR1), which transports Fe^{3+} bound to transferrin (TF) into the cell through receptor-mediated endocytosis. Prostate six segment transmembrane epithelial antigen 3 (STEAP3) reduces Fe^{3+} to Fe^{2+}, which is then released from the nucleus into the cytoplasmic unstable iron pool and ferritin through the mediation of solute carrier family 11 member 2 (SLC11A2) (also known as divalent metal ion transporter 1 (DMT1)). Ferritin is a protein complex composed of ferritin light chain (FTL) and ferritin heavy chain (FTH) 1, which can isolate Fe^{2+} and prevent its oxidation. It is worth noting that after binding with nuclear receptor coactivator 4 (NCOA4), it can be transported to autophagosomes for lysosomal degradation (also known as ferritin autophagy), leading to the release of Fe^{2+}. Upregulation of FTL/FTH1 expression or inhibition of NCOA4 can inhibit ferroptosis. When the intracellular iron homeostasis is imbalanced and iron overload occurs, excess intracellular free Fe^{2+} will generate a large amount of reactive oxygen species (ROS) that damage the membrane system through the Fenton reaction, thereby catalyzing lipid peroxidation and ultimately triggering iron death.

2.2.2. Glutathione metabolism and iron death

The mechanism of ferroptosis is not only related to the imbalance of intracellular iron homeostasis, but also closely related to the dysfunction of the antioxidant defense system. The antioxidant system composed of glutathione (GSH) and glutathione peroxidase 4 (GPX4) as the core is an important mechanism for protecting cells from iron death. GSH, as an important intracellular antioxidant molecule, is synthesized from glutamic acid, cysteine, and glycine tripeptides under the catalysis of glutamate cysteine ligase (GCL) and glutathione synthase (GSS). Among them, cysteine serves as the rate limiting substrate for GSH synthesis, and its deficiency can directly lead to the inhibition of GSH synthesis, thereby inducing ferroptosis. System Xc - is a cysteine glutamate reverse transporter located on the cell membrane, consisting of the light chain subunit (x CT) encoded by SLC7A11 and the heavy chain subunit (4F2hc) encoded by SLC3A2. The System Xc - system can mediate cysteine uptake and glutamate efflux in a 1:1 ratio. Activation of this system can lead to an increase in intracellular cysteine concentration, which can promote downstream synthesis of GSH and GPX4. Therefore, once the activity of System Xc - decreases, the uptake of cysteine by cells will decrease, and the raw material for GSH synthesis, cysteine, will also decrease, resulting in indirect inhibition of GPX4 activity. Due to the inactivation of the System Xc -/GSH/GPX4 axis, the antioxidant stress capacity of cells decreases, leading to an increase in ROS production and accumulation, ultimately inducing ferroptosis. In recent years, studies have found that the small molecule compound Erastin can induce conformational changes in its transmembrane helical domain TM6b by specifically binding to the Phe254 site of the xCT subunit, effectively inhibiting the transport activity of System Xc -. When System Xc - system activity is inhibited by Erastin, the level of iron death in cells significantly increases. Similarly, iron death inducers such as RSL3 and FIN56 can block antioxidant defense by directly inhibiting GPX4 activity or promoting its degradation. These findings not only deepen our understanding of the molecular mechanisms of ferroptosis, but also provide new therapeutic approaches for targeted regulation of the System Xc -/GSH/GPX4 axis to intervene in ferroptosis.

2.2.3. Lipid peroxidation and ferroptosis

As mentioned earlier, the Fenton reaction caused by abnormal iron metabolism leads to an increase in ROS. The antioxidant system represented by GPX4 can eliminate the toxicity of ROS to cells, and the connection between the two is the lipid metabolism within cells. Lipid peroxidation is a hallmark of ferroptosis, and some studies suggest that lipid peroxidation can occur through two pathways:

(1) Enzymatic pathway

Mainly relying on the catalytic action of lipoxygenases (LOXs);

(2) Non enzymatic pathway

Triggered by ROS directly attacking polyunsaturated fatty acids (PUFAs).

It is worth noting that free PUFAs cannot directly induce ferroptosis and need to be activated into membrane lipids to exert their effects. This integration process is accomplished by the collaboration of two key enzymes: firstly, long-chain acyl CoA synthetase 4 (ACSL4) catalyzes the formation of CoA AA/AdA complexes between arachidonic acid (AA) or adrenal acid (AdA) and coenzyme A; Subsequently, lysophosphatidylcholine acyltransferase 3 (LPCAT3) esterifies these activated PUFAs and inserts them into cell membrane phospholipids. In the enzymatic pathway, the iron containing 15 lipoxygenase (ALOX15) first forms a complex with phosphatidylethanolamine binding protein 1 (PEBP1), which then specifically oxidizes PUFAs in phospholipids to generate phosphatidylethanolamine peroxide (PE-

PUFA-OOH), promoting the occurrence of ferroptosis. It is worth noting that the Fenton reaction and the lipoxygenase pathway generate a large amount of ROS, which attack PUFAs in membrane phospholipids, triggering a chain peroxidation reaction and forming a vicious cycle, leading to severe damage to the cell membrane structure. Overall, the accumulation of iron ions, free radical bursts, increased supply of PUFAs, and accumulation of lipid peroxides constitute the "quartet" of ferroptosis, collectively determining the fate of cell ferroptosis.

3. Iron death and ICM

Iron death is closely related to the pathogenesis of ischemic cardiomyopathy (ICM). Research has shown that the application of iron death inhibitors such as Liproxstatin-1 (Lip-1) in a mouse myocardial cell ischemia model can effectively protect myocardial cells, suggesting that iron death plays an important role in the occurrence of ICM and may provide new strategies for its treatment.

When myocardial cells are exposed to ischemia for a long time, iron metabolism imbalance, especially iron overload, can promote the generation of excessive ROS and oxygen free radicals in the oxidative system, thereby exacerbating oxidative stress, leading to myocardial cell membrane damage and cardiovascular endothelial cell dysfunction. For example, in the state of myocardial ischemia, chronic ischemia can induce stable expression of hypoxia inducible factor-1 alpha (HIF-1 alpha), thereby upregulating TfR1, promoting iron uptake in myocardial cells and causing iron overload, ultimately exacerbating ROS mediated oxidative damage. In the mouse myocardial ischemia model, downregulation of FTH expression was also observed, significantly weakening the ability of myocardial cells to bind free iron, thereby inducing increased oxidative stress and even cell death. Another study has confirmed that administering iron chelators to myocardial cells after ischemic injury can help reverse cardiac dysfunction.

Cardiomyocytes are rich in mitochondria, and their membrane structure contains a large number of PUFAs, which are susceptible to oxidative attacks. Studies have shown that under ischemic stress, the expression of ACSL4 and LPCAT3 is significantly increased, which esterifies more PUFAs and inserts them into membrane phospholipids, providing abundant substrates for lipid peroxidation. Alox15 has been identified as a key mediator of ischemia induced phospholipid peroxidation, and its derivative 15 HpETE can promote the binding of peroxisome proliferator activated receptor gamma co activator 1 alpha (PGC-1 alpha) to E3 ubiquitin ligase ring finger protein 34 (RNF34), thereby accelerating PGC-1 alpha degradation, inducing mitochondrial dysfunction, and iron death in cardiomyocytes. Knocking down Alox15 or using its specific inhibitor ML351 can significantly increase PGC-1 α levels and inhibit iron death in myocardial cells.

In ischemic cardiomyopathy, especially after myocardial ischemia-reperfusion injury (MIRI), it can be observed that the levels of ACSL4, Fe^{2+}, and malondialdehyde (MDA) in myocardial tissue increase, while the level of GPX4 decreases. Further research has shown that the protein expression and activity of GPX4 in ICM animal models and heart failure patients' myocardium are significantly reduced. The environment of ischemia, hypoxia, and oxidative stress itself can inhibit the activity of System Xc -, leading to insufficient uptake of cysteine and subsequent inhibition of GSH synthesis. At the same time, sustained oxidative stress consumes a large amount of GSH, resulting in a sharp decrease in intracellular GSH levels. Studies have shown that the specific iron death inhibitor lipoxstatin-1, which is suitable for animal models, can protect mouse myocardium from MIRI injury by downregulating voltage dependent anion channel protein 1 (VDAC1) expression and upregulating GPX4

expression.

Iron death is not an isolated event, as it forms a vicious cycle with the inflammatory immune response in ICM, jointly driving disease progression. A review suggests that ferroptosis can affect inflammatory responses through immunogenicity, and ferroptosis inhibitors may benefit cardiovascular disease patients through anti-inflammatory effects. Iron death can activate Toll like receptors (such as TLR4) by releasing damage associated molecular patterns (DAMPs) (such as high mobility group protein B1 (HMGB1) and ATP), recruit and activate innate immune cells (such as macrophages and neutrophils), trigger inflammatory responses, and release inflammatory factors such as interleukin-1β (IL-1β) and tumor necrosis factor-α (TNF-α). On the contrary, the inflammatory microenvironment further promotes ferroptosis. For example, TNF-α can downregulate the expression of System Xc - and GPX4. The inflammatory mediators released by M1 macrophages can directly damage myocardial cells and enhance their sensitivity to ferroptosis. Neutrophils exacerbate oxidative stress through myeloperoxidase (MPO).

Immune response activation is involved in the occurrence and development of various cardiovascular diseases, whether they involve congenital or adaptive immunity. A study found through the ssGSEA algorithm that various immune cells (including activated B cells, mast cells, eosinophils, monocytes, neutrophils, and Th17 cells) significantly infiltrate ICM cardiac tissue. Iron death can regulate the recruitment of neutrophils to the infarcted area, while inhibiting iron death can alleviate this process and promote repair. In addition, macrophages derived from monocytes are involved in poor ventricular remodeling, and their peripheral blood levels can serve as prognostic markers for ICM. Recent studies have also found that $CD8^+$ T cells are activated and induce cardiomyocyte apoptosis in ischemic myocardium. More noteworthy is that multiple immune checkpoints (such as PDCD1/LG2, LAG3, TIGIT) are highly expressed in ICM, which may indirectly promote ferroptosis and ventricular remodeling by inhibiting protective immune responses or enhancing inflammatory responses. This positive feedback loop of "iron death DAMPs release inflammation activation iron death exacerbation" continues to drive myocardial injury, fibrosis, and ventricular remodeling, which may be the core mechanism of ICM disease progression.

4. ICM therapy strategy targeting ferroptosis

Given the central role of ferroptosis in ICM, targeting its key components has become a highly promising therapeutic strategy. Therefore, inhibiting ferroptosis may be a promising target for treating ICM. Therefore, scientists have begun to identify a targeted anti ferroptosis method for ICM treatment. Many drugs have been believed to have therapeutic effects on ICM treatment by inhibiting ferroptosis.

4.1. Iron death inhibitors

Fer-1 and Lip-1, as classic free radical scavenging antioxidants, can directly neutralize lipid free radicals and interrupt the chain reaction of lipid peroxidation. In MIRI and ICM animal models, both exhibit significant cardioprotective effects and are currently one of the most promising candidate drugs for treatment. As a novel iron death inhibitor, polydopamine nanoparticles (PDA NPs) can inhibit the accumulation of Fe^{2+} in H9c2 cells, restore mitochondrial function, and alleviate Fe^{2+} deposition and lipid peroxidation in a mouse model of myocardial ischemia/reperfusion (I/R) injury. Atorvastatin inhibits iron death and reverses hypoxia/reoxygenation (H/R) - induced H9C2 cell damage by upregulating FPN1 expression and reducing intracellular Fe^{2+} levels. In addition,

the drug can upregulate SMAD7 expression and downregulate hepcidin expression in H/R-induced H9C2 cells, and synergistically protect the myocardium from ischemia-reperfusion injury through multiple mechanisms. At present, two clinical studies on the treatment of dilated cardiomyopathy and hypertrophic cardiomyopathy with atorvastatin have been completed. However, its application in ICM treatment has not yet entered the clinical research stage and remains a scientific issue that needs to be explored in the future.

4.2. Iron chelators

Iron chelators, such as deferoxamine, dexmedetomidine, and cyclohexanone, can effectively inhibit lipid peroxidation by reducing Fe^{2+} levels, inhibiting Fenton reaction and LOX activity. Recent studies have shown that in models of acute hemorrhagic myocardial infarction, compared to deferoxamine and Deferasirox, the iron chelator deferiprone can more rapidly alleviate bleeding, reduce inflammatory reactions, and improve chronic adverse myocardial remodeling after acute hemorrhage. Therefore, iron chelates may serve as a potential preventive treatment for acute hemorrhagic myocardial infarction. Although iron chelators have limitations in non-specific binding, which limits their widespread clinical application, current research is focused on developing iron chelators with higher myocardial targeting, or improving therapeutic specificity and safety by regulating key iron metabolism proteins (such as using NCOA4 inhibitors).

4.3. Activating agents for system Xc -

Icariin is the main flavonoid component extracted from the traditional Chinese medicine Epimedium, which has various pharmacological activities such as anti-aging, anti-inflammatory, antioxidant, and anti-fibrosis. As an effective inducer of nuclear factor E2 related factor 2 (Nrf2), icariin can upregulate GPX4 expression in cardiomyocytes, reduce ACSL4 and Fe^{2+} levels, and inhibit H/R-induced ferroptosis by activating the Nrf2/HO-1 pathway. Its derivatives icariin II and icariin also show promising drug development potential.

Xanthohumol is derived from hops and has anti-inflammatory, antioxidant, and anticancer effects. Lin et al. found that it resists ferroptosis by inhibiting lipid peroxidation and reactive oxygen species generation, chelating iron, regulating the Nrf2/GPX4 pathway, and downregulating ACSL4. However, its poor water solubility and stability limit its application.

In addition, Dexmedetomidine is a highly selective α_2 - adrenergic receptor agonist that can inhibit ferroptosis and counteract MIRI by activating the AMPK/GSK-3 β/Nrf2/SLC7A11/GPX4 pathway. Naringenin improves ischemic myocardial injury by regulating the Nrf2/SLC7A11/GPX4 axis.

5. Summary and outlook

Iron death, as a newly discovered mode of cell death, plays a central role in the pathological process of ICM. It mainly leads to the loss of myocardial cells through three major mechanisms: iron metabolism disorders, lipid peroxidation, and dysfunction of the antioxidant defense system (especially the System Xc -/GSH/GPX4 axis). More noteworthy is that a vicious cycle is formed between ferroptosis and inflammatory immune response, jointly promoting ventricular remodeling and deterioration of heart function, becoming a key driving mechanism for disease progression. Although significant progress has been made in understanding the mechanisms and preclinical interventions, translating this achievement into clinical benefits still faces multiple challenges. Firstly, there is currently a lack of specific biomarkers that can accurately and non invasively monitor the progression

of myocardial iron death, which limits early diagnosis and risk stratification of patients; Secondly, drug delivery efficiency and safety remain important issues in translational medicine, namely how to achieve heart specific delivery of iron death inhibitors and avoid potential side effects (such as tumor risk) that may arise from long-term interventions; Thirdly, existing evidence mainly comes from animal models, and the exact role of ferroptosis in human ICM and its effectiveness as a therapeutic target still need to be validated through high-quality clinical studies. In summary, ferroptosis plays an important role in the occurrence and development of ICM. Further in-depth research on its molecular mechanism and regulatory network is expected to provide new directions for clinical intervention strategies targeting ferroptosis, ultimately improving the prevention and treatment effectiveness of ICM.

Disclosure statement

The authors declare no conflict of interest.

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Construction and Empirical Study of a Standardized Nursing Protocol for CO_2 Angiography in Patients with Lower Extremity Arteriosclerosis Obliterans Complicated by Renal Insufficiency

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Abstract: *Objective*: To develop and empirically analyze a standardized nursing protocol for CO_2 angiography in patients with lower extremity arteriosclerosis obliterans (ASO) complicated by renal insufficiency. *Methods*: A standardized nursing protocol for CO_2 angiography was first established for patients with lower extremity ASO complicated by renal insufficiency. Subsequently, 30 patients who underwent interventional therapy for lower extremity ASO complicated by renal insufficiency in the interventional vascular surgery department of our hospital from October 2025 to December 2025, following the standardized protocol, were selected as the experimental group. Another 20 patients who received treatment without the standardized protocol from October 2024 to December 2024 were selected as the control group. Intraoperative cooperation time, hospital stay, cost-effectiveness indicators, complications, and patient satisfaction were analyzed. *Results*: Compared with the control group, the experimental group exhibited a reduction in intraoperative cooperation time and hospital stay ($p < 0.05$). Although the cost of surgical consumables in the experimental group decreased compared to the control group, this difference was not statistically significant ($p > 0.05$). However, the costs of medications and total hospitalization expenses significantly decreased in the experimental group ($p < 0.05$). The overall incidence of complications was lower in the experimental group than in the control group ($p < 0.05$), and patient satisfaction was higher in the experimental group. *Conclusion*: The development and application of a standardized nursing protocol for CO_2 angiography can effectively improve nursing quality, reduce the risk of complications, and enhance patient prognosis, demonstrating clinical value for widespread adoption.

Keywords: Lower extremity arteriosclerosis obliterans; Renal insufficiency; Carbon dioxide angiography; Standardized nursing

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1. Introduction

Arteriosclerosis obliterans (ASO) of the lower extremities is a common age-related disease, characterized pathologically by thickening of the arterial walls in the lower limbs, narrowing or even complete occlusion of the lumens, leading to the onset of limb ischemia symptoms. With the intensification of population aging and the rising prevalence of chronic diseases such as diabetes and hypertension, the incidence of ASO has been increasing year by year [1,2]. ASO not only severely affects patients' quality of life but may also lead to severe complications such as gangrene due to limb ischemia, posing a threat to life. However, when patients also suffer from renal insufficiency, the difficulty of treatment significantly increases. Patients with renal insufficiency, due to decreased glomerular filtration rate and impaired renal tubular function, are prone to contrast-induced acute kidney injury (PC-AKI) when undergoing traditional iodinated contrast agent angiography. PC-AKI is a common type of iatrogenic acute kidney injury that can further exacerbate renal impairment and prolong hospital stays [3,4]. Carbon dioxide (CO_2) angiography, as an alternative imaging technique, has gradually been applied in the diagnosis and treatment of lower extremity arterial diseases. Compared to traditional iodinated contrast agents, CO_2 angiography offers the advantage of having a lesser impact on renal function, making it particularly suitable for patients with renal insufficiency or iodine allergy. However, CO_2 angiography still faces numerous challenges in clinical practice, including high operational complexity and image quality interference from various factors [5,6]. Currently, there is a lack of standardized nursing protocols for CO_2 angiography in patients with lower extremity arteriosclerosis obliterans complicated by renal insufficiency. This not only limits the widespread application of this technique but may also affect patients' prognostic outcomes. Based on this, this study aims to construct a standardized nursing protocol for CO_2 angiography in patients with lower extremity arteriosclerosis obliterans complicated by renal insufficiency and conduct an empirical analysis to provide certain reference value for subsequent clinical research.

2. Subjects and methods

2.1. Subjects

Thirty patients with lower extremity arteriosclerosis obliterans (ASO) complicated by renal insufficiency who underwent interventional diagnosis and treatment using the standardized protocol in the Interventional Vascular Surgery Department of our hospital from October 2025 to December 2025 were selected as the experimental group. Twenty patients who received treatment without the standardized protocol in our hospital from October 2024 to December 2024 were selected as the control group. The general characteristics of the two groups were balanced and comparable ($p > 0.05$), as shown in **Table 1**.

Table 1. Comparison of general characteristics between the two groups

Group	Number of cases (n)	Gender (M/F)	Age (years)	Body mass (kg/m^2)
Control group	20	14/6	72.35 ± 6.82	24.31 ± 2.57
Experimental group	30	20/10	71.97 ± 7.14	24.58 ± 2.85
χ^2/t		0.061	0.187	0.341
p		0.804	0.851	0.735

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria for lower extremity arteriosclerosis obliterans (ASO)

(2) Comorbid renal insufficiency (eGFR < 60 mL/min/1.73 m^2)
(3) Scheduled for CO_2 angiography-guided interventional therapy
(4) Voluntary participation in this study with signed informed consent

2.1.2. Exclusion criteria

(1) Comorbid severe cardiopulmonary dysfunction
(2) Presence of contraindications to CO_2 angiography
(3) Incomplete clinical data

2.2. Therapeutic approaches

This study constructed a comprehensive nursing protocol for CO_2 angiography in patients with lower extremity arteriosclerosis obliterans (ASO) complicated by renal insufficiency through multidisciplinary collaboration and systematic evidence-based methods. Initially, a dedicated research team was established, comprising the head nurse of the interventional operating room, the chief physician of interventional vascular surgery, the deputy chief technician of radiology, and two undergraduate nursing students, responsible for literature analysis, protocol development, expert coordination, and opinion integration.

During the literature analysis phase, databases including Medlive, CNKI, Wanfang, PubMed, and Web of Science were systematically searched using both Chinese and English keywords, covering the period from database inception to May 23, 2025. Two researchers employed content analysis to progressively refine items related to preoperative, intraoperative, and postoperative care, culminating in a preliminary draft of the nursing protocol after multiple rounds of group discussions.

To further refine the protocol, the research team conducted expert interviews, inviting 12 experts from two tertiary hospitals, including interventional vascular surgeons (5, with associate senior titles or above), radiologists (1), interventional vascular surgery nurses (2), renal care nurses (1), and interventional operating room nurses (3). All experts had over 10 years of work experience, with 7 holding senior titles and 5 possessing master's degrees, ensuring high authority.

Based on the interview feedback, the research team revised the protocol, ultimately forming a standardized, comprehensive nursing protocol covering preoperative assessment, intraoperative cooperation, complication prevention and management, and postoperative monitoring. This protocol emphasizes preoperative renal function assessment and mastery of CO_2 angiography indications; standardized intraoperative operations and close monitoring; and enhanced postoperative condition observation and complication alerts, providing systematic and feasible operational guidance for clinical nursing practice.

2.2.1. Control group treatment method

The conventional nursing model was adopted. Preoperative care included completing routine admission education, preoperative examinations, skin preparation, and establishing intravenous access, informing patients of surgical precautions, but without systematic respiratory training guidance or specific risk assessment for CO_2 angiography. Intraoperative care involved assisting patients in assuming a supine position, connecting electrocardiographic monitoring to monitor vital signs, and cooperating with physicians for CO_2 injection, with injection pressure, dosage, and frequency primarily based on the physician's personal experience, lacking standardized gas injection parameters (e.g., flow rate limit, total volume control). Intraoperative observation of patient discomfort was

mostly empirically managed, without establishing a "respiration-injection" coordination mechanism, necessitating repeated image acquisition due to respiratory motion artifacts. Postoperative care included routine monitoring of vital signs after returning to the ward, compression hemostasis and bandaging at the puncture site, without implementing a standardized hydration protocol, with fluid volume administered according to routine medical orders. Blood creatinine was rechecked 24–48 hours postoperatively, but without setting alert thresholds or dynamic monitoring procedures. Lower extremity observation was primarily based on routine experience, without specified observation frequency or quantitative recording standards. Complication management adopted symptomatic treatment, lacking standardized emergency plans.

2.2.2. Experimental group treatment method

Preoperative care included stratified assessment using a renal function grading assessment form, excluding contraindications with a screening form, guiding patients in "inhalation-breath-hold-exhalation" respiratory training twice daily, and formulating individualized hydration protocols based on renal function grading, starting intravenous infusion of 0.9% sodium chloride solution 3 hours before surgery. Intraoperative care involved establishing a "nurse-technician-physician" tripartite coordination mechanism with clear division of labor, setting standardized injection parameters (flow rate ≤ 20 mL/s, single dose ≤ 50 mL, total volume ≤ 200 mL), using a dedicated CO_2 injection system to ensure gas purity, implementing a "respiration-injection" coordination mechanism with nurses instructing patients to hold their breath before injection to reduce respiratory motion artifacts, continuously monitoring vital signs with set abnormal alert thresholds, and establishing standardized emergency management procedures for complications such as gas embolism and vasospasm. Postoperative care included continuing the standardized hydration protocol for 6–12 hours, dynamically monitoring renal function with set AKI alert thresholds (initiation of alert when blood creatinine increases > 26.5 μmol/L or > 50%), adopting quantitative recording for lower extremity observation (every 30 minutes within 2 hours postoperatively, every 2 hours from 2–24 hours), recording puncture site observations according to specified frequencies, initiating multidisciplinary collaborative care for patients requiring combined use of iodinated contrast agents, and conducting patient satisfaction surveys using the MSQ scale 24–48 hours postoperatively.

2.3. Indicator detection

2.3.1. Intraoperative cooperation time and hospital stay

The circulating nurse in the interventional operating room used a stopwatch for real-time timing, simultaneously extracting the start and end times of surgery from the surgical nursing record in the hospital's nursing management information system for verification. The timing started when the physician began the puncture operation and ended when hemostasis at the puncture site was completed and the physician declared the end of surgery.

2.3.2. Cost-effectiveness indicators

(1) Surgical consumable costs

Charging records for surgical-related consumables were extracted from the hospital's material management system and patient hospitalization expense details, independently verified by two researchers, and then entered into the database.

(2) Medication costs

Charging records for medications were extracted from the hospital's pharmacy management system and

patient hospitalization expense details, independently verified by two researchers.

(3) Total hospitalization costs

Summary sheets of patient hospitalization expenses were extracted from the hospital's hospitalization charging system, independently verified by two researchers, and then entered.

2.3.3. Adverse reactions

Adverse reactions, including acute kidney injury, lower extremity burning sensation, nausea, and vomiting, were recorded by healthcare personnel.

2.3.4. Patient satisfaction

Patient satisfaction was evaluated using the short form of the Minnesota Satisfaction Questionnaire (MSQ)[7]. This scale includes three dimensions: intrinsic satisfaction, extrinsic satisfaction, and general satisfaction, with a total of 20 items. Each item employs a Likert 3-point scoring method (1 = dissatisfied, 2 = moderately satisfied, 3 = satisfied). The total scale score ranges from 20–100, with higher scores indicating higher satisfaction.

3. Results

3.1. Comparison of intraoperative cooperation time and hospital stay between groups

As shown in **Table 2**, compared with the control group, the experimental group exhibited a reduction in both intraoperative cooperation time and hospital stay, with statistically significant differences ($p < 0.05$).

Table 2. Comparison of intraoperative cooperation time and hospital stay between groups ($\overline{x} \pm s$)

Group	Number of cases (n)	Intraoperative cooperation time (min)	Hospital stays (d)
Control group	20	58.65 ± 8.23	9.55 ± 2.08
Experimental group	30	45.26 ± 6.18	7.23 ± 1.31
t value		6.567	4.847
p value		0.001	0.001

3.2. Comparison of cost-effectiveness indicators between groups

As shown in **Table 3**, compared with the control group, the experimental group demonstrated a decrease in surgical consumable costs, with no statistically significant difference ($p > 0.05$), while showing a reduction in medication costs and total hospitalization expenses, with statistically significant differences ($p < 0.05$).

Table 3. Comparison of cost-effectiveness indicators between groups ($\overline{x} \pm s$)

Group	Number of cases (n)	Surgical supplies cost (yuan)	Medication cost (yuan)	Total hospitalization cost (yuan)
Control group	20	3512.32 ± 402.58	1123.40 ± 187.54	22348.85 ± 2678.35
Experimental group	30	3245.69 ± 358.82	876.56 ± 124.30	18765.41 ± 2154.62
t value		2.452	5.607	5.225
p value		0.112	0.001	0.001

3.3. Comparison of adverse reactions between groups

As shown in **Table 4**, the overall incidence of adverse reactions in the experimental group was lower than that in the control group, with a statistically significant difference ($p < 0.05$).

Table 4. Comparison of adverse reactions between groups [n (%)]

Group	Number of cases (n)	Acute kidney injury	Burning sensation in lower limbs	Nausea and vomiting	Total incidence rate
Control group	20	3 (15.00)	2 (10.00)	1 (5.00)	6 (30.00)
Experimental group	30	1 (3.33)	1 (3.33)	0 (0.00)	2 (6.67)
χ^2 value					4.861
p value					0.027

3.4. Comparison of patient satisfaction between groups

As shown in **Table 5**, the satisfaction level in the experimental group was higher than that in the control group, with the difference being statistically significant ($p < 0.05$).

Table 5. Comparison of patient satisfaction between groups [n (%)]

Group	Number of cases (n)	Satisfied	Moderately satisfied	Dissatisfied	Overall satisfaction
Control group	20	6 (30.00)	8 (40.00)	6 (30.00)	14 (70.00)
Experimental group	30	15 (50.00)	14 (46.67)	1 (3.33)	29 (96.67)
χ^2 value					7.087
p value					0.008

4. Discussion

During the interventional diagnosis and treatment of patients with lower extremity arteriosclerosis obliterans (ASO) complicated by renal insufficiency, ensuring image quality while minimizing renal damage is a key and challenging aspect of clinical nursing management [8]. CO_2 angiography has gradually become an ideal choice for such patients due to its advantages of being non-nephrotoxic and free from allergic reactions. However, its complex operation and susceptibility to image interference necessitate a highly standardized and collaborative nursing process [9].

The results of this study indicate that, compared to the control group, the experimental group experienced reductions in intraoperative cooperation time and hospital stay. While surgical consumable costs in the experimental group decreased compared to the control group, this difference was not statistically significant ($p > 0.05$). However, medication costs and total hospitalization expenses significantly decreased. Analysis of the reasons reveals that the standardized nursing protocol contributes to enhancing surgical efficiency and postoperative recovery. This may be closely related to preoperative systematic respiratory training and the establishment of an intraoperative "breathing-injection" coordination mechanism. By standardizing operational procedures and clarifying division of responsibilities, repetitive operations due to improper handling or poor image quality are reduced, improving surgical fluency and thus shortening intraoperative cooperation time [10,11]. The implementation of a postoperative standardized hydration protocol and dynamic renal function monitoring

aids in early identification and intervention of potential complications, promoting early patient recovery and shortening hospital stays. In terms of cost-effectiveness, although surgical consumable costs in the experimental group decreased, the lack of statistical significance may be related to the small sample size or consumable pricing mechanisms. However, the significant reduction in medication costs and total hospitalization expenses is closely associated with factors such as decreased postoperative complications, shortened hospital stays, and individualized medication regimens [12,13]. The standardized protocol emphasizes preoperative assessment and individualized hydration, reducing unnecessary medication use and additional treatment costs incurred due to complications, demonstrating favorable health economic benefits.

The study also found that the overall incidence of adverse reactions in the experimental group was lower than that in the control group. Analysis of the reasons reveals that this is closely related to the strict setting of CO_2 injection parameters during surgery and the establishment of emergency procedures for gas embolism. Standardized operations reduce vascular stimulation and discomfort caused by rapid or excessive gas injection, enhancing surgical safety.

Furthermore, the study results indicate that patient satisfaction in the experimental group was higher than that in the control group. Analysis of the reasons reveals that the standardized nursing protocol not only improves medical quality but also enhances the patient's healthcare experience. Preoperative thorough communication, intraoperative coordinated cooperation, and postoperative meticulous observation and humanistic care strengthen patients' trust and recognition of nursing work.

5. Conclusion

In summary, the application of a standardized CO_2 angiography nursing protocol in patients with ASO complicated by renal insufficiency effectively improves nursing quality, reduces the risk of complications, shortens hospital stays, alleviates economic burdens, and enhances patient satisfaction, demonstrating high clinical promotion value. However, due to the limited sample size and short follow-up period in this study, future research should expand the sample size and prolong the observation period to further validate the long-term effects and feasibility of promoting this protocol.

Disclosure statement

The authors declare no conflict of interest.

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A Study on the Correlation between Anxiety Levels, Family Resilience and Hope Levels in Patients after Benign Prostatic Hyperplasia Surgery

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Abstract: *Objective:* This study aims to explore the correlations between anxiety levels, family resilience, and hope levels in postoperative patients with benign prostatic hyperplasia, providing a theoretical basis for reducing anxiety in postoperative patients. *Methods*: Convenience sampling was used to conduct a questionnaire survey among 150 patients who underwent prostatic hyperplasia resection in our hospital from June 2024 to December 2025. The questionnaire included a general information questionnaire, an anxiety scale, a family resilience scale, and a hope level scale. Multiple linear regression was used to analyze the factors influencing anxiety after prostatic hyperplasia surgery. *Results*: A total of 140 questionnaires were retrieved, with an effective recovery rate of 93.33%. Patients scored 51.71 ± 16.49 in anxiety level, 29.67 ± 10.44 in family resilience, and 29.67 ± 11.44 in hope level. Anxiety level was negatively correlated with erectile function (r = -0.379, p < 0.001*)*. Negatively correlated with family resilience (r = -0.380, p < 0.001), negatively correlated with hope level (r = -0.476, p < 0.001), The results of multiple linear regression showed that age, chronic disease status, smoking status, family resilience, and hope level were factors influencing anxiety levels in patients after benign prostatic hyperplasia surgery (p < 0.05). *Conclusion*: The anxiety level of patients after prostatic hyperplasia surgery is at a moderate level. The improvement of family resilience and hope level is of great significance in postoperative rehabilitation. It is recommended to strengthen psychological support and family intervention in clinical management, and pay attention to older patients, those with chronic diseases and smokers to improve the overall quality of life and treatment effect of patients.

Keywords: Benign prostatic hyperplasia; Sexual dysfunction; Anxiety; Family resilience; Hope level

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1. Introduction

Benign Prostatic Hyperplasia (BPH) is a common benign disease among older men, and its incidence is increasing

year by year worldwide. Studies have reported that the prevalence of BPH in men aged 60 and above is as high as 50%, and in men aged 80 and above it can reach 90% [1]. The disease not only affects the physical health of patients, but also their mental state and quality of life, especially after surgical treatment, many patients often face problems such as postoperative sexual dysfunction, anxiety and depression, further increasing the psychological burden of patients [2].

At present, the treatment methods for benign prostatic hyperplasia mainly include drug therapy and surgical treatment, among which surgical treatment is considered the most effective approach. However, despite the continuous advancement of surgical techniques, the incidence of postoperative complications and psychological problems remains high. Studies show that about 40 percent of patients experience varying degrees of anxiety and depression after surgery, which not only affects their recovery process but also reduces their quality of life [3]. Transurethral resection of the prostate for benign prostatic hyperplasia is not only a physical challenge, but also intensifies patients' negative emotions, inducing psychological problems such as anxiety and depression, thus forming a vicious cycle. In the field of mental health, negative emotions are widely regarded as an important factor affecting patients' recovery paths. Negative emotions can not only exacerbate disease symptoms, but also reduce patients' treatment compliance and life satisfaction. At the same time, family resilience, as the family's ability to cope with adversity, can provide emotional support and resource security for patients, enhancing their confidence and ability to cope with the disease. The level of hope reflects the patient's positive expectations for the future and is an important psychological resource for promoting disease recovery and psychological adaptation. The existing literature has initially revealed the role of negative emotions, family resilience and hope levels in the management of chronic diseases, but there is a lack of research on the correlation in patients after benign prostatic hyperplasia surgery.

Therefore, this study investigated the current status of anxiety and depression, family resilience and hope levels in patients after BPH surgery in our hospital through questionnaires, explored the intrinsic correlations among negative emotions, family resilience and hope levels, and through systematic quantitative analysis, comprehensively revealed the psychosocial characteristics and influencing mechanisms of patients after benign prostatic hyperplasia surgery To gain a deeper understanding of the psychological state and family support of patients, to provide a scientific basis for clinical intervention, to promote the overall improvement of patients' physical and mental health, and to promote the interdisciplinary integration of urology and psychology.

2. Subjects and methods of study

2.1. Research subjects

Convenience sampling was used to select patients after prostatic hyperplasia surgery in the Department of Urology, First People's Hospital of Linchuan District, Jiangxi Province from June 2024 to December 2025 as the research subjects. A mixed online and offline questionnaire survey was adopted.

2.1.1. Inclusion criteria

(1) Age ≥ 18 years;
(2) Benign prostatic hyperplasia and male sexual dysfunction met the diagnostic criteria in Surgery (9th Edition);
(3) Complete transurethral resection of the prostate;

(4) Be aware of your condition and cooperate with the study.

2.1.2. Exclusion criteria

(1) Patients with concurrent malignant tumors in other parts of the body;

(2) Patients with complications such as urinary incontinence;

(3) Patients with severe mental disorders;

(4) Patients with consciousness disorders.

In a multivariate analysis of a cross-sectional study, the sample size is calculated at 5 to 10 times the number of variables or dimensions of the scale according to the sample estimation method. There were a total of 24 study variables in this study, taking into account 10% of invalid questionnaires. Therefore, based on the statistical formula: sample size N = [24 × (5–10) × [1 + 10%], the total sample size was 132–264 cases. A total of 150 questionnaires were distributed in this survey, and 140 were effectively retrieved, with an effective recovery rate of 93.3%.

2.2. Research methods

2.2.1. General demographic data and disease information questionnaires

This questionnaire is self-compiled and designed with reference to literature review and practical experience. The demographic information mainly covered the following variables: age, marital status, educational attainment, economic status, medical expense payment method, residence pattern, family relationship. The questionnaire for disease-related information includes: erectile function score, whether one has a chronic disease (hypertension or diabetes), whether one smokes, etc.

2.2.2. Self-rating anxiety scale

The Self-rating Anxiety Scale (SAS) was developed by Zung in 1971. It has good reliability and validity and is mainly used to assess the frequency of subjective symptoms of anxiety subjects in the past week. The SAS consists of 20 multiple-choice questions, with each item on the test scale representing the frequency of a symptom, and it is scored on a 4-point scale (1 to 4 points per item). The SAS score is calculated as a total score. The sum of the scores of all the questions on the test sheet equals the rough score, which is converted according to the formula, that is, the rough score is multiplied by 1.25 and rounded to the nearest whole number to get the standard anxiety score. The lower the score, the milder the anxiety symptoms.

2.2.3. Chinese version of family hardiness index (FHI)

The scale, developed by McCubbin et al., was translated into Chinese by Chinese scholars in 2014. It consists of three dimensions: responsibility, control, and challenge, and has 20 items. It uses a Liker 4-level rating system, with values ranging from 1 to 4 from “strongly disagree” to “strongly agree”. Items 1, 2, 3, 8, 10, 14, 16, 19, and 20 are scored in reverse, with a total score ranging from 12 to 48 points. The higher the score, the better the resilience of the family, the scale A Cronbach’s α coefficient of 0.8 indicates good reliability.

2.2.4. Herth hope index scale

The Hope Level Scale (HHI) is an assessment tool developed by American nurse Kathryn Herth in 1991 to measure an individual’s sense of hope for the future and positive emotions. The Chinese version of the Hope Scale,

translated by Zhao Haiping, is mainly used for the expression of an individual's attitude towards life and beliefs. It consists of 12 items and 3 dimensions (attitude towards life, taking positive action, maintaining close relationships with others), and is scored using the Liker 4 scale, where 1 indicates strong opposition and 4 indicates strong agreement, with scores ranging from 12 to 48. The higher the score, the more positive the individual's attitude towards life and firm confidence. Items 3 and 6 are the reverse ones. The Cronbach's α coefficient of the scale was 0.870, indicating good credibility.

2.3. Data collection

Data collection was conducted using a combination of online and offline methods to investigate patients who met the inclusion and exclusion criteria. Informed consent forms were sent to the study subjects first, stating the purpose and significance of the study, ensuring the voluntariness and confidentiality of the participants, and the correct filling method. Questionnaires were then distributed to the study subjects after obtaining the informed consent of the patients. At the same time, to ensure the accuracy of the data, each device or IP address was limited to filling out the questionnaire only once, and all options were required to be filled in to ensure no data was omitted for the successful submission of the questionnaire.

2.4. Statistical analysis

Statistical description and analysis of variables were performed using SPSS 26.0. Qualitative data were described using frequency (n) and percentage (%). Quantitative data conforming to normal distribution were described using mean ± standard deviation ($\overline{x} \pm s$). Differences between groups were compared using independent sample *t*-tests and one-way analysis of variance. For data that did not satisfy homogeneity of variance and normal distribution, the arbitrary distribution test was used, and the LSD test was used for comparative analysis after analysis of variance. Pearson correlation was used to measure the degree of linear correlation between two variables. Take the test level $\alpha = 0.05$.

3. Results

3.1. General information of the respondents

A total of 150 questionnaires were distributed and 140 were retrieved, with an effective recovery rate of 93.33%. The age range of the respondents was 45–84 (63.83 ± 7.52), and other general information is shown in **Table 1**.

Table 1. General Information and Univariate analysis of anxiety after Benign prostatic hyperplasia surgery (n = 140)

Items	Number of cases	Composition (%)	Anxiety score ($\overline{x} \pm s$, points)	Test statistic (*F* value)	*p* value
Age (years)					
< 60	36	25.714	47.868 ± 13.156	3.205	0.044*
60–69	74	52.857	52.116 ± 13.296		
≥ 70	30	21.429	56.398 ± 15.066		
Marital status					
unmarried	12	8.571	53.990 ± 11.716	1.227	0.302
Married	100	71.429	52.892 ± 14.455		

Table 1 (Continued)

Items	Number of cases	Composition (%)	Anxiety score ($\bar{X}$ ± s, points)	Test statistic (*F* value)	*p* value
Divorced	11	7.857	49.382 ± 15.634		
Widower	17	12.143	46.561 ± 9.348		
Educational attainment					
Primary school	50	35.714	52.103 ± 14.613	0.315	0.814
Junior high school	42	30.000	51.220 ± 12.580		
High school or technical secondary school	36	25.714	51.379 ± 14.645		
College and above	12	8.571	55.941 ± 13.813		
Family financial status (yuan/month)					
< 2000	43	30.714	52.904 ± 13.255	0.155	0.857
2000–4000	62	44.286	51.387 ± 13.807		
> 4000	35	25.000	51.740 ± 15.024		
Medical payment ways					
Rural	67	47.857	51.485 ± 13.760	0.560	0.573
Town	38	27.143	55.172 ± 16.177		
Workers	35	25.000	50.980 ± 5.372		
Family relations					
Good	59	42.143	53.989 ± 14.850	1.424	0.244
General	54	38.571	51.300 ± 12.479		
Poor	27	19.286	48.750 ± 14.079		
Living style					
Live with a spouse	72	52.857	50.613 ± 13.243	0.581	0.628
Live with children	29	20.714	52.117 ± 15.327		
Living alone	35	15.714	54.221 ± 14.640		
Others	4	10.714	54.621 ± 5.328		
Do you have a chronic illness					
have	84	60.000	54.941 ± 13.911	10.489	0.002*
no	56	40.000	47.442 ± 12.643		
Whether or not to smoke					
no	100	71.429	49.779 ± 13.462	8.990	0.003*
have	40	28.571	57.941 ± 13.553		

3.2. Results of a univariate analysis of anxiety in patients after prostatic hyperplasia surgery

The results of the univariate analysis showed that there were statistically significant differences in total anxiety scores among patients of different age groups, with or without chronic disease, and with or without smoking ($p < 0.05$), as shown in **Table 1**.

3.3. Scores and correlation analysis of anxiety, erectile function, family resilience and hope level in patients after benign prostatic hyperplasia surgery

The self-rated anxiety score of patients after prostatic hyperplasia surgery was (51.71 ± 16.49), the score of erectile function was (12.35 ± 6.68), the score of family resilience was (29.67 ± 11.44), and the score of hope level was (29.77 ± 10.41). The results of the correlation analysis showed that anxiety was negatively correlated with erectile function score (r = -0.379, $p < 0.001$), anxiety level was negatively correlated with family resilience score (r = -0.380, $p < 0.001$), and anxiety score was negatively correlated with hope level score (r = -0.476, $p < 0.001$).

3.4. Results of multivariate linear model analysis of anxiety levels in patients after benign prostatic hyperplasia surgery

The total score of the Self-Rating Anxiety Scale for patients after prostatic hyperplasia surgery was used as the dependent variable, and the statistically significant variables in the univariate analysis and correlation analysis were included as independent variables in the multivariate linear model. The assignment of independent variables is shown in **Table 2**. The analysis results showed that age, presence of chronic disease, smoking status, family resilience, and level of hope were independent factors affecting anxiety in patients after prostatic hyperplasia surgery, as shown in **Table 3**.

Table 2. Assignment of independent variables

Independent variables	Assignment method
Age (years)	< 60 ($Z_1 = 1$, $Z_1 = 0$), 60–69 ($Z = 0$, $Z = 1$), ≥ 70 ($Z = 0$, $Z = 0$))
Are there any chronic diseases	Yes ($Z_1 = 1$, $Z_0 = 0$), no ($Z = 0$, $Z = 1$)
Whether or not smoking	Yes ($Z_1 = 1$, $Z_0 = 0$), no ($Z = 0$, $Z = 1$)
Erection function	Original value input
Family resilience	Original value input
Hope level	Original value input

Table 3. Results of general linear model analysis of anxiety levels in patients after prostatic hyperplasia surgery

Variables	Regression coefficient *B*	Standard error *SE*	Standardization coefficient β	*t* value	*p* value	95%*CI*
Constant	34.333	4.862		7.061	< 0.001	24.715–43.950
Age	3.944	1.573	0.196	2.507	0.013	0.832–7.055
Whether there is a chronic disease	8.742	2.231	0.310	3.919	< 0.001	4.329–13.154
Whether there is a history of smoking	8.839	2.405	0.289	3.675	< 0.001	4.082–13.596
Erectile function score	-0.202	0.235	-0.082	-0.857	0.393	0.667–0.264
Family resilience score	-0.285	0.124	-0.197	-2.305	0.023	0.529–0.040
Hope level score	-0.555	0.146	-0.350	-3.800	< 0.001	0.844–0.266

4. Discussion

4.1. The anxiety level of patients after benign prostatic hyperplasia surgery is at a moderate level

This study shows that anxiety levels are moderate after transurethral resection of benign prostatic hyperplasia. Chen Hui pointed out that there was widespread anxiety among patients after prostatic hyperplasia surgery due to concerns about the surgical outcome, postoperative complications and recovery process, and most patients had a moderate level of anxiety, which was highly consistent with the results of this study [4]. Another study used SAS to assess the anxiety status of patients after transurethral resection of the prostate and found that although the postoperative anxiety score was significantly lower than that before the operation, it was still at a moderate level, which was consistent with the overall manifestation of postoperative anxiety in patients in this study, suggesting that although surgical treatment can relieve the physical symptoms of patients, it does not completely eliminate their psychological anxiety distress [5]. The reasons for this are mainly related to the fact that most patients after benign prostatic hyperplasia surgery are elderly, have a relatively weak psychological endurance, and have a temporary lack of awareness of postoperative complications such as abnormal urination and urinary incontinence, which can easily lead to "catastrophic thinking" and thereby cause moderate anxiety; At the same time, physical discomfort such as postoperative pain and indwelling catheters can further increase patients' anxiety, which is consistent with the emotional characteristics of postoperative patients observed in urology clinical nursing, that is, physical discomfort and psychological anxiety interact and jointly cause patients' anxiety levels to remain in a moderate state [6].

4.2. The older the patient, the higher the anxiety level after prostatic hyperplasia surgery

The study showed that older patients had higher levels of anxiety after prostatic hyperplasia surgery ($p < 0.05$). The relationship between age and anxiety levels reveals vulnerability to mental health in older patients. Studies showed that patients aged 70 and above had significantly higher anxiety scores than younger patients, which may be associated with a higher burden of chronic diseases and concerns about surgical complications in the older population [7]. Older patients often face multiple comorbidities such as cardiovascular disease and diabetes, which interact to form complex psychological and physiological burdens [8]. It is also noted in the literature that elderly patients tend to have a more negative perception of rehabilitation ability when facing surgery, and this cognitive bias may exacerbate their anxiety [9]. There are also studies suggesting that age ≥ 60 years may also lead to a lack of confidence in postoperative recovery in patients, thereby increasing anxiety levels, which is consistent with the analysis of risk factors affecting the mood of patients after prostatic hyperplasia surgery in related studies [10]. Therefore, psychological intervention measures for elderly patients need to pay particular attention to their psychological resilience and social support in order to reduce anxiety and improve the overall therapeutic effect.

4.3. Patients with chronic diseases and those who smoke have higher levels of anxiety

The study showed that patients with chronic diseases and smoking had higher levels of anxiety after prostatic hyperplasia surgery ($p < 0.05$). Patients with chronic diseases often face a higher burden of symptoms and more complex treatment options, which not only increase concerns about their health status but may also lead to a decline in their self-efficacy, thereby exacerbating anxiety [11,12]. Relevant studies suggest that anxiety in patients with chronic diseases is often associated with a reduced sense of control over treatment outcomes, and patients may feel helpless and desperate when facing multiple health problems, an emotional state that directly affects their

mental health [3]. In addition, the depletion of mental resources in patients with chronic diseases (such as lower levels of hope and increased fatigue) is also considered an important factor contributing to anxiety [13]. Therefore, comprehensive intervention programs should focus on the overall health status of patients with chronic diseases and design personalized psychological support strategies.

The association between smoking behavior and postoperative anxiety reveals the complexity of the physiological-psychological interaction. Studies have shown that smoking is not only closely related to physical health but also has a significant impact on mental health, with smokers being more prone to anxiety and depression symptoms [14]. Physiologically, nicotine dependence may exacerbate anxiety and stress responses by affecting the brain's reward system [15]. In addition, smoking as a poor coping strategy may reflect smokers' inefficient management of stress, which further exacerbates anxiety. In this context, smoking withdrawal interventions can not only improve physical health, but may also promote psychological adaptation in patients by reducing anxiety levels. Therefore, in perioperative care, it is particularly important to strengthen the combination of smoking cessation support and psychological intervention.

4.4. The better the family resilience, the lower the anxiety level after prostatic hyperplasia surgery

The study found that the better the family resilience, the lower the anxiety level in patients after prostatic hyperplasia surgery, and the two were significantly negatively correlated. This conclusion corroborates the existing research results and highlights the important role of family resilience in alleviating postoperative anxiety in patients. Mccubbin et al. proposed the concept of "Family Resilience" in 1988 [16]. Family resilience, also known as family resistance or family recovery, is a protective factor, adaptation method, or the result of family reconfiguration in the face of adversity. Family resilience focuses on the entire family and emphasizes during times of crisis. How a family, as a collaborative team, uses its own strengths and resources to build its own support system to deal with possible difficulties or challenges in the future is the response and adaptation of the family as a functional unit as a whole [17]. The family is the direct environment in which the patient lives. When the patient themselves face illness or setbacks, good family resilience can help the patient and their family better cope with and get out of the crisis, transform the stress caused by illness into the driving force for family growth and progress, and better promote the patient's recovery from illness [18,19]. When patients face crises and setbacks such as illness and adversity, family resilience can help families get out of the crisis, turn stress into the driving force for family progress and growth, and promote the recovery of family functions [20]. Studies show that well-adapted families are characterized by stronger problem-solving skills, a warm family atmosphere, more composure in the face of difficulties, the ability to quickly identify the root cause of problems and solve them effectively, more happiness and less anxiety and depression among family members, and greater unity and higher family cohesion in the process [21]. It has also been found that the psychological state and quality of companionship of family members are closely related to the anxiety of patients after prostatic hyperplasia surgery. The empathy and support of family members can help patients relieve psychological burden and reduce anxiety episodes, which is a core manifestation of the emotional support dimension in family resilience, echoing the conclusion in this study that the better the family resilience, the lower the anxiety level of patients. This indicates that family resilience helps patients cope with postoperative rehabilitation stress by enhancing family support, thereby reducing anxiety levels. This mechanism also provides a theoretical basis and practical support for the intervention of patients' anxiety through enhancing family resilience in clinical nursing [22].

4.5. The higher the level of hope, the lower the level of anxiety after prostatic hyperplasia surgery

The results of this study show that the higher the level of hope, the lower the level of anxiety in patients after prostatic hyperplasia surgery, which is consistent with the conclusions of many studies at home and abroad on the psychological state of patients after prostatic hyperplasia surgery, clarifying the key role of the level of hope in alleviating postoperative anxiety in patients. The level of hope is the patient's positive expectation of future recovery and confidence in achieving rehabilitation goals, which can help patients deal with difficulties and stress during the postoperative rehabilitation process with a positive attitude, thereby reducing anxiety [23]. The effect of psychological intervention on the quality of life of patients after transurethral resection of the prostate (TURP) research shows that enhancing patients' confidence in rehabilitation through psychological intervention can significantly reduce their anxiety scores and improve their psychological state, which is essentially achieved by increasing patients' level of hope, consistent with the conclusion of this study [24]. Synergistic intervention based on caring behavior also found that improving the mood state of patients after prostatic hyperplasia surgery through intervention could reduce their anxiety score, and the improvement in the level of hope is an important manifestation of the improvement in mood state, further confirming the negative correlation between the level of hope and the level of anxiety [5]. Analyzing the mechanism of action, patients with high levels of hope after prostatic hyperplasia surgery can have a clearer understanding of the process and pattern of postoperative rehabilitation, have a more objective cognition of possible discomforts such as abnormal urination and pain after surgery, and are less likely to have excessive worry and fear, thereby reducing the generation of anxiety; At the same time, high levels of hope can stimulate patients' self-management ability, making them more actively cooperate with postoperative rehabilitation training and nursing measures to promote physical recovery, and the relief of physical symptoms can further enhance patients' confidence in recovery, forming a virtuous cycle of "increased level of hope–active cooperation in rehabilitation–relief of physical symptoms–reduced level of anxiety" [24]. This is in line with the conclusion in related studies that "psychological care combined with urination function training can relieve negative emotions by enhancing patients' confidence in rehabilitation", indicating that the level of hope, as an important positive indicator of patients' psychological state, can effectively buffer the impact of postoperative stress on anxiety, providing an important entry point for clinical psychological nursing intervention [23].

There are several limitations in this study. First, the use of convenience sampling and the fact that the samples originated from only one medical institution may lead to sample selection bias, limiting the universality of the study results. The family resilience, levels of hope, and anxiety experiences of patients from specific regions and medical backgrounds may not fully represent the broader post-prostatic hyperplasia population. Secondly, the study was designed as a cross-sectional survey that could only reveal correlations among variables, but could not infer the direction of the causal effects of family resilience and hope levels on anxiety. For example, it is not clear whether higher levels of hope reduce anxiety or lower anxiety promotes an increase in the sense of hope. This needs to be further verified through prospective longitudinal studies or intervention trials.

5. Conclusion

To sum up, this study identified age, comorbidity, smoking history, family resilience, and level of hope as key factors influencing anxiety in patients after surgery for benign prostatic hyperplasia. The innovation lies in

integrating and quantifying the independent predictive effects of family system resources (family resilience) and individual psychological capital (hope level) on anxiety for the first time in this specific patient group, going beyond the conventional perspective that focuses only on individual or disease factors. This finding has clear practical implications, suggesting that clinical interventions need to shift from traditional symptom management to an integrated model that combines psychosocial support and family system interventions. Future research should focus on developing and evaluating structured psychosocial intervention programs centered on enhancing family resilience and hope levels, and testing their efficacy in reducing postoperative anxiety and improving long-term quality of life through randomized controlled trials.

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Research on the Risk Classification Nursing Model in the Prevention of Pressure Injuries in Critically Ill Patients in ICU

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Abstract: *Objective*: The purpose of the study was to explore the application effect of the risk classification nursing model in the prevention of pressure injury in critically ill patients in the ICU. *Methods*: A total of 186 critically ill patients admitted to the ICU of our hospital from January 2024 to December 2024 were randomly divided into the control group and the observation group according to the time of admission, with 93 cases in each group. Conventional pressure injury prevention nursing measures were used in the control group, while risk classification nursing model was adopted in the observation group. The incidence, staging, time of occurrence, length of hospital stay and nursing satisfaction of pressure injury were compared between the two groups. *Results*: The results showed that the incidence of pressure injury in the observation group was 5.38%, significantly lower than 15.05% in the control group ($p < 0.05$); The proportion of stage I pressure injury in the observation group was higher than that in the control group, and the proportion of stage II and above was lower than that in the control group ($p < 0.05$); The occurrence time of pressure injury in the observation group was later than that in the control group, and the length of hospital stay was shorter than that in the control group ($p < 0.05$); The nursing satisfaction score of the observation group was higher than that of the control group ($p < 0.05$). *Conclusion*: The risk classification nursing model can effectively reduce the incidence of pressure injury in critically ill patients in the ICU, delay the occurrence time, shorten the length of hospital stay, and improve nursing satisfaction. It is worthy of clinical promotion and application.

Keywords: Risk-graded nursing; ICU; Critical care; Pressure injury; Preventive effects

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1. Introduction

Pressure injury is one of the common complications for critically ill patients in the ICU. It not only adds to the patient's suffering and prolongs the hospital stay, but also significantly increases the medical burden. ICU patients are at high risk of stress injury due to long-term bed rest, consciousness disorders, hemodynamic instability, poor nutritional status, etc. Conventional preventive care mostly follows a uniform standard, lacking specificity and

dynamics, and fails to meet the individualized needs of patients at different risk levels. The risk classification nursing model is based on the risk assessment results of patients and adopts a stratified and differentiated management approach to preventive measures for patients, with the aim of optimizing nursing resources. This paper mainly studies the application effect of the risk classification nursing model in the prevention of pressure injury in critically ill patients in the ICU, providing a basis for clinical nursing practice [1].

2. Data and methods

2.1. General information

186 critically ill patients admitted to our ICU from January 2024 to December 2024.

2.1.1. Inclusion criteria

Age at least 18 years; Stay in the ICU for at least 48 hours; Braden score less than or equal to 18; The patient or family member gave informed consent to participate in this study.

2.1.2. Exclusion criteria

Pressure injury at admission, skin disease affecting skin observation, and extremely critical condition with an expected survival time of less than 48 hours.

2.1.3. Study design

A total of 93 patients admitted from January 2022 to December 2022 were divided into the control group, and 93 patients admitted from January 2023 to December 2023 were divided into the observation group in order of admission time. There were 52 males and 41 females in the control group, aged 28–79 years, with an average age of (56.83 ± 12.47) years; APACHEII score (18.64 ± 4.32) points; Braden score (12.35 ± 2.18) points. There were 54 males and 39 females in the observation group; The age ranged from 26 to 81 years, with an average age of (57.21 ± 13.05) years; APACHEII score (18.92 ± 4.57) points; Braden score (12.18 ± 2.34) points. There was no statistically significant difference ($p > 0.05$) in general information such as gender, age, APACHEII score and Braden score between the two groups of patients, and they were comparable [2].

2.2. Methods

The control group received conventional pressure injury prevention care measures such as turning over every 2 hours, keeping the bed unit clean and dry, using an air cushion bed, placing a soft pillow on the bony protrusion for decompression, enhancing nutritional support, and observing and recording the skin condition.

The observation group adopted a risk-graded care model with the following measures.

(1) Risk assessment

Within 2 hours after admission to the ICU, patients were evaluated using the Braden Scale, which included six aspects: sensation, moisture, mobility, nutritional status, friction, and shear force, with a total score of 6 to 23. According to the Braden score, patients were divided into the low-risk group (15–18 points), the medium-risk group (13–14 points), the high-risk group (10–12 points), and the extremely high-risk group (≤ 9 points). Assess twice a week and reassess and adjust the risk level at any time if the condition changes.

(2) Graded care measures

The low-risk group takes basic preventive measures such as using standard mattresses, turning over every 2–3 hours, keeping the skin clean and dry, guiding patients to move actively, and nutritional screening and support. The medium-risk group, on top of the low-risk group, added the use of decompression dressings to protect bony protrusions (sacrococcygeal region, heel, etc.), the use of alternating inflatable mattresses, turning over every 2 hours, and enhanced skin observation. The high-risk group turned over every 1–2 hours on top of the medium-risk group, used high-specification decompression mattresses, used foam dressings preventatively on key areas, conducted a comprehensive daily skin assessment, and strengthened position management (30° lateral position). The very high-risk group turned over every hour on top of the high-risk group, with a multidisciplinary team intervention (doctors, nutritionists, wound therapists), continuous low-pressure turning beds, microenvironment management (temperature and humidity control), individualized nutritional support plans, and daily recording of changes in pressure injury risk assessment trends.

(3) Quality control

Establish a pressure injury management team, with the head nurse as the team leader, the wound therapist as the technical advisor, and the responsible nurse as the team member. The group is responsible for supervising the implementation of graded nursing measures, conducting a quality inspection once a week, and organizing a specialized training assessment once a month, covering risk assessment skills, the use of new dressings, turning techniques, etc. Establish a continuous improvement mechanism, provide timely feedback and rectification of existing problems to ensure the continuous improvement of nursing quality.[3]

2.3. Observation indicators

(1) Occurrence of pressure injury

The incidence of pressure injury during ICU stay was recorded in both groups of patients, which was classified as stage I, stage II, stage III, stage IV, unstaged, and deep tissue injury according to the 2016 NPUAP pressure injury staging criteria.

(2) Time of occurrence of pressure injury

The time from ICU admission to the first occurrence of pressure injury.

(3) Length of hospital stay

Record the number of days a patient stays in the ICU.

(4) Nursing satisfaction

Evaluation using a self-made nursing satisfaction questionnaire, which included 10 items such as nursing skills, service attitude, health education, psychological support, etc. Each item was scored on a 5-point scale (1–5 points), with a total score of 10–50 points. The higher the score, the higher the satisfaction. The questionnaire was filled out by the patients before they were transferred out of the ICU [4].

2.4. Statistical processing

Data analysis was conducted using SPSS 25.0 statistical software. Measurement data were expressed as mean ± standard deviation ($\overline{x} \pm s$), and independent sample *t*-tests were used for comparisons between groups; Count data were expressed as frequency and percentage (%), and the χ^2 test was used for comparison between groups. $p < 0.05$ was considered statistically significant [5].

3. Result

3.1. Comparison of the incidence of pressure injury between the two groups

The incidence of pressure injury was 5.38% in the observation group, which was lower than 15.05% in the control group. The difference between the two groups was statistically significant ($p < 0.05$). See **Table 1** for details.

Table 1. Comparison of incidence of pressure injury between the two groups [n(%)]

Groups	Number of cases	Pressure injury occurs	No pressure injury occurred
Control group	93	14 (15.05)	79 (84.95)
Observation group	93	5 (5.38)	88 (94.62)
χ^2 value		4.812	
p value		0.028	

3.2. Comparison of staging of pressure injury between the two groups of patients

Of the 5 cases of pressure injuries in the observation group, 4 cases (80.00%) were stage I, 1 case (20.00%) was stage II, and no stage III or higher pressure injuries occurred; Of the 14 cases of pressure injuries in the control group, 6 cases (42.86%) were stage I, 5 cases (35.71%) were stage II, 2 cases (14.29%) were stage III, and 1 case (7.14%) was deep tissue injury. There was a statistically significant difference in the staging distribution of pressure injuries between the two groups ($p < 0.05$).

3.3. Comparison of time of occurrence of pressure injury and length of hospital stay between the two groups of patients

The occurrence time of pressure injury in the observation group was later than that in the control group, and the hospital stay was shorter than that in the control group. The differences between the two groups were statistically significant ($p < 0.05$). See **Table 2** for details.

Table 2. Comparison of time to pressure injury and length of hospital stay between the two groups ($\overline{x} \pm s$)

Groups	Number of cases	Time of occurrence of pressure injury (d)	Length of hospital stay (d)
Control group	93	5.24 ± 1.86	12.58 ± 3.74
Observation group	93	8.37 ± 2.15	9.26 ± 2.83
t value		3.128	4.356
p value		0.004	< 0.001

3.4. Comparison of nursing satisfaction between the two groups

The nursing satisfaction score of the observation group was (45.37 ± 3.28) points, which was higher than that of the control group [(39.84 ± 4.16) points], and the difference between the two groups was statistically significant ($t = 4.925$, $p < 0.001$).

4. Discussion

ICU critically ill patients are a high-risk group for pressure injuries, and there are problems such as poor targeting

and inadequate dynamic adjustment of routine preventive care measures. The risk classification nursing model, based on the risk assessment results of patients, implements stratified and differentiated preventive measures, embodying the idea of precision nursing. According to the research results, the incidence of pressure injuries in the observation group was significantly lower than that in the control group, indicating that this risk-stratified nursing model can effectively reduce the occurrence of pressure injuries in ICU patients. Patients were classified as high-risk and extremely high-risk based on the Braden score, and more intensive and proactive preventive measures were taken for high-risk and extremely high-risk patients, such as shortening the turning interval, using high-specification decompression equipment, and multidisciplinary team intervention, to prevent the occurrence and development of stress injuries at key points.

The staging of pressure injuries reflects the severity of tissue damage. In this study, the majority of pressure injuries in the observation group were stage I, accounting for 80.00%, while in the control group, the proportion of pressure injuries above stage II was 57.14%, with one case of stage III and one case of deep tissue injury. The differences suggest that the risk classification nursing model can reduce the occurrence of pressure injuries and also alleviate the severity of the injuries. Risk-graded care emphasizes early identification, early intervention, preventive dressing protection for high-risk patients, and more frequent skin observation, which can detect and treat pressure injuries while they are still in the reversible stage and prevent the damage from progressing to deep tissues.

The time of occurrence of pressure injury is an indicator for evaluating the preventive effect. Pressure injury occurred later in the observation group than in the control group, indicating that risk classification nursing can delay the occurrence of pressure injury. The risk of ICU patients was assessed immediately upon admission, and corresponding preventive measures were taken based on the risk, providing effective protection during the window period of pressure injury occurrence. The length of hospital stay in the observation group was significantly shorter than that in the control group. The incidence of pressure injury was reduced, the degree of injury was lessened, and the problem of complicated treatment and prolonged hospital stay caused by pressure injury was improved.

Nursing satisfaction is a dimension for evaluating the quality of nursing. The observation group scored higher than the control group in terms of nursing satisfaction, indicating that the risk classification nursing model was recognized by patients. The model emphasizes individualized care, patients feel the targeted and professional nature of the care measures, enhances skin care and health education, improves the effect of nurse-patient communication, and the reduction in the incidence of pressure injuries directly increases patients' trust in the care work.

5. Conclusion

In summary, the risk classification nursing model is based on scientific risk assessment and uses stratified preventive measures to reduce the incidence, occurrence time, injury degree, length of hospital stay of pressure injuries in critically ill patients in the ICU and improve nursing satisfaction. This model has good clinical application value and can be promoted and applied in ICU nursing work. The sample size of this study is small, and subsequent multi-center large-sample studies can be conducted to verify its effect.

Disclosure statement

The author declares no conflict of interest.

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Application Research of Collaborative Decision-Making Nursing Intervention Based on Information Asymmetry Theory in Postoperative Limb Functional Rehabilitation of Patients with Lower Limb Fractures

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Abstract: Lower limb fractures are a prevalent clinical orthopedic condition, primarily caused by factors such as trauma and osteoporosis. Surgical treatment serves as the main intervention method; however, the postoperative rehabilitation of limb function is characterized by a lengthy and challenging process. Patients often experience suboptimal rehabilitation outcomes due to a lack of rehabilitation knowledge and insufficient compliance. The information asymmetry theory elucidates the information imbalance between doctors and patients resulting from disparities in professional knowledge. Collaborative decision-making nursing intervention effectively alleviates information asymmetry by establishing a mechanism for information sharing between doctors and patients, thereby fully mobilizing patients' initiative in rehabilitation. This paper synthesizes relevant domestic and international research in recent years to summarize the application methods and implementation effects of collaborative decision-making nursing intervention based on information asymmetry theory in the postoperative limb functional rehabilitation of patients with lower limb fractures. It aims to provide theoretical references and practical evidence for optimizing clinical rehabilitation nursing models and enhancing rehabilitation quality following lower limb fracture surgery.

Keywords: Information asymmetry theory; Collaborative decision-making; Lower limb fractures; Postoperative rehabilitation; Limb function

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1. Introduction

Lower limb fractures account for over 30% of all fractures in the body, with their incidence showing an upward trend due to population aging and the development of the transportation and construction industries [1]. Surgery can effectively reduce fractured bone ends, but long-term functional training is required postoperatively to restore

limb function and reduce the incidence of complications [2]. However, approximately 40% of patients experience issues such as non-standardized rehabilitation training and poor compliance after surgery, leading to delayed recovery of limb function and increased medical burdens on families and society [3]. One of the core reasons for this is the information asymmetry between doctors and patients; in traditional nursing care, patients are at an informational disadvantage and find it difficult to actively participate in rehabilitation [4]. The information asymmetry theory, proposed by Akerlof in 1970 and later extended to the medical field, refers to the disadvantage suffered by the less informed party due to differences in information between the two parties in a transaction. Collaborative decision-making nursing intervention emphasizes information sharing and joint decision-making between doctors and patients; combining this theory can compensate for patients' informational disadvantages and improve rehabilitation outcomes [5]. This paper provides a comprehensive review of its application to offer clinical references.

2. Application of collaborative decision-making nursing intervention based on information asymmetry theory in postoperative limb function rehabilitation of patients with lower limb fractures

2.1. Establishing a professional nursing team

Form a professional nursing team consisting of orthopedic surgeons, rehabilitation therapists, and responsible nurses, clarifying the responsibilities of each member to collaboratively carry out collaborative decision-making nursing interventions [6]. Orthopedic surgeons are responsible for assessing the patient's fracture healing status, formulating a basic rehabilitation plan, and answering patients' questions regarding fracture diagnosis and treatment. Rehabilitation therapists guide patients in conducting scientific rehabilitation exercises, adjust exercise intensity and methods, and evaluate limb function recovery. Responsible nurses are tasked with conveying rehabilitation information, communicating daily with patients and their families, observing the patient's rehabilitation progress and psychological state, providing psychological interventions and health guidance, and coordinating the work of team members. Team members hold regular communication meetings to exchange information on the patient's rehabilitation progress and optimize rehabilitation plans.

2.2. Establishing a multi-channel information dissemination mechanism

To alleviate information asymmetry between healthcare providers and patients, establish a multi-channel information dissemination mechanism to ensure that patients can promptly obtain accurate and effective rehabilitation information [7].

(1) Oral communication

After the patient regains consciousness post-surgery, the responsible nurse promptly explains the fracture healing status, postoperative precautions, and the initial rehabilitation plan to the patient and their family using simple language, avoiding medical jargon, and patiently answering the patient's questions.

(2) Written communication

Develop personalized rehabilitation guidance manuals covering fracture-related knowledge, rehabilitation exercise steps, exercise precautions, complication prevention methods, and rehabilitation evaluation criteria, and distribute them to patients and their families for easy reference at any time.

(3) Visual guidance

Utilize images, videos, and models to demonstrate specific rehabilitation exercises and the fracture healing process to patients, helping them intuitively understand relevant information. Establish a rehabilitation exercise video library, allowing patients to watch training videos on their mobile phones or tablets to standardize exercise movements.

(4) Online communication

Establish a WeChat group for healthcare provider-patient communication, where healthcare providers regularly post rehabilitation knowledge, exercise reminders, and answers to common questions. Patients and their families can consult questions and provide feedback on rehabilitation progress at any time, with healthcare providers responding promptly to ensure real-time information transmission.

2.3. Conducting two-way communication to alleviate information interpretation differences

Establish an effective two-way communication mechanism between healthcare providers and patients to alleviate information interpretation differences and ensure effective information transmission and understanding.

(1) Regular communication

The responsible nurse communicates daily with patients and their families to understand the patient's rehabilitation experience, difficulties encountered during exercises, psychological state, and information needs, promptly answering the patient's questions. Weekly healthcare provider-patient communication meetings are organized, where orthopedic surgeons and rehabilitation therapists explain the rehabilitation progress and evaluation results in detail to patients and their families, answer common questions, and collect patient feedback and suggestions [8].

(2) Optimizing communication skills

Healthcare providers use communication techniques such as listening, empathy, and guidance to patiently listen to patients' concerns and worries, empathize with their pain, and encourage patients to actively express their feelings and questions. Avoid using medical jargon and interpret rehabilitation evaluation indicators and exercise plans in simple language, repeating explanations if necessary to ensure patient understanding.

(3) Encouraging patient participation

Encourage patients and their families to actively consult healthcare providers, provide feedback on abnormal situations during rehabilitation, and participate in the formulation and adjustment of rehabilitation plans, enabling patients to fully understand their rehabilitation status and improve their information interpretation abilities.

2.4. Jointly formulating and implementing personalized rehabilitation plans

Collaborate with patients and their families to develop personalized postoperative limb function rehabilitation plans based on individual patient conditions, clarifying rehabilitation goals, exercise content, intensity, and schedule to ensure the feasibility and applicability of the rehabilitation plan [9].

(1) Rehabilitation evaluation

Within 24 hours post-surgery, the nursing team conducts a comprehensive evaluation of the patient, including fracture site, type, healing status, joint range of motion, muscle strength, physical condition, psychological state, rehabilitation needs, and educational level, to provide a basis for formulating the rehabilitation plan [10].

(2) Plan formulation

Healthcare providers explain the advantages, disadvantages, risks, and prognosis of different rehabilitation plans to patients and their families in detail, and jointly formulate a rehabilitation plan based on the patient's evaluation results and preferences. For example, for young patients with rapid fracture healing, a rehabilitation plan with moderate intensity and rapid progress is formulated, focusing on restoring joint range of motion and muscle strength. For elderly patients with poor physical condition and slow fracture healing, a rehabilitation plan with gentle intensity and slow progress is formulated, emphasizing complication prevention and gradual limb function recovery.

(3) Plan implementation

Healthcare providers guide patients to exercise according to the rehabilitation plan, with rehabilitation therapists demonstrating exercise movements on-site and correcting non-standard movements. The responsible nurse observes the patient's exercise progress daily and adjusts exercise intensity and progress promptly. Patients and their families strictly follow the rehabilitation plan for exercises, actively providing feedback on feelings and abnormal situations during exercises, which healthcare providers address promptly.

(4) Dynamic adjustment

Conduct a rehabilitation evaluation of the patient weekly and a comprehensive evaluation monthly, adjusting the rehabilitation plan jointly with the patient based on the patient's fracture healing status, limb function recovery, psychological state, and preferences to ensure that the rehabilitation plan always meets the patient's individual needs.

2.5. Strengthening psychological interventions and social support

Postoperative patients with lower limb fractures are prone to negative emotions such as anxiety, fear, inferiority, and depression due to limb dysfunction, a long rehabilitation cycle, and concerns about prognosis, which can affect their rehabilitation enthusiasm and compliance and exacerbate information asymmetry [11]. Therefore, healthcare providers need to strengthen psychological interventions for patients based on the concept of collaborative decision-making and encourage family members to provide social support.

(1) Psychological evaluation

Regularly evaluate the patient's psychological state using tools such as the Self-Rating Anxiety Scale (SAS) and the Self-Rating Depression Scale (SDS) to identify the causes of negative emotions.

(2) Psychological counseling

Address the patient's negative emotions through one-on-one communication with healthcare providers, listening to the patient's worries, and using cognitive-behavioral therapy and relaxation training to help the patient adjust their cognition and alleviate negative emotions. Introduce successful rehabilitation cases to enhance the patient's rehabilitation confidence.

(3) Family support

Encourage family members to spend more time with and care for the patient, providing emotional and financial support. Guide family members to participate in the patient's rehabilitation exercise process, supervise the patient's standard exercises, and help the patient establish rehabilitation confidence and improve rehabilitation compliance.

2.6. Establishing a rehabilitation effect evaluation system

Establish a scientific rehabilitation effect evaluation system to regularly evaluate the patient's limb function rehabilitation progress, promptly identify problems and adjust rehabilitation plans, while enabling patients to clearly understand their rehabilitation progress and enhance their rehabilitation enthusiasm [12]. Evaluation indicators include limb function indicators and patient subjective feeling indicators: Limb function indicators include joint range of motion, muscle strength, walking function, and fracture healing time, evaluated using tools such as a goniometer and muscle strength grading method. Patient subjective feeling indicators include rehabilitation compliance, rehabilitation satisfaction, and psychological state, evaluated using tools such as the Rehabilitation Compliance Scale, Nursing Satisfaction Scale, SAS, and SDS. Regularly provide feedback on evaluation results to patients and their families, jointly analyze the strengths and weaknesses of the rehabilitation process with the patient, and adjust rehabilitation strategies to ensure rehabilitation effectiveness.

3. Application effects

3.1. Improving patient rehabilitation compliance

The collaborative decision-making nursing intervention based on the information asymmetry theory compensates for patients' information disadvantages through a multi-channel information dissemination mechanism, enabling them to fully understand the importance, methods, and precautions of rehabilitation exercises, thereby enhancing their awareness of rehabilitation nursing [13]. Meanwhile, equal communication between healthcare providers and patients, along with the formulation of personalized rehabilitation plans, makes patients feel respected and valued, fully mobilize their initiative and enthusiasm for rehabilitation, effectively improving their rehabilitation compliance [14].

3.2. Reducing the risk of complications

The collaborative decision-making nursing intervention effectively prevents complications such as joint stiffness, muscle atrophy, deep vein thrombosis, and pressure ulcers by comprehensively conveying information on complication prevention and guiding patients to perform rehabilitation exercises, limb massages, turning over and patting the back, etc., in a standardized manner [15]. Additionally, healthcare providers regularly observe the patient's rehabilitation progress, promptly identify early signs of complications, and take joint intervention measures with the patient, reducing the severity of complications [16].

3.3. Improving postoperative limb function in patients

The collaborative decision-making nursing intervention based on the information asymmetry theory effectively promotes the recovery of postoperative limb function in patients by jointly formulating personalized rehabilitation plans, standardizing rehabilitation exercise behaviors, and dynamically adjusting exercise intensity and progress [17]. Through standardized rehabilitation exercises, patients experience significant improvements in joint range of motion, muscle strength, and walking ability, along with a noticeable reduction in fracture healing time [9].

3.4. Alleviating negative emotions and improving quality of life in patients

The collaborative decision-making nursing intervention alleviates negative emotions such as anxiety, fear,

and depression in patients through enhanced psychological interventions, thereby boosting their rehabilitation confidence [18]. Meanwhile, improvements in limb function and a reduction in the incidence of complications enhance patients' self-care abilities, subsequently improving their quality of life [19].

4. Conclusion

The collaborative decision-making nursing intervention based on the information asymmetry theory effectively alleviates information asymmetry between healthcare providers and patients during the postoperative rehabilitation of patients with lower limb fractures by establishing a comprehensive information dissemination mechanism, strengthening two-way communication between healthcare providers and patients, and jointly formulating personalized rehabilitation plans. This intervention enhances patient rehabilitation compliance and improves limb function recovery outcomes, while also mitigating healthcare provider-patient conflicts, demonstrating significant clinical application value. As healthcare and nursing models continue to evolve and advance, collaborative decision-making nursing intervention will gradually become the mainstream approach for postoperative rehabilitation care in patients with lower limb fractures. In the future, further research is needed to explore more scientific and comprehensive application models of information asymmetry theory and collaborative decision-making nursing intervention. Additionally, leveraging advanced technologies such as artificial intelligence and big data can optimize information dissemination mechanisms, construct intelligent healthcare provider-patient communication platforms, and achieve precise and personalized delivery of rehabilitation information.

Disclosure statement

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Research Progress on Risk Perception of Skeletal-Related Events in Patients with Solid Tumors

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Abstract: Skeletal-related events are common complications in patients with advanced solid tumors and bone metastases, significantly affecting their quality of life and survival prognosis. Risk perception refers to an individual's recognition, judgment, and understanding of risky matters, which holds great significance in promoting healthy behaviors and improving preventive actions among patients. Understanding the level of risk perception for bone-related events in patients with solid tumors is a crucial approach to enhancing their subjective initiative and compliance in bone health management behaviors. This article provides a comprehensive review of the current status, measurement tools, influencing factors, and intervention strategies related to the risk perception of bone-related events in patients with solid tumors. The aim is to enhance the awareness of bone-related events among patients with solid tumors and clinical practitioners, providing references for promoting bone health management behaviors and improving patients' quality of life.

Keywords: Solid tumor; Skeletal-related events; Risk perception; Review; Nursing

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1. Introduction

Skeletal Related Events (SREs) refer to clinical complications primarily manifested as pathological fractures, bone pain, and spinal cord compression in patients with advanced solid tumors, resulting from bone metastases and/or cancer treatment-induced bone loss [1]. During disease progression, 30% to 60% of solid tumor patients experience SREs, with over 30% suffering from multiple SREs, severely impacting their quality of life and survival prognosis [2,3]. Currently, although prevention guidelines for SREs in solid tumor patients are relatively well-established, insufficient attention to SRE risks among healthcare providers, patients, and caregivers leads to

poor adherence to preventive behaviors, inadvertently increasing the risk of SREs and creating a vicious cycle. Risk perception refers to patients' cognition, judgment, and understanding of risky situations [4]. Enhancing disease risk perception can promote improvements in health behaviors and strengthen treatment adherence [5]. Therefore, understanding the level of SRE risk perception among solid tumor patients represents an important approach to improving their adherence to preventive behaviors and subjective initiative. This article reviews the current status, measurement tools, influencing factors, and intervention strategies of SRE risk perception in solid tumor patients, aiming to enhance this population's awareness of SREs, thereby improving their adherence to bone health management behaviors and quality of life.

2. Current status of risk perception for SREs

The concept of SREs risk perception originates from the cognition of SREs-related knowledge. Studies have found that both nurses and patients have deficiencies or gaps in their understanding of SREs [6,7]. To improve the management of SREs in patients with solid tumors, several international expert consensuses on SREs management have been published, covering lung cancer and breast cancer, among others [8,9]. Multiple international surveys on the awareness of SREs among solid tumor patients have shown that over half (58%) of patients receive insufficient or no information about SREs, patients have limited awareness of their potential SREs risks during treatment, 60% of patients have not received bone-protecting agent therapy, and 62% of patients are not completely satisfied with the bone health education they receive [5,10]. Domestic researchers have primarily conducted SREs awareness surveys among nurses, revealing that although over half of oncology nurses have extensive work experience, they lack adequate knowledge in bone health prevention and identification of SREs risk factors, and more than two-thirds of nurses lack confidence in managing bone health in solid tumor patients. Due to insufficient SREs-related knowledge, the risk perception level of SREs across different groups is generally poor, which to some extent diminishes the effectiveness of health education and nursing interventions provided by healthcare professionals. This can easily lead to issues such as poor patient compliance and inadequate implementation of preventive measures, thereby increasing the risk of SREs occurrence.

3. Research tools for risk perception of SREs

Overseas research on the perception of SREs risk began relatively early. Fang Lei et al. used a self-developed chronic disease patient risk perception questionnaire to investigate awareness of SREs among 125 patients with solid tumors (lung cancer, breast cancer, prostate cancer) and multiple myeloma [11]. The questionnaire comprised five modules: demographics, clinical characteristics, BTA use, bone health awareness, and educational experience, and included two open-ended questions. The study showed that awareness of SREs among solid tumor patients was at a low-to-moderate level, and there was a significant gap in bone health education between those who had experienced SREs and those who had not [12]. Subsequently, they conducted a special survey targeting 200 breast cancer patients with bone metastases. The results were not optimistic, revealing a clear information deficit in bone health education, with patients expressing a strong need for diverse, repeatable information formats. Regarding the investigation of nursing staff awareness, some scholars used a self-developed "Cancer Patient Bone Health Management Questionnaire" to survey 283 oncology nurses [13]. The survey covered multiple aspects including work environment, nursing experience, confidence in managing patients with bone metastases, bone

health knowledge, and the use of bone-protecting agents. The survey found that oncology nurses generally had insufficient awareness of SREs and inadequate management practices, lacking training, funding, knowledge, or professional development opportunities.

Research on SREs risk perception in China started later, with studies primarily focusing on nurses. Researchers mainly used a self-developed "SREs Cognition and Management Questionnaire", covering nurses' roles and responsibilities, cognition of SREs and CTIBL, and understanding and confidence in bone health management, comprising 23 items. The questionnaire had a content validity of 0.95. Research findings were similar to those from overseas studies, indicating significant room for improvement in the management of SREs in solid tumor patients in China. In recent years, with increasing attention to cancer symptom management, researchers have developed a series of risk perception assessment tools, which can be categorized as either universal or specific. Universal scales include the Chronic Disease Patient Risk Perception Questionnaire, Fall Risk Perception Questionnaire, etc [14]. Specific scales include tools for measuring lymphedema risk perception after breast cancer surgery, venous thromboembolism risk perception in hospitalized patients, etc. However, a complete and targeted tool for assessing SREs risk perception in solid tumor patients remains lacking.

4. Factors influencing risk perception of SREs

The risk perception of solid tumor patients towards SREs plays a crucial supportive role in their preventive behaviors. Numerous factors influence this perception, primarily encompassing the following aspects.

4.1. Demographic factors

Research indicates that factors such as age, occupation, education level, and family support are the main influences on SREs risk perception. Patients with solid tumors undergo long treatment cycles, and studies have shown that strong family support can alleviate the psychological stress caused by the illness, helping patients proactively pay attention to disease risks, thereby enhancing the comprehensiveness of their risk awareness. Conversely, Lobchuk et al. pointed out that if caregivers experience "role strain" (such as excessive care burden or emotional exhaustion), the quality of communication with the patient declines [15]. This may delay the patient's recognition of important health signals, reduce their willingness to seek medical attention, and indirectly weaken their risk perception.

4.2. Disease and treatment factors

Disease characteristics (such as tumor pathological type and bone metastasis status) and treatment-related factors (such as treatment side effects and accessibility of examinations) constitute the "objective basis" influencing SREs risk perception [16]. Patients with advanced solid tumors are more prone to focus on complication risks. SREs have an insidious onset, and some patients often underestimate the risk of SREs due to the "absence of significant early discomfort". Moreover, local pain caused by chemotherapy and radiotherapy is frequently confused with early symptoms of SREs (such as bone pain). During the use of medications such as bisphosphonates and denosumab, some patients exhibit cognitive biases (e.g., believing that "the risk of drug side effects is higher than that of SREs themselves" or developing an "excessive sense of security" regarding the medication), thereby reducing the accuracy of risk perception or neglecting the prevention of SREs, ultimately leading to an increased risk of SREs occurrence [17].

4.3. Health literacy

Health literacy, defined as an individual's ability to access, understand, evaluate, and apply health information is a core intrinsic factor influencing SREs risk perception. Patients with high health literacy can translate SREs-related knowledge provided by healthcare professionals into proactive risk assessment awareness, whereas those with low health literacy are prone to "information transformation barriers", leading to biased judgments regarding the "benefit-cost ratio of preventive measures". This results in a "fragmented" perception of risk and indirectly diminishes the importance attributed to SREs risk [18].

4.4. Trust relationship among doctors, nurses, and patients

The trust relationship among physicians, nurses, and patients is a key influencing factor in medical interactions. Surveys indicate that patients with high trust in healthcare providers are more receptive to disease risk notifications and more proactive in adopting preventive measures. In contrast, patients with low trust tend to perceive physicians or nurses as "exaggerating risks" and avoid consultations, leading to blind spots in risk perception. As the primary implementers of bone health education, nurses serve as intermediaries between physicians and patients. Their professional competence and communication skills are crucial for establishing effective physician-patient communication and nurse-patient trust [19]. If healthcare providers can enhance their professional competence, prioritize risk management and communication regarding SREs, and improve their risk communication skills, they can not only increase patients' awareness of SREs risks but also promote active patient cooperation in treatment and preventive measures, thereby playing a positive role in improving patient prognosis.

4.5. Cancer self-efficacy

Cancer self-efficacy refers to the confidence and belief of cancer patients in their ability to cope with cancer and related issues, playing a significant role in the perception of SREs risk among solid tumor patients. Patients with higher self-efficacy are more likely to proactively seek knowledge about SREs, have a more acute perception of SREs risk, and are more willing to accept health education and guidance provided by healthcare professionals, adopting effective preventive measures to reduce the risk of SREs occurrence [20]. Conversely, patients with lower self-efficacy often lack confidence in their ability to cope with the disease, which can easily lead to anxiety and fear. These negative emotions can interfere with their accurate judgment of SREs risk, resulting in insufficient risk perception or even neglect of the existence of risks. They may also be skeptical of nursing interventions and unwilling to cooperate, thereby increasing the difficulty of nursing care and hindering effective management of SREs risk by nurses. When facing difficulties and challenges during treatment, patients with low self-efficacy are more likely to give up, thus increasing the likelihood of SREs occurrence. Healthcare professionals can help patients enhance their self-efficacy by providing personalized health education and encouraging patient participation in self-management, thereby better coping with SREs risk.

5. Intervention strategies

5.1. Factors related to medical institutions and healthcare professionals

Bone health management in patients with solid tumors is often regarded as an adjunct to cancer treatment and tends to be marginalized. It presents a highly challenging task. Studies have shown that there remains significant room for improvement among nurses in China regarding their knowledge of SREs, as well as in the management

and guidance of bone protection strategies. The specialized setup for bone metastases in China is incomplete, the implementation of standardized treatment is suboptimal, and the disciplinary configuration, treatment concepts, and approaches in this subspecialty urgently need updating. There is a severe resource imbalance in bone health management for cancer patients. In contrast, foreign countries have established relatively mature nurse-led bone health management models. Through the involvement of multidisciplinary teams, they have achieved comprehensive, multi-faceted management throughout the entire course of SREs. This process has also clarified the role of oncology nurses in the bone health management of patients with solid tumors. Enhancing the awareness and management capabilities of healthcare institutions and professionals regarding SREs will effectively improve bone health outcomes and quality of life for patients with solid tumors. This model provides a practical foundation for China to construct intervention programs for SREs risk perception in solid tumor patients. Simultaneously, the state and relevant departments need to provide strong support and coordination in terms of funding investment and policy guidance. By establishing a sound institutional framework and promoting the coordinated development of various disciplines, the management of SREs can be advanced towards standardization and high-quality development.

5.2. Patient-related factors

The lack of knowledge about SREs among solid tumor patients often leads to a low level of risk perception regarding SREs, which in turn affects patients' bone health management behaviors. Previous studies have shown that solid tumor patients' understanding of SRE-related knowledge is not optimistic, and their information acquisition primarily relies on healthcare professionals. It is recommended to implement improvements in three aspects: the timing, content, and format of education. The management of SREs should be integrated throughout the entire process of diagnosis and treatment. Referring to relevant guidelines for bone metastases in solid tumors, SRE risk assessment and health education should be conducted when solid tumor patients are at high risk of bone metastases or are diagnosed with bone metastases, before initiating bone-modifying agents, during the use of bone-modifying agents (especially before the first administration), when SRE-related symptoms appear, and when imaging examinations indicate abnormalities. This should be accompanied by continuous dynamic health education.

The educational content should be comprehensive and systematic, and the formats should be diversified. Methods such as oral explanations, printed or video-based educational materials, establishing WeChat platforms, medication reminders and follow-up notifications, and setting up "Bone Health Mini-Class" group education sessions should be employed to encourage and guide patients to actively participate in the prevention and treatment of SREs. This is of great significance for delaying the occurrence of SREs and maintaining bone-related quality of life. Simultaneously, emphasis should be placed on stratified education (based on education level, age, disease course, etc.) and synchronous education for caregivers, forming a "patient-caregiver-medical staff" three-dimensional risk closed-loop. This will comprehensively enhance patients' risk perception of SREs and their compliance with bone health management.

6. Conclusion

SREs have an insidious onset, and patients face significant "financial toxicity" after onset. Standardized prevention and treatment are crucial for reducing the incidence of SREs and improving symptom experiences. Prevention,

identification, diagnosis, and treatment based on guidelines have been validated in clinical practice; however, numerous influencing factors still result in suboptimal risk management of SREs in clinical settings, with patient-related factors being a significant contributor. Low patient adherence and poor health literacy undermine nurses' confidence in conducting SREs health education, significantly affecting their work enthusiasm. Currently, domestic research on SREs risk perception primarily focuses on nursing staff, with limited studies on SREs perception, preventive behaviors, adherence, and preventive outcomes among solid tumor patients. No assessment tools related to SREs risk perception in solid tumor patients have been developed domestically, nor have foreign-developed scales been localized and translated. In the future, assessment tools with good reliability and validity could be developed or translated, and theory-based intervention measures for SREs risk perception in solid tumor patients could be actively explored to promote changes in bone health behaviors among these patients, improve their prognoses, and drive in-depth development in the field of cancer prevention and nursing in China.

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Visual Analysis of the Current Situation of Elderly Care for Empty-Nest Seniors in Rural China Based on CiteSpace

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Abstract: *Objective:* To analyze the hotspots and trends in the current state of care for rural empty-nest elderly in China over the past two decades, providing insights for future research on this topic. *Methods:* Chinese literature related to the care of rural empty-nest elderly was retrieved from the China National Knowledge Infrastructure (CNKI) database, covering the period from January 2005 to December 2024. Citespace software was employed to generate visualizations of publication volume, author collaboration patterns, keyword co-occurrence, clustering, and emergent themes. *Results:* A total of 808 articles were included. Publication volume exhibited a trend of "slow growth—rapid surge—gradual decline", with room for improvement in author collaboration. Co-occurrence and clustering maps revealed that research hotspots primarily revolved around issues such as care provision, security, services, and influencing factors for rural empty-nest elderly. *Conclusion:* Research on elderly care for rural empty-nest elderly in China has transitioned from foundational conceptual studies to a stage of substantive development. Establishing a three-dimensional network integrating "care strategy innovation, technology empowerment, and policy coordination" is key to addressing

Keywords: Rural areas; Empty-nest seniors; Current state of elderly care; Visual analysis

Online publication: Apr 7, 2026

1. Introduction

Due to the accelerated pace of urbanization, uneven socioeconomic development between urban and rural areas, and the combined effects of large-scale population migration, China's aging population is increasingly exhibiting a pronounced urban-rural inversion, with rural areas now surpassing urban areas in aging severity, a trend whose gravity continues to intensify [1]. Statistics indicate that by 2024, China's population aged 60 and above will reach 310 million, accounting for 22% of the total population. Among them, 84 million reside in rural areas, where the aging rate is significantly higher than in urban areas [2]. While urban elderly care systems were established earlier and are relatively well-developed, rural areas lag significantly in related infrastructure development, making their

elderly care challenges more complex and formidable [3]. To systematically grasp research trends in China's rural empty-nest elderly care landscape, this study employs CiteSpace visualization software to comprehensively review and analyze relevant literature. The aim is to clarify research hotspots, frontiers, and development trends, thereby providing reference for subsequent academic exploration and policy formulation.

2. Data and methods

2.1. Data sources and screening

Data for this study were sourced from the China National Knowledge Infrastructure (CNKI) database, retrieved from January 2005 to December 2024. The Chinese search terms were: "rural empty-nest elderly OR rural homebound elderly OR rural empty-nest seniors" AND "elder care OR current state of elder care".

2.1.1. Inclusion criteria

(1) Literature related to the current state of elder care for rural empty-nest elderly;
(2) Resource types, journals and theses

2.1.2. Exclusion criteria

(1) Duplicate literature
(2) Incomplete literature
(3) Conference papers, call for papers, reports, and similar materials;
(4) Literature inconsistent with the research topic.

2.1.3. Processing data source

Following inclusion and exclusion criteria, the themes, abstracts, and keywords of retrieved literature were reviewed. Data were imported into Citespace software for deduplication, yielding 808 valid articles.

2.2. Research methods

This study employs the knowledge mapping software Citespace to extract key information, research hotspots, and emerging trends regarding the current state of elderly care for empty-nest seniors in China. This is achieved by analyzing literature volume, author collaboration patterns, keyword co-occurrence, clustering, and emergent themes.

3. Results

3.1. Distribution of publications

Through effective retrieval, 808 documents were obtained, including 501 journal articles and 307 master's/doctoral theses. A line chart was plotted based on publication dates (see **Figure 1**). The chart indicates that from 2005 to 2009, the number of publications on elderly care for empty-nest seniors grew slowly, reflecting an exploratory phase. This was largely because the social phenomena of rural population aging and household emptying had not yet fully manifested, with academic research sensitivity and alignment with societal needs still in their infancy [4]. From 2010 to 2017, publication volume experienced explosive growth, surging from 20 to a peak of 76 papers,

the fastest and most concentrated growth period. During this phase, urban migration intensified as rural laborers migrated en masse to cities, causing a sharp rise in empty-nest elderly populations and bringing eldercare issues to the forefront. From 2018 to 2024, publication volume gradually declined. This shift reflects dynamic adjustments in research focus rather than diminished importance of elderly care issues. It likely stems from substantial prior research accumulation, prompting some scholars to pivot toward more specialized domains such as smart elderly care in rural areas and age-friendly renovations.

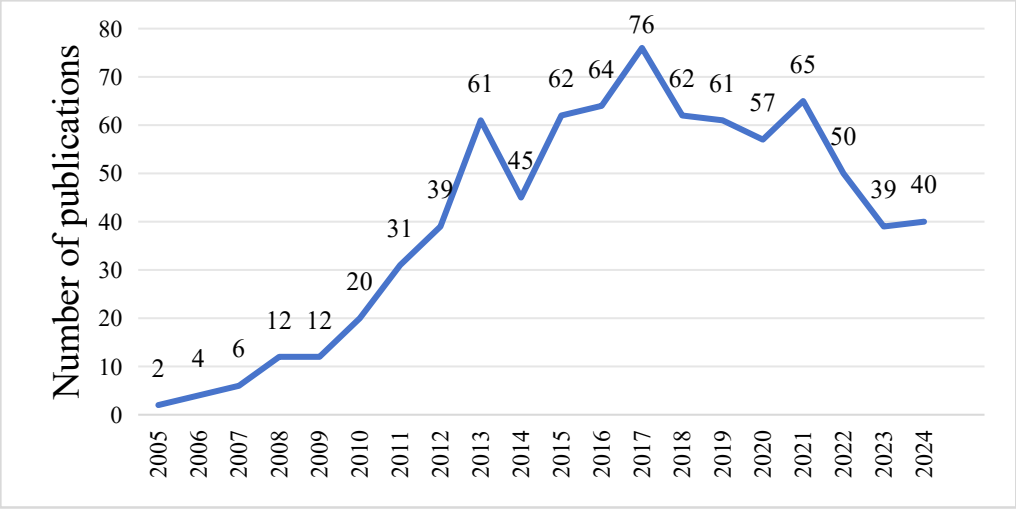


Figure 1. Annual publication volume chart on research into the current state of elderly care for empty-nest seniors in rural China.

3.2. Distribution of author collaboration networks in the literature

Collaboration primarily occurs within institutions, but links between authors are relatively dispersed, indicating that communication and cooperation among scholars still require further enhancement [5]. According to Price's theory, an author becomes a core contributor in this field upon publishing m papers. Using the formula $m = 0.749(\eta max)^{1/2}$, where ηmax represents the maximum publication volume of authors, and the highest publication volume in this study being 7 papers, m is calculated as 1.9 [6]. Thus, authors with > 2 publications are considered core contributors in this field. Statistics reveal 38 core authors in this field. Among them, author Bi Hongxia has the highest publication count (7 papers), followed by scholar Nie Zhiping (5 papers). This indicates a relatively small number of highly productive authors in this field.

3.3. Co-occurrence map of document keywords

Using keywords as nodes in Citespace analysis, this study obtained a co-occurrence map of keywords related to the current state of elderly care for rural empty-nest seniors in China, as shown in **Figure 2**.

Figure 2 presents the keyword analysis results in a "dendrogram" format: the size of each dendrogram corresponds to the keyword's frequency of occurrence; the color transition from inner to outer rings reflects temporal shifts in keyword activity; and the thickness of a dendrogram within a specific time interval is proportional to the keyword's frequency during that period. As can be seen from **Figure 2**, keywords such as "rural empty-nest elderly", "empty-nest elderly", "rural areas", "old-age security", "elderly care issues", "elderly care services", and "mutual-aid elderly care" occupy important positions in the research literature. These keywords are not only the absolute core of the literature collection, but also establish extensive connections with directions such

as “home-based care”, “elderly care models”, “spiritual support”, “countermeasures”, and “influencing factors”, forming a complex network structure. This indicates that the research field on the current situation of elderly care for rural empty-nest elderly in China is continuously becoming more comprehensive and mature.

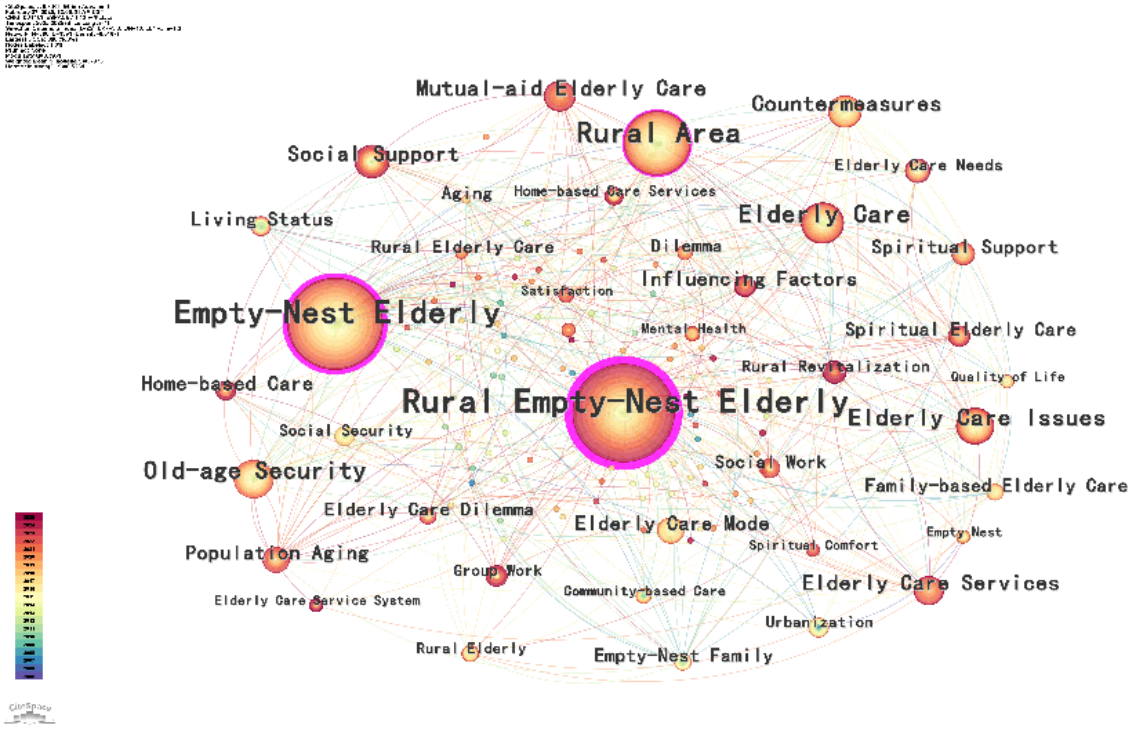


Figure 2. Co-occurrence map of keywords in research on the current state of elderly care for empty-nest seniors in rural China.

3.4. Keyword clustering map of literature

Using CiteSpace to perform keyword clustering analysis on relevant literature, hierarchical clustering was applied based on keyword similarity levels [7]. This aims to reveal the intrinsic connections among thematic keywords in studies concerning the current state of elderly care for rural empty-nest seniors, as detailed in **Figure 3**.

As shown in **Figure 3**, this study formed 11 keyword clusters numbered #0 to #10. Research in this field has developed a multidimensional, multi-tiered framework centered on the core theme of rural empty-nest seniors (#0). Studies focus not only on the empty-nest senior population itself, examining the fundamental challenges of home-based care practices and rural eldercare (#1), but also delve into the limitations of family-based eldercare models and the actual living conditions of seniors (#2). Concurrently, they actively explore mutual-aid eldercare as a novel model suited to rural contexts, emphasizing the crucial role of social support in addressing aging (#3). At the micro level, research examines how key factors like mental health and satisfaction impact care quality (#4), extending into spiritual care to prioritize emotional fulfillment and quality-of-life enhancement for the elderly (#5). Practically, studies explore care service system development and social work interventions within rural revitalization contexts (#6), directly addressing diverse care challenges arising from urbanization-driven empty-nest households (#7). Within the macro context, research positions rural eldercare within the broader trend of population aging, exploring countermeasures like community-based care (#8). It simultaneously addresses top-level design and foundational safeguards, focusing on establishing and refining eldercare security systems (#9). Additionally, it examines pathways to enhance the livability of rural eldercare environments from a living

conditions perspective (#10). Collectively, this forms a comprehensive research framework spanning core groups to diverse models, and from micro-level needs to macro-level systems.

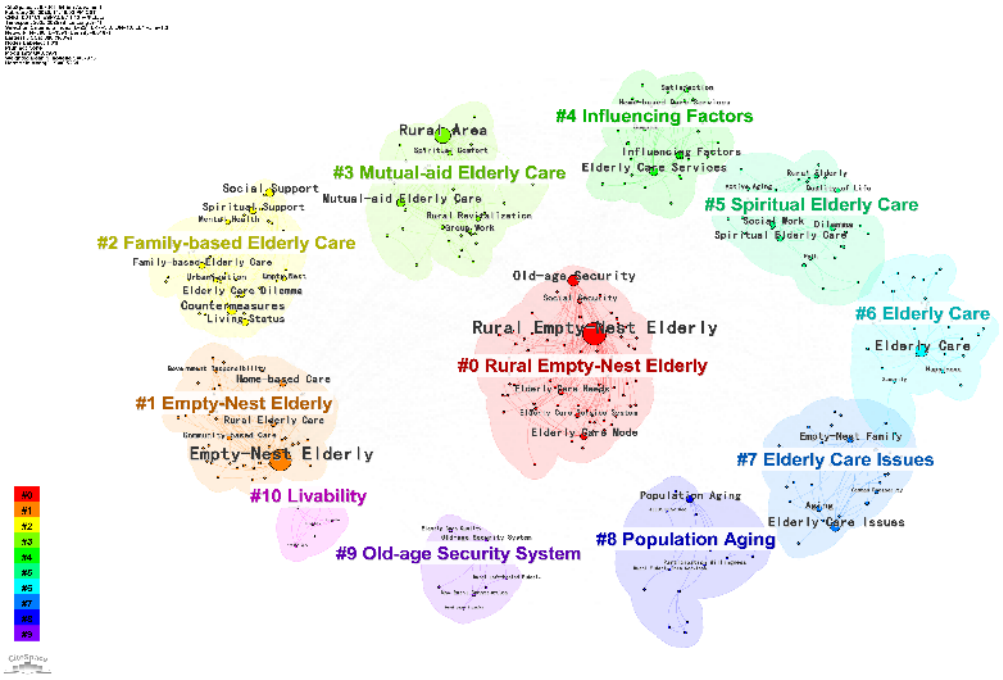


Figure 3. Keyword clustering map of research on the current state of elderly care for empty-nest seniors in rural China.

3.5. Keyword burst analysis of literature

Burst terms refer to keywords whose frequency of occurrence rises significantly within a specific time period. By analyzing their burst strength and dynamic changes, this study can depict the evolutionary trajectory of research frontiers, thereby providing a basis for predicting future research directions [8]. Among the burst terms, the most long-lasting hotspots include Influencing Factors, Mutual-aid Elderly Care, Elderly Care Services, and Spiritual Support, which have remained in a high-impact burst phase since 2019, representing the current and future research trends.

4. Discussion

4.1. Insights from research hotspots on the current state of elderly care for rural empty-nesters

4.1.1. Expanding the scope of needs: holistic coverage from material security to mental well-being

As physical functions decline with age and economic security becomes insufficient, empty-nesters increasingly rely on intergenerational financial support from their children. Intergenerational financial support from children is a critical factor in safeguarding the quality of life for empty-nest seniors, effectively helping them mitigate poverty risks stemming from insufficient income or health issues. Therefore, it is essential to encourage children to strengthen their financial care for the elderly. When necessary, government agencies may clarify children's intergenerational support obligations through legal regulations and institutional frameworks [9]. In recent years, China's rural pension insurance system has been rapidly expanded and gradually popularized, with the basic pension level steadily increasing. This has effectively improved the economic security of empty-nest seniors.

Additionally, the children and society should pay attention to the emotional needs of rural empty-nest seniors. Due to their children working away from home, these seniors live alone and receive less care and companionship from their children. This can easily lead to feelings of isolation and disconnection from society, thereby affecting their mental health. Research indicates[10] that feelings of isolation are inversely proportional to the self-care capabilities of rural empty-nest seniors. Prolonged exposure to isolation stemming from loneliness and helplessness often diminishes their confidence in managing daily challenges. Therefore, strengthening rural infrastructure and organizing diverse cultural, educational, and recreational activities, such as establishing senior associations and interest clubs, which is crucial. Teaching seniors to use smartphones and social media platforms, while integrating resources from village doctors, volunteers, and their children, enables them to initiate health consultations and request daily assistance with simple mobile commands. This approach breaks their emotional isolation, enhances their sense of social belonging, and ensures more rural empty-nest seniors can enjoy a high-quality later life.

4.1.2. Diversified elderly care strategies: from single-subject to multi-subject collaborative model innovation

Family-based care remains the dominant model in China's rural areas, centered on adult children providing financial support and daily care for their elderly parents. However, this traditional approach faces severe challenges due to rural industrial restructuring, significant labor outflow, and shifting family structures, rendering it unsuitable for all rural regions. Consequently, new models of eldercare are emerging, such as social eldercare, self-reliant eldercare, and mutual-aid eldercare, to overcome the limitations of a single-model approach [10]. Social eldercare leverages the participation of governments, markets, and social organizations to fill professional gaps in family-based care. Elderly care enterprises are integrating rural ecological advantages, with some regions exploring distinctive models like "retirement tourism" and "wellness agriculture". These initiatives drive upgrades in rural eldercare facilities while boosting employment and income. Self-reliant care centers on the capabilities of the elderly themselves, enabling autonomous care by activating the labor value and self-reliance of rural empty-nest seniors. For instance, younger seniors in relatively good health can engage in small-scale farming and animal husbandry using rural land resources, generating income while maintaining physical fitness. Mutual aid eldercare, as an emerging model, demonstrates value across economic support, medical assistance, daily care, and emotional comfort. Typical practices include the "time bank" model, where younger seniors provide services like shopping, medical accompaniment, and companionship to older seniors. Accumulated "service time" is deposited into accounts, to be redeemed for equivalent care services when needed in the future. This approach activates local human resources and effectively alleviates the challenges of "shortage of professionals and high operational costs" in rural elderly care services. Addressing the care dilemmas of rural empty-nest seniors requires collaborative efforts among stakeholders, government support, resource integration, and precise matching. Cultivating local elderly care talent is essential to ensure that diverse care strategies truly take root in rural realities.

5. Conclusion

This study employed CiteSpace software to analyze the current state of elderly care for rural empty-nest seniors. Research over the past two decades has shifted from foundational conceptual studies to a phase focused on developing substantive frameworks. Establishing a three-dimensional network integrating "care strategy innovation—technological empowerment—policy coordination" is key to addressing the challenges of elderly

care for rural empty-nest seniors. This analysis was limited to CNKI data, and future research will incorporate additional databases to provide comprehensive insights into the current landscape of rural empty-nest elderly care.

Disclosure statement

The authors declare no conflict of interest.

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Self-Management Experiences and Challenges in Patients with Metabolic Dysfunction-associated Steatotic Liver Disease: A Qualitative Study Guided by Pender's Health Promotion Model

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Abstract: *Objective*: The study aims to explore experiences of patients with metabolic dysfunction–associated steatotic liver disease (MASLD) in self-management, identify the challenges they encountered and their needs during the self-management process. *Methods*: This qualitative study was conducted at an integrated tertiary hospital between March and May 2025. Semi-structured interviews with 15 participants were analyzed using Colaizzi's seven-step method, and the resulting themes were mapped onto the constructs of the Pender health promotion model (HPM). *Result*: Three themes and nine sub-themes were mapped onto the HPM as challenges and obstacles in the self-management process of patients with MASLD. The themes encompass individual characteristics and negative experiences (personal factors and previous experiences with weight loss and rebound), cognitive and emotional deficits in self-management behaviors (insufficient recognition of the benefits of self-management, lack of interpersonal and situational support, negative emotional impact related to behavior, and low self-efficacy), and temporary needs and compromises with hobbies (unhealthy dietary preferences and long-term dietary habits, behavioral compromises in social situations, and temporary needs conflicting with healthy behaviors). *Conclusion*: Healthcare professionals should comprehensively assess the individual characteristics of patients with MASLD and provide personalized dietary and exercise management tailored to their lifestyle and behavioral preferences, while also paying close attention to their psychological and emotional well-being. Addressing patients' behavioral, psychological, and social needs enhance the feasibility and sustainability of lifestyle changes, thereby promoting more effective and long-term self-management.

Keywords: Metabolic dysfunction–associated steatotic liver disease; Pender health promotion model; Self-management; Lifestyle intervention; Qualitative research; Patient experience

Online publication: Apr 10, 2026

1. Introduction

In 2023, a multi-society consensus statement, spearheaded by the American Association for the Study of Liver Diseases, recommended renaming nonalcoholic fatty liver disease (NAFLD) as metabolic dysfunction–associated steatotic liver disease (MASLD). MASLD is a chronic progressive liver disease whose pathogenesis is closely related to genetics, environment, and metabolic stress. Its main characteristic is the occurrence of fatty degeneration and fat accumulation in liver parenchymal cells in the absence of a history of excessive alcohol consumption [1]. Additionally, at least one metabolic risk factor must be present, including obesity, dyslipidemia, type 2 diabetes, hypertension, and metabolic syndrome [2]. Currently, MASLD has become the predominant cause of chronic liver disease, with a prevalence rate approximately 30% [3]. MASLD is the most common type of chronic liver disease. Still, it has also emerged as the primary cause of abnormal liver biochemical indicators in health check-up populations, presenting a significant public health challenge [4]. The increasing global prevalence and mortality of MASLD, together with escalating healthcare expenditures and reduced health-related quality of life, raise serious concerns [5].

Several guidelines emphasize the significance of targeting lifestyle behavior change in all patients with MASLD, regardless of disease severity [6,7]. Lifestyle intervention remains the first-line treatment for MASLD. Promoting and maintaining healthy behaviors through a balanced diet, regular physical activity, and behavioral modification is crucial to improving overall health [8]. The effectiveness of such interventions relies heavily on patients' capacity for effective self-management [9]. Nonetheless, evidence indicates that the overall self-management status among individuals with MASLD remains suboptimal [10,11]. Existing studies have predominantly focused on the current status of self-management among patients with MASLD and its influencing factors, with limited in-depth exploration of patients' subjective experiences and challenges during the self-management process.

The Pender health promotion model (HPM) provides a systematic theoretical framework for analyzing individual health behaviors, emphasizing that the formation of health behaviors is influenced by three dimensions: individual characteristics and prior experiences (including personal factors and previous related behaviors), behavior-specific cognitive and affective factors (including the perceived benefits of behavior, perceived barriers of behavior, perceived self-efficacy, activity-related affect, and interpersonal and situational influences), and behavioral outcomes (temporary needs and hobbies and commitment action plan). The model has been extensively utilized in the fields of chronic disease management and health behavior intervention research, where it has demonstrated notable effectiveness in enhancing patients' self-management capacity, treatment adherence, and overall quality of life [12–14]. Therefore, this study is based on the HPM and employs a semi-structured, in-depth interview method to explore experiences of patients with metabolic dysfunction–associated steatotic liver disease (MASLD) in self-management, identify the challenges they encountered and their needs during the self-management process.

2. Materials and methods

2.1. Study design

This study adopted a descriptive phenomenological methodology rooted in Husserl's philosophy, which emphasizes returning "to the things themselves" and grounding knowledge in lived experience rather than abstract theorization [15]. By suspending preconceived notions and focusing on participants' narratives, this method

allows for an in-depth understanding of their subjective experiences. This theoretical framework aligns with the objectives of this study, which seeks to capture the authentic lived experiences and challenges encountered by patients with MASLD in the context of self-management. Data is collected through semi-structured interviews, enabling participants to engage in in-depth exploration while allowing them to express their perspectives flexibly and comprehensively. This study was approved by the Ethics Committee of the Affiliated Hospital of Hangzhou Normal University (2025E2-KS-098). All participants provided informed consent before the study.

2.2. Participant selection

Two researchers recruited potential participants from the Hepatology Outpatient Clinic of the Affiliated Hospital of Hangzhou Normal University between March and May 2025. A maximum variation sampling strategy was employed, encompassing diverse genders, ages, educational levels, occupations, and other characteristics, to ensure a comprehensive and rich understanding of the difficulties and obstacles faced by patients with MASLD in self-management.

2.2.1. Inclusion criteria

(1) Individuals aged 18 years or older, possessing adequate comprehension and language expression abilities;
(2) Diagnosed with MASLD according to the Guidelines [7]
(3) Provided informed consent and volunteered to participate in this study

2.2.2. Exclusion criteria

(1) Having hepatitis B or C virus;
(2) Being diagnosed with cirrhosis or hepatocellular carcinoma

2.2.3. Study design

In this study, all patients with MASLD were classified based on liver fat content and fibrosis stage measured by FibroScan. Based on controlled attenuated parameter (CAP) values, hepatic steatosis was categorized into three grades: mild hepatic steatosis: 248–268 dB/m; moderate hepatic steatosis: 269–294 dB/m; severe hepatic steatosis: > 294 dB/m. The degree of hepatic steatosis corresponds to the severity of fatty liver disease.

2.3. Data collection

The hepatologist referred patients with MASLD who met the inclusion criteria from their daily outpatient clinics to the researchers, who then established good relationships with the interviewees. Before the interviews, the researchers explained the purpose, importance, and main questions of the study to the patients to ensure their complete understanding and voluntary participation. After obtaining their consent, H.J. conducted face-to-face semi-structured interviews. The time and location of each interview were mutually agreed upon by the participants and researchers. To ensure a quiet and private environment, all interviews were conducted face-to-face in a hospital conference room. The interviews were conducted using on-site recording, each lasted between 30 to 45 minutes. Data collection persisted until thematic saturation was achieved, characterized as the juncture at which no additional themes, sub-themes, or notable variants surfaced from the data [16]. To protect participant privacy and ensure data authenticity, numerical codes were used in place of names.

The interview outline was developed based on a literature review and the HPM. It was finalized after group

discussions and consultation with a hepatology expert (PhD, with over 20 years of experience in liver disease treatment). The finalized interview outline is:

(1) How did you previously manage your MASLD?
(2) What benefits do you see in self-management behaviors such as controlling your diet and increasing physical activity? What difficulties or obstacles have you encountered during the self-management process?
(3) In the process of self-management, how have your family and friends supported or influenced you?
(4) How does your living environment influence your self-management behaviors?
(5) What feelings and experiences arise during the process of self-management? How does it impact your health behaviors?
(6) How confident are you in your ability to consistently and effectively practice self-management?
(7) In daily life, what temporary needs or personal preferences influence your self-management behaviors?
(8) Regarding managing MASLD, in which aspects would you most like to make further progress or changes?

2.4. Data collation and analysis

Interview data were transcribed verbatim within 24 hours and double-coded by two independent researchers to ensure reliability and accuracy. This study utilized NVivo 15.0 software and applied Colaizzi's seven-step analysis method to analyze the interview data [17]. First, two researchers carefully read and repeatedly reviewed the interview transcripts to gain a comprehensive understanding of the participants' narratives. Second, the interview transcripts were imported into NVivo software, which was used to conduct a verbatim analysis of the data to identify and extract important and meaningful statements related to participants' self-management experiences. One researcher extracts meaningful statements relevant to the theme, while the other researcher verifies them. Third, one researcher codes the statements that appear repeatedly. Fourth, two researchers categorize the codes with common characteristics to form themes. At this stage, three themes and nine subthemes were identified. Fifth, the identified themes were continuously compared against the original data to ensure that they accurately reflected the participants' experiences. Sixth, the fundamental structure of participants' self-management experiences were described through interpretations of themes, thematic clusters, and participant quotes. Finally, the findings were returned to participants to verify their accuracy and authenticity. During member checking, participants were informed that the process aimed solely to confirm the correctness of the data and the researchers' interpretation, rather than to introduce new insights or alternative explanations. They were only requested to point out factual inaccuracies or misunderstandings. No modifications were suggested in this study.

2.5. Reflexivity

(1) To ensure study rigor, interviews were conducted by an expert with over ten years of interview experience and a nurse with three years of nursing experience;
(2) Data processing was performed using triangulation, with two researchers independently analyzing and extracting valuable data information to improve the objectivity of data analysis. During the analysis process, the results were compared with the original interviews, and the organized findings were fed back to the patients for verification to ensure the authenticity of the study;
(3) All researchers received systematic training in qualitative research methods, were proficient in interview

techniques, and contributed to the development of the interview guide and the refining of coding results;

(4) This study complied with the Comprehensive Standards for Reporting Qualitative Research guidelines, ensuring dependability and transparency in the procedures of the data collection, analysis, and reporting [18].

3. Result

3.1. Study participant characteristics

This study included 15 participants, ranging in age from 20 to 68 years (mean = 40.4, SD = 15.5). Among them, 66.7% were married. The mean Body Mass Index (BMI) was 28.2 kg/m^2 (SD = 3.3). The duration of MASLD among the participants varied from a diagnosis within the last two months to as long as ten years. **Table 1** illustrates the characteristics of the 15 participants.

Table 1. General information about the study population

Code	Gender	Age	Educational level	Marital status	Career	Duration of MASLD (month)	Severity of MASLD	BMI (kg/m^2)
P1	**Male**	32	Middle school	Married	Self-employed	96	Severe	29.23
P2	Male	40	High school	Unmarried	Skilled worker	84	Moderate	26.03
P3	Male	20	Undergraduate	Unmarried	Student	11	Severe	34.72
P4	Female	55	Primary school	Married	No work	120	Moderate	32.17
P5	Male	22	Undergraduate	Unmarried	Student	14	Mild	24.80
P6	Female	50	Middle school	Married	Self-employed	96	Severe	27.93
P7	Female	25	Junior college	Unmarried	Office worker	3	Mild	25.15
P8	Male	61	Undergraduate	Married	Teacher	17	Moderate	25.81
P9	Male	47	High school	Married	Office worker	120	Severe	28.09
P10	Male	58	Primary school	Married	No work	13	Moderate	27.05
P11	Male	38	High school	Married	Self-employed	24	Moderate	26.12
P12	Female	39	Junior college	Married	Self-employed	12	Moderate	25.06
P13	Male	68	Primary school	Married	Retired	7	Severe	28.96
P14	Male	26	Junior college	Unmarried	Office worker	2	Severe	34.69
P15	Male	25	Junior college	Unmarried	Student	17	Severe	27.60

Abbreviations: kg, kilogram; BMI, Body Mass Index

3.2. Interview data analysis results

Based on the research results, three central themes were identified through data analysis. Researchers summarized three themes and nine sub-themes regarding the difficulties and obstacles these patients face in self-management:

(1) Individual characteristics and negative experiences;

(2) Cognitive and emotional deficits in self-management behaviors;

(3) Temporary needs and compromises with hobbies.

These findings underscore the multifactorial challenges faced by patients with MASLD in terms of self-management.

3.3. Individual characteristics and negative experiences

3.3.1. Personal factors

Individual factors include the patient's gender, age, occupation, educational level, sleep quality, and physiological characteristics, all of which are correlated with participants' self-management capabilities.

P1: "I work as a chef and usually spend about 12 hours a day on the job. I'm so busy that I hardly do any exercise".

P4: "I'm from the countryside and didn't receive much education. We can't acquire seafood like shrimp in the countryside".

P10: "I have synovitis in my legs, so I can't do strenuous exercise".

P11: "I don't do much physical labor. I usually sit while I work".

P14: "I sometimes don't want to exercise when I've had too little sleep".

3.3.2. Previous experiences with weight loss and rebound

Some participants have attempted weight loss through dietary control and exercise, but they commonly experience significant initial results followed by difficulty maintaining the regimen over the long term. Additionally, certain patients encounter weight rebound after initial weight loss, significantly compromising the durability and efficacy of self-management approaches.

P1: "I've been losing weight faster lately, down about five kilograms. At this stage, most of the weight loss is likely water weight".

P5: "I was losing weight in the first half of last year, and I was at my thinnest around November. I tend to consume food excessively and hastily, which has resulted in weight gain once more".

P9: "I lost weight once about ten years ago, dropping ten kilograms. Now I still want to get back to around 80 kilograms".

P15: "I previously participated in a weight loss experiment and lost about ten kilograms, but then I didn't control my diet and gained it all back".

3.4. Cognitive and emotional deficits in self-management behaviors

3.4.1. Insufficient recognition of the benefits of self-management

The HPM posits that patients' perception of positive outcomes from healthy behaviors is beneficial in promoting changes in their health behaviors [19]. This study found that some participants were aware that they had MASLD, but their understanding of the disease was flawed, and they exhibited a deficiency in self-awareness regarding their health.

P1: "I found out I had MASLD eight years ago, but I believed I was merely overweight, so I didn't take it seriously".

P7: "I've had MASLD for two years now. I didn't think it had much impact on my life, so I never bothered to manage it".

P14: "I know how many calories are in food, but I don't usually pay attention to it".

3.4.2. Lack of interpersonal and situational support

Effective social support can alleviate patients' stress responses, improve their perception of their illness, and increase their proactive disease management behaviors [20]. Some participants' families are able to provide them

with familial and situational support.

P3: “My mother supervises me and cooperates with me in terms of diet. She cooks relatively light meals”.

P7: “My family also exercises with me. Two years ago, I bought a treadmill for our home, and my sister runs with me”.

In addition, some participants may lack understanding and support from family members, and their living environment may be devoid of a conducive cultural atmosphere, which could weaken their willingness to self-manage and increase the probability of discontinuing self-management behaviors.

P4: “No one in my family exercises. There is no environment for exercise and no fitness equipment nearby”.

3.4.3. Negative emotional impact related to behavior

The HPM suggests that positive behavioral emotions toward a specific behavior can reinforce behavioral motivation, prompting patients to continue engaging in it. Conversely, negative behavioral emotions can make them more likely to abandon the behavior and even develop avoidance tendencies [21]. In this study, some participants experienced negative emotions such as anxiety, irritability, depression, and resentment during the process of self-management, which in turn diminished their motivation to persist with self-management behaviors.

P1: “I even had depression two years ago. My mental state hasn’t been perfect. I am employed in the restaurant industry; however, if I cease smoking and consuming alcohol, how can I maintain social interactions when I go out?”

P4: “Initially, I kept exercising for a while, but then my family said no one could watch my kids. I was really upset about that”.

P12: “I feel exhausted, and my sleep quality isn’t excellent, which makes me somewhat anxious”.

P14: “If I don’t consume enough carbohydrates on the day I exercise, I feel irritable”.

3.4.4. Low self-efficacy

Patients with higher self-efficacy have greater confidence and perseverance in completing tasks and are more proactive in acquiring disease-related knowledge and participating in their health management [22]. This study revealed that, although some participants were aware of the importance of a nutritious diet and regular exercise, they frequently struggled to adhere to these practices in reality due to insufficient confidence or diminished willpower.

P8: “Sometimes it’s just impossible to stick with it. Many people know about nutrition, but it’s difficult to put it into practice in terms of behavior and attitude”.

P10: “Doctors always tell us how to manage our diet and exercise, but we rarely do it”.

P15: “I know I should eat less and exercise, but I don’t have the confidence to stick with it”.

3.5. Temporary needs and compromises with hobbies

3.5.1. Unhealthy dietary preferences and long-term dietary habits

This study revealed that specific participants, swayed by individual taste preference, long-term unhealthy eating patterns, and familial dietary culture, persistently ingested high-fat, high-salt, or high-sugar foods. This makes it difficult to adhere to nutritionally balanced meal plans, thereby posing a significant obstacle to effective self-management.

P1: “I’m a chef, so the dishes I prepare are usually quite oily. Being from the north, I also tend to use more

salt in my daily diet".

P13: "All of my family members have a strong preference for meat. So when I cook, I just make whatever we feel like eating".

P14: "I usually eat many desserts. I can't maintain a low-sugar diet for a long time".

3.5.2. Behavioral compromises in social situations

During social activities such as holidays, gatherings with friends, and work entertainment, many participants are often influenced by external environments and find it difficult to adhere to their predetermined self-management plans, leading to interruptions or adjustments in their healthy behaviors.

P1: "On New Year's Day, my son wanted to take the family out for barbecue, so I had to go. And when we host friends and guests, I have to join them for food and drinks".

P8: "When you're away on business for a long time, it's difficult to manage your health".

3.5.3. Temporary needs conflicting with healthy behaviors

Due to heavy workloads, frequent family matters, and other temporary demands, some participants are often forced to sacrifice their original healthy lifestyle habits, such as maintaining a balanced diet, exercising regularly, and adhering to a regular sleep schedule.

P2: "When I work the night shift, I usually arrive home after midnight, which makes it tough to wake up in the morning, and I often end up missing breakfast".

P5: "When preparing for exams, I become so busy that I don't feel like exercising. When I'm under a lot of pressure, I want to eat more".

P6: "I planned to exercise in the evenings, but occasionally my son needs help with his homework, which prevents me from doing so".

P7: "Work pressure or work-related issues may interfere with my normal exercise plans".

P9: "Work or children may get in the way, so I really have to sacrifice my time".

4. Discussion

This study aims to utilize the HPM to analyze the difficulties and barriers encountered by patients with MASLD during the process of self-management. All the obstacles identified in this study could be organized and explained according to the three components of the HPM.

4.1. Strengthen personalized management and cognition to improve compliance

Findings from this study indicate that patients with MASLD demonstrate considerable heterogeneity across various dimensions, including occupational type, educational level, family and social background, and physiological status. This is consistent with the present study, in which most participants engaged in sedentary occupations and reported conflicts between their health behaviors and work schedules. Moreover, higher education levels are usually associated with greater risk awareness and a greater emphasis on disease treatment. This finding is consistent with prior research, which further identified marital status, smoking history, and the severity of fatty liver disease as additional factors influencing patients' self-management capacity [23]. This study found that although several participants achieved short-term weight loss through temporary interventions or individual

efforts, these results were frequently unsustainable due to unscientific approaches or limited disease-related knowledge, sometimes even leading to weight rebound. Such setbacks negatively influenced patients' motivation and compliance with following self-management practices. These findings correspond with previous research, which has identified insufficient knowledge and limited awareness of MASLD as key factors contributing to patients' difficulty in achieving and maintaining successful weight loss [24,25]. During the interviews, certain patients exhibited a deficiency in comprehension concerning their situation and self-management strategies. In alignment with other studies, patients reported that the self-management guidance provided by healthcare professionals was perceived as overly general and insufficiently tailored to their needs [26]. The HPM emphasizes the importance of individual characteristics and prior experiences in shaping health behaviors, suggesting that effective self-management support must be tailored to patients' lifestyles, disease awareness, and past experiences [21]. In practice, healthcare professionals should assess patients' behavioral characteristics and individual factors, develop personalized management plans, and establish interactive feedback mechanisms to optimize interventions. Combining health education with motivational interviewing can help identify reasons for past failures and provide targeted support [27].

4.2. Provide emotional and social support to enhance behavioral motivation

The findings show that social support from family, friends, and the living environment influences self-management in patients with MASLD. This result is in accordance with previous studies [28]. Supportive relationships facilitate behavior maintenance, whereas a lack of support or negative environments can reduce motivation, with family involvement additionally helping to alleviate negative emotions and promote disease awareness [29]. Numerous participants indicated that although they possessed fundamental health knowledge and recognized the positive significance of lifestyle changes for MASLD management, they generally lacked confidence and experienced wavering willpower, primarily stemming from insufficient self-efficacy. This aligns with prior research [30,31]. Disease severity further shapes self-management experiences: patients with mild MASLD often show limited risk awareness and undervalue long-term management, while those with moderate to severe disease are more prone to negative emotions such as anxiety and irritability. Consequently, the severity of the disease may influence patients' emotional conditions, risk perception, and adherence to self-management behaviors. These findings align with other research [32,33]. Moreover, previous research indicated a substantial correlation between severe hepatic steatosis and mood problems, including anxiety [34]. Evidence also suggests a bidirectional relationship between MASLD and mental health, whereby MASLD may elevate the risk of depression and anxiety, and psychological well-being may, in turn, influence disease progression and behavioral management [35]. According to the HPM, interventions should target behaviors patients can control independently, as confidence in goal achievability strengthens self-efficacy and promotes sustained behavior change [13]. Strategies include setting incremental goals, providing visual feedback, integrated shared decision-making, collaborative meal planning, creating home exercise corners, leveraging peer role models, and emphasizing positive behaviors. Ongoing self-management can be further improved by the implementation of reward mechanisms, consensus on healthy routines, and emotional support from healthcare professionals and family.

4.3. Guiding the adjustment of temporary needs to promote continuous self-management

Through the interviews, we found that the majority of participants were frequently distracted by immediate needs such as dietary temptations, social engagements, work pressure, and mood fluctuations during the process of

self-management. These distractions frequently resulted in disruptions to food compliance, regular exercise, and sleep management. Such temporary needs typically arise from the pursuit of instant gratification or psychological comfort, which may undermine patients' commitment to long-term health goals. This discovery is consistent with prior research, which has demonstrated that patients' temporary requirements, long-standing unhealthy dietary patterns, and diverse cultural backgrounds pose significant obstacles to self-management [36]. Future interventions should balance patients' life contexts with behavioral priorities through individualized assessments that identify high-risk situations and inform tailored coping strategies. Techniques such as dietary adjustments, behavioral substitution, and interest diversion can help align immediate preferences with long-term health goals. Co-creating self-management plans with patients enhances participation, strengthens intrinsic motivation, and supports the sustainability of healthy behaviors.

5. Conclusion

Guided by the HPM, the present study employed qualitative interviews to examine the specific challenges that patients with MASLD face during the self-management process. To address these challenges, future interventions should focus on identifying behavioral triggers, aligning healthy behaviors with lifestyle preferences, and stimulating patients' subjective motivation. Strengthening doctor-patient collaboration, optimizing social and family support systems, and incorporating digital health tools may further improve the sustainability of healthy behaviors and open new avenues for MASLD management. Additionally, integrating the perspectives of family caregivers and healthcare professionals could provide a more comprehensive understanding of patient needs and barriers. Finally, stratified analyses based on disease severity may offer valuable insights for designing stage-specific, targeted interventions that support long-term lifestyle modification and overall disease management.

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Disclosure statement

The authors declare no conflict of interest.

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Implementation Path and Effect Evaluation of Health Education in Pediatric Nephrology Nursing

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Abstract: *Objective*: To explore the scientific implementation path of health education in pediatric nephrology nursing and evaluate its impact on children's rehabilitation and parents' nursing ability. *Methods*: A total of 80 children with pediatric nephropathy admitted to our hospital from January 2023 to December 2024 were randomly divided into an experimental group and a control group, with 40 cases in each group. The control group received routine health education, while the experimental group implemented a systematic health education path of "admission assessment–phased education–discharge guidance–follow-up reinforcement". The parents' mastery of nursing knowledge, children's treatment compliance, and disease recurrence rate were compared between the two groups. *Results*: The parents' nursing knowledge score in the experimental group (89.6 ± 5.3) was significantly higher than that in the control group (67.2 ± 7.1). The children's treatment compliance rate in the experimental group was 95.0%, which was higher than 72.5% in the control group, and the recurrence rate was 7.5%, which was lower than 25.0% in the control group. All differences were statistically significant ($p < 0.05$). *Conclusion*: The systematic health education path can improve parents' nursing ability, enhance children's treatment compliance, and reduce the risk of disease recurrence, which is worthy of clinical promotion.

Keywords: Pediatric nephropathy; Health education; Implementation path; Effect evaluation; Treatment compliance

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1. Introduction

Pediatric nephropathy is characterized by a long course, high recurrence rate, and complex treatment, such as nephrotic syndrome and glomerulonephritis, which seriously threaten children's physical and mental health. Due to the children's young age and insufficient cognitive ability, the effect of treatment and nursing is highly dependent on the cooperation of parents. Clinical practice has found that most parents lack professional knowledge of nephropathy nursing and have misunderstandings in diet management, medication supervision, etc., leading to poor treatment compliance and repeated illness in children. Traditional health education is single in form and scattered in content, with limited effect. Therefore, constructing a scientific implementation path of health

education and strengthening parents' nursing ability are crucial to improving the prognosis of children. This study took 80 children as subjects to explore the application effect of systematic health education, providing a basis for clinical nursing.

2. Research data and methods

2.1. General information

A total of 80 children with pediatric nephropathy admitted to the Department of Pediatric Nephrology of our hospital from January 2023 to December 2024 were selected.

2.1.1. Inclusion criteria

Meeting the diagnostic criteria for pediatric nephropathy in "Nephrology", course of disease ≥ 1 month, parents' informed consent and cooperation with the study;

2.1.2. Exclusion criteria

Complicated with severe cardiopulmonary, hepatic and renal diseases, neurological disorders, and inability to complete follow-up.

2.1.3. Study group

They were divided into two groups with 40 cases each by random number table method. In the control group, there were 23 males and 17 females, aged 3–12 years, with an average of (7.5 ± 2.3) years, including 22 cases of nephrotic syndrome and 18 cases of nephritic nephropathy; In the experimental group, there were 21 males and 19 females, aged 3–13 years, with an average of (7.8 ± 2.1) years, including 20 cases of nephrotic syndrome and 20 cases of nephritic nephropathy. There were no statistically significant differences in gender, age, condition and other data between the two groups ($p > 0.05$), which were comparable.

2.2. Experimental methods

In order to ensure the scientificity and comparability of the study, the two groups adopted different health education modes on the basis of the same standardized drug treatment and routine nursing. The control group implemented the traditional routine health education mode, which was relatively simple and extensive. Specifically, after the child was admitted to the hospital, the responsible nurse would conduct a brief verbal explanation to the parents within 1–2 days, mainly involving the basic ward system (such as visiting time, ward hygiene requirements, safety precautions, etc.), the general concept of pediatric nephropathy, common clinical symptoms and the general direction of treatment. At the time of discharge, the nurse would briefly inform the parents of the key points of the child's diet (such as "eat less salt and light food") and medication (such as "take medicine on time"), and distribute a general health education manual printed uniformly by the hospital. The manual mainly includes the basic knowledge of pediatric nephropathy, common nursing problems and simple solutions, but there is no personalized content for each child. After the child is discharged, there is no special follow-up and reinforcement measure for health education, and only the parents are reminded to bring the child to the hospital for re-examination on time according to the doctor's advice. The experimental group adopted a systematic, whole-process and personalized health education path, which was carefully designed and strictly implemented around the four core links of

"admission assessment–phased education–discharge guidance–follow-up reinforcement", forming a closed-loop management of health education. The specific implementation details are as follows:

(1) Admission assessment

Within 24 hours after the child is admitted to the hospital, the responsible nurse with rich clinical experience and good communication skills is responsible for conducting a comprehensive and detailed assessment. The assessment content includes two aspects: the child's side and the parent's side. For the child, the nurse mainly understands the specific type of nephropathy, the course of the disease, the current clinical symptoms (such as edema, urine changes), the results of relevant examinations (such as urine routine, blood biochemistry), the child's age, personality characteristics, living habits and the degree of fear of treatment. For parents, the nurse focuses on understanding their educational level, occupation, daily care time for the child, the existing knowledge of pediatric nephropathy nursing (through a self-made preliminary questionnaire), cognitive needs (such as which aspects of nursing they want to know most), and even the family's economic situation (to provide reference for formulating a cost-effective diet plan). Based on the assessment results, the nurse establishes a personalized health education file for each child, clearly records the key points of education and the focus of guidance, and lays a foundation for the subsequent phased education.

(2) Phased education

This link is carried out throughout the child's hospitalization period, and is divided into three stages: early, middle and late, with different educational focuses. In the early stage of hospitalization (1–3 days), the focus is on alleviating the parents' anxiety and popularizing the basic knowledge of the disease. The nurse uses easy-to-understand language to explain the etiology, pathogenesis, clinical manifestations and treatment principles of the child's specific type of nephropathy to the parents, and answers the parents' doubts one by one to eliminate their misunderstandings about the disease. In the middle stage of hospitalization (4–7 days), the focus is on in-depth explanation of key nursing knowledge and skills. The nurse carries out centralized lectures twice a week, with each lecture lasting about 40 minutes. The lecture content covers diet management (detailed explanation of low-salt and high-quality protein intake standards, such as how much salt to eat per day, which foods are high-quality protein and their appropriate intake, and which foods should be avoided), medication norms (detailed introduction of the type, dosage, administration time, action mechanism of the drugs used by the child, especially the observation of the side effects of hormone drugs and coping methods), and complication prevention (such as how to prevent infection, skin damage caused by edema, etc.). In addition to centralized lectures, the nurse also conducts one-on-one targeted demonstrations for parents, such as teaching parents how to accurately measure the child's urine volume, how to observe the color and properties of urine, how to do skin care for edematous children, and how to take the child's body temperature and blood pressure correctly. For the child, the nurse uses vivid and interesting animations, picture books and cartoon videos to popularize the relevant knowledge of the disease and treatment, and through interactive games, alleviate the child's fear of injection, medication and examination, and improve the child's initiative to cooperate with treatment. In the late stage of hospitalization (1–2 days before discharge), the focus is on reviewing and consolidating the nursing knowledge and skills learned by the parents, and checking the mastery of the key points through on-site questions and return demonstrations.

(3) Discharge guidance

Before discharge, the nurse formulates a personalized discharge guidance plan based on the child's recovery and the results of the phased education assessment. The core content includes customizing a detailed diet recipe (combining the child's taste preferences and family economic conditions, specifying the types and amounts of three meals a day, snacks and fruits), formulating a detailed medication schedule (making a medication reminder card with the drug name, dosage, administration time and precautions, and reminding parents to set a mobile phone reminder), and demonstrating the key points of home nursing operations again (such as urine output monitoring, edema care, infection prevention). At the same time, the nurse informs the parents of the signs of disease recurrence (such as sudden deteriorate of edema, significant reduction of urine volume, abnormal urine color) and the emergency treatment measures, and leaves the contact information of the responsible nurse and the department, so that the parents can consult in time when encountering problems.

(4) Follow-up reinforcement

This link is the extension of in-hospital health education and the key to ensuring the long-term effect of nursing. The nurse establishes a WeChat group for the parents of the children in the experimental group, and arranges a special nurse to be responsible for daily management. The nurse pushes a piece of targeted nursing knowledge every week (such as nursing points in different seasons, dietary adjustments during the child's recovery period, etc.), and releases the latest information about pediatric nephropathy treatment and nursing. Every month, the nurse conducts a telephone follow-up for each child, inquiring about the child's medication compliance, diet implementation, physical condition (such as whether there is edema, abnormal urine), and the parents' nursing problems in the process of home care, and gives timely answers and guidance. Every 3 months when the child comes to the hospital for re-examination, the nurse conducts a face-to-face health education effect evaluation, uses the self-made nursing knowledge questionnaire to test the parents again, understands the implementation of home nursing, and provides supplementary guidance for the existing problems, so as to ensure the continuity and effectiveness of health education. Throughout the implementation of the entire health education path, the head nurse of the department conducts regular supervision and inspection every week, checks the completion of the health education file, listens to the feedback of parents and nurses, and adjusts and optimizes the education plan in time to ensure the quality of health education.

2.3. Observation indicators

(1) Parents' mastery of nursing knowledge

A self-made questionnaire was used for evaluation at discharge, covering 6 dimensions including nephropathy knowledge, diet nursing, and medication nursing, with a full score of 100 points, and ≥ 80 points as qualified.

(2) Children's treatment compliance

Evaluated through outpatient follow-up and parents' feedback. Children who can take medicine on time, cooperate with re-examination, and follow dietary requirements are fully compliant; those who partially do so are partially compliant; those who cannot do so at all are non-compliant. Compliance rate = (number of fully compliant + partially compliant cases) / total number of cases × 100%.

(3) Disease recurrence rate

During 6 months of follow-up, count the number of children with aggravated symptoms due to improper

nursing or treatment interruption and the recurrence rate.

2.4. Research statistics

SPSS 26.0 statistical software was used to process the data. Measurement data were expressed as ($\overline{x} \pm s$), and inter-group comparison was performed by *t*-test; Count data were expressed as rate (%), and χ^2 test was used. $p < 0.05$ was considered statistically significant. This study was approved by the hospital ethics committee, and all children's parents signed informed consent forms.

3. Results

There were statistically significant differences in parents' mastery of nursing knowledge, children's treatment compliance, and disease recurrence rate between the two groups ($p < 0.05$), as shown in **Table 1**.

Table 1. Comparison of parents' mastery of nursing knowledge, children's treatment compliance and disease recurrence rate between the two groups

Group	Number of cases	Parents' nursing knowledge score (points, $\overline{x} \pm s$)	Treatment compliance rate (%)	Recurrence rate (%)
Experimental group	40	89.6 ± 5.3	95.0 (38/40)	7.5 (3/40)
Control group	40	67.2 ± 7.1	72.5 (29/40)	25.0 (10/40)
t/χ^2 Value	-	17.236	6.461	4.501
p Value	-	< 0.001	0.011	0.034

Note: Compared with the control group, $p < 0.05$

4. Discussion

This study provides robust evidence for the clinical value of the systematic health education path in pediatric nephrology nursing. Specifically, compared with the control group, parents in the experimental group demonstrated significantly higher scores in nursing knowledge assessment, children exhibited better treatment compliance, and the overall disease recurrence rate was notably lower. These findings fully confirm that the systematic health education path can effectively address the inherent deficiencies of the traditional health education model and substantially enhance the quality of pediatric nephrology nursing services.

The core contradiction in pediatric nephrology nursing lies in the mismatch between the "highly professional nursing needs" of the disease and the "insufficient cognitive and nursing abilities" of children and their parents. As the main force of family nursing, parents' abilities directly determine the nursing effect. However, the traditional health education, characterized by "one-way indoctrination and one-size-fits-all", results in vague content and disconnection between in-hospital and out-of-hospital education, leading to parents' unclear mastery of key nursing knowledge. This is precisely the main reason for the high recurrence rate in the control group [1].

In contrast, the systematic health education path developed for the experimental group precisely targets and resolves this core issue, with its advantages manifested in three key aspects. Firstly, personalized design based on admission assessment: by comprehensively evaluating the child's condition and the parents' cognitive needs, the education program avoids the blindness of a uniform approach, ensuring that the content is more aligned

with the actual needs of each family [2]. For instance, for parents with lower educational attainment, nurses utilize more intuitive demonstrations and simplified language, while for busy working parents, the focus is placed on teaching efficient nursing methods and setting up convenient reminders, thereby significantly improving parents' acceptance and mastery of nursing knowledge. Secondly, phased in-hospital education that transforms professional knowledge into actionable skills: unlike the traditional model which merely informs parents of "what to do", the systematic path elaborates on "why it is necessary" and "how to do it well". Through group lectures and one-on-one demonstrations, abstract concepts such as "low-salt and high-quality protein diet" are translated into specific food lists and intake standards, and complex tasks like "urine output monitoring" are broken down into simple, clear operational steps. This not only strengthens parents' confidence in providing nursing care but also ensures the standardization of nursing practices. Thirdly, post-discharge follow-up reinforcement that fills the gap in out-of-hospital nursing management. Given that pediatric nephropathy requires long-term treatment, the duration of out-of-hospital nursing far exceeds that of in-hospital care. The systematic path employs WeChat group knowledge pushes and monthly telephone follow-ups to maintain unobstructed communication between nurses and parents, promptly addressing problems encountered by parents in home nursing and preventing the interruption of health education after discharge [3]. This continuous supervision and guidance ensure the long-term implementation of nursing measures, effectively reducing the risk of disease recurrence caused by improper home care. Additionally, the systematic path also attends to the emotional needs of children, which is another important factor in improving treatment compliance. By using animations, picture books, and interactive games, nurses communicate with children in an accessible manner, alleviating their fear of treatment and helping them recognize that "cooperating with treatment can be a positive experience", thus transforming children from passive recipients to active participants in their care. This benign nursing model featuring "parent-led and child-participated" forms a synergistic force for the child's recovery, which is distinctly superior to the traditional model that focuses solely on parents while neglecting children's emotional states. Furthermore, the head nurse's full-process supervision ensures the quality of the health education implementation, with regular inspections and feedback mechanisms preventing perfunctory execution by individual nurses and guaranteeing strict adherence to each step of the path [4].

Despite these promising results, this study has certain limitations that warrant attention. First, the effective implementation of the systematic health education path imposes high requirements on nurses' comprehensive qualities, including professional knowledge, communication skills, assessment capabilities, and sense of responsibility. Currently, there are variations in the professional competence of nurses across different hospitals, which may affect the large-scale promotion of this path. Therefore, hospitals should strengthen specialized training for pediatric nephrology nurses, with a particular focus on enhancing their health education abilities to provide talent support for the path's popularization. Second, the 6-month follow-up period of this study primarily focuses on the short-term effects of the health education path. Since the treatment and prognosis of pediatric nephropathy are long-term concerns, the long-term impacts of the path on children's growth and development, renal function protection, and quality of life require further observation. In the future, extending the follow-up period to 1–2 years and incorporating additional assessment indicators such as children's growth and development parameters, renal function indices, and family quality of life would enable a more comprehensive evaluation of the path's long-term value. Third, as a single-center study with participants all recruited from our hospital, there may be potential selection bias. The generalization of the research findings to other regions and hospitals of different levels necessitates verification through multi-center, large-sample clinical studies. Additionally, with the advancement of information technology, integrating more intelligent tools into the health education path, such

as developing a dedicated health education APP for pediatric nephropathy with functions including personalized knowledge pushes, medication reminders, online consultations, and data recording, would further improve the convenience and efficiency of health education, providing more robust support for the rehabilitation of children with nephropathy [5].

5. Conclusion

In conclusion, the systematic health education path encompassing "admission assessment–phased education–discharge guidance–follow-up reinforcement" demonstrates significant advantages in enhancing parents' nursing abilities, improving children's treatment compliance, and reducing disease recurrence rates. It not only optimizes the quality of pediatric nephrology nursing but also innovates the nursing service model, establishing a new type of nursing relationship centered on the child and involving family participation. This model aligns with the development trend of modern pediatric nursing and holds important clinical significance and promotion value. It is anticipated that through the popularization and continuous optimization of this path, more children with nephropathy will benefit, and their quality of life and long-term prognosis will be further improved.

Disclosure statement

The authors declare no conflict of interest.

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Development of a Protection Motivation Theory–Based Health Education Program for Patients with Diabetes and Periodontitis

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Abstract: *Background*: Diabetes mellitus (DM) is a metabolic disorder characterized by persistent hyperglycemia, with a prevalence of approximately 11.2% in China that continues to rise. Periodontitis is a microorganism-initiated, multifactorial infectious disease and is regarded as the sixth complication of diabetes. Nearly 90% of individuals with diabetes are affected by periodontitis. The relationship between these two conditions is bidirectional: periodontitis worsens glycemic control, increases insulin resistance, and contributes to the development of diabetic complications, including higher mortality from ischemic heart disease and diabetic nephropathy. Conversely, sustained hyperglycemia, longer disease duration, and inadequate self-management increase the risk of periodontitis. In addition, severe periodontitis and tooth loss impose a substantial social and economic burden. However, oral-health knowledge among diabetic patients remains limited. This study aimed to develop a Protection Motivation Theory (PMT)-based health education program for patients with diabetes and periodontitis. *Objective*: To develop a PMT-based health education program for patients with diabetes and periodontitis and provide a replicable intervention for clinical practice. *Methods*: Guided by PMT, this study used evidence synthesis and Delphi expert consultation. Literature retrieval, screening, quality appraisal, evidence extraction, and grading were conducted to develop a draft program, which was then refined through expert consultation on content, delivery, intervention cycle, and expected outcomes. *Results*: Of 448 records identified, 22 studies were included, yielding 31 best-evidence items. Evidence confirmed the bidirectional relationship between diabetes and periodontitis and the importance of health education in improving glycemic and periodontal outcomes. After two Delphi rounds, the final program included 7 primary and 48 secondary items. Expert participation was 100% in both rounds; the authority coefficient was 0.87; coefficients of variation ranged from 0.10 to 0.25; Kendall's W values were 0.466 and 0.301 ($p < 0.01$), indicating good agreement. *Conclusion*: A structured PMT-based health education program with sound scientific basis and feasibility was developed for patients with diabetes and periodontitis.

Keywords: Diabetes; Periodontitis; Health education; Protection motivation theory; Program development

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1. Introduction

Diabetes mellitus (DM) is a complex metabolic disorder characterized by chronic hyperglycemia. In China, it has become a major public health concern, with a prevalence of approximately 11.2% that continues to rise steadily [1]. Emerging evidence has established a strong bidirectional relationship between diabetes and periodontitis, a multifactorial infectious disease initiated by microbial dysbiosis [2,3]. Periodontitis is now widely recognized as the "sixth complication" of diabetes and affects nearly 90% of individuals diagnosed with DM [4–6].

The interaction between these two conditions forms a vicious cycle. Periodontitis acts as a chronic systemic inflammatory burden that impairs glycemic control, exacerbates insulin resistance, and accelerates the development of diabetic complications [7–9]. It is also associated with increased mortality from ischemic heart disease and diabetic nephropathy [6]. Conversely, the diabetic environment marked by persistent hyperglycemia, prolonged disease duration, and frequently inadequate self-management, significantly increases susceptibility to periodontal tissue breakdown [6]. As a result, progression to severe periodontitis and subsequent tooth loss substantially diminishes patients' quality of life and imposes a considerable socioeconomic burden on both individuals and the healthcare system [10].

Diabetes is one of the major chronic diseases in China and is a metabolic–endocrine disease principally characterized by impaired glucose metabolism [11]. Periodontitis is also one of the most common oral diseases. Chronic periodontitis is an infectious disease initiated by microorganisms and affected by multiple factors [12]. Diabetes is a risk factor for periodontitis; conversely, periodontitis adversely affects glycemic control and promotes the occurrence and progression of diabetic complications [12]. Surveys indicate that the overall prevalence of oral diseases among patients with diabetes is 83.37%. In a screening of 1,613 eligible patients with type 2 diabetes, 80.8% were found to have periodontitis, of whom 21.8% had severe periodontitis [13]. Although periodontitis seriously endangers the health of people with diabetes and imposes substantial personal and social burdens, patients' awareness of the interplay between diabetes and periodontitis is low. Investigations report poor knowledge and application rates of oral-health-related information among diabetic patients, and limited understanding of the diabetes–periodontitis relationship [6]. Periodontitis in diabetic patients is easily overlooked by the public; therefore, targeted health education and guidance are warranted to help patients form correct understanding and improve self-management behaviors to prevent or mitigate periodontitis and improve glycemic control.

2. Theoretical basis

Protection Motivation Theory (PMT) was proposed by Rogers and explains how individuals respond to perceived threats and how attitudes and behaviors change accordingly [14]. PMT posits that when faced with a threat, individuals perform threat appraisal and coping appraisal, generating protection motivation that leads to specific actions [15]. The behavioral process in PMT comprises three parts: sources of information, threat appraisal, and coping appraisal. Sources of information are the internal and external triggers for health behaviors. Threat appraisal includes intrinsic rewards, extrinsic rewards, perceived severity, and perceived vulnerability (susceptibility). Coping appraisal subfactors include response efficacy, self-efficacy, and response costs. Under the PMT framework, interventions should augment positive factors, for example, perceived susceptibility and severity, response efficacy, and self-efficacy, while reducing internal and external rewards and response costs that discourage protective behaviors [16]. Specifically, perceived severity refers to an individual's perception of the

seriousness of a threat; perceived susceptibility denotes how likely the individual thinks they are to be affected; internal rewards are the subjective pleasures from engaging in unhealthy behaviors (for example, reducing blood-glucose monitoring to avoid repeated finger pricks); external rewards are social gains from unhealthy behaviors (such as accepting more food to fit in socially); self-efficacy denotes confidence in one's ability to undertake protective actions; response efficacy denotes perceived benefits of the protective behavior; response costs are the perceived social or economic costs associated with the protective behavior. PMT performs dual appraisals of environment and individual factors to stimulate self-protective motivation and serves as a useful tool for improving individual self-management capacity.

PMT has been widely applied in health promotion and behavior-change interventions and is an established theory for explaining, predicting, and intervening on behaviors. It has been used in HIV prevention, breast cancer screening, smoking cessation, and childhood myopia prevention among other fields. In recent years PMT has also been widely applied to chronic disease prevention and management.

Domestically, PMT has been used in various clinical interventions. For example, Yin Xue-mei applied a PMT-based health education intervention to 32 patients with duodenal ulcer and found that the intervention group showed higher overall adherence and improved daily-life and emotional-management abilities post-treatment [17]. Zhao Xiao-ling et al. applied PMT-guided nursing interventions to older adults with diabetes and demonstrated improved glycemic control and self-care ability [18]. Bai Ya-nan used PMT to guide pelvic-floor muscle training in patients with postpartum urinary incontinence and found significant improvement and neural recovery [19]. Zhao Qing-qing constructed a PMT-based family-support educational model for children with myopia, improving knowledge of proper eye habits and forming correct behavior [20]. However, PMT-based interventions specifically targeting patients with diabetes complicated by periodontitis remain scarce.

Internationally, PMT has been applied in public dental health education, and baseline health-education programs aimed at reducing childhood caries, resulting in decreased periodontal disease and increased oral-care engagement [21]. Sotoudeh et al. found PMT effective in analyzing sailors' skin-cancer preventive behaviors and proposed it as a framework for health-education planning [22]. Sherine Hassan and colleagues [23]. applied PMT to improve foot-care behaviors among diabetic patients, showing that PMT-based education strengthened foot-care adherence by enhancing self-efficacy and perceived severity while reducing perceived barriers. Although there are many international PMT application reports, application of PMT specifically for diabetes with periodontitis is limited [24].

In summary, PMT-based health education positively influences behavior motivation, facilitates behavior change, and strengthens individual beliefs through both personal and environmental mechanisms, offering promising clinical utility. Although PMT has been applied across multiple domains including diabetes and its complications, application to diabetes complicated by periodontitis is lacking. Given the bidirectional relationship and high prevalence of periodontitis among people with diabetes, and the generally suboptimal self-management observed in this population, a PMT-based, theory-driven, targeted intervention program is warranted to enhance motivation for behavior change and improve self-management.

3. Methods

3.1. Formulation of the evidence question

The evidence question for this study was formulated according to the PICO framework: Population (P): patients

with diabetes complicated by periodontitis; Intervention (I): health education; Outcome (O): glycemic and periodontal-related outcome measures.

3.2. Search strategy

Using the "6S" evidence model as guidance, Chinese search terms included "diabetes", "periodontitis", "health education", "health promotion", "blood glucose", "blood glucose management", "glycated hemoglobin", and "oral hygiene". English search terms included "Diabetes Mellitus", "periodontitis", "Health Education", "Community Health Education", "Health Promotion", "Blood Glucose", "blood glucose control", and "oral hygiene". The search targeted clinical guidelines, expert consensus statements, systematic reviews, randomized controlled trials (RCTs), and related studies on health education for patients with diabetes and periodontitis. Databases searched included UpToDate, National Guideline Clearinghouse (NGC), BMJ Best Practice, JBI Evidence-based Health Care database, SIGN, NICE, RNAO, PubMed, Ovid, Web of Science, Embase, Cochrane Library, VIP, Wanfang, and CNKI [25]. Both subject headings and free-text terms were used and adapted per database. The search window extended from database inception to January 1, 2025.

3.3. Inclusion and exclusion criteria

3.3.1. Inclusion criteria

(1) Study population
Patients with diabetes complicated by periodontitis, or patients with diabetes;
(2) Study content
Health-education interventions addressing oral health in patients with diabetes (not restricted to periodontal disease);
(3) Study types
Clinical guidelines, expert consensus statements, clinical decision documents, systematic reviews, and randomized controlled trials;
(4) Language
Chinese or English.

3.3.2. Exclusion criteria

(1) Duplicate publications or documents superseded by later updates;
(2) Studies with incomplete information or for which the full text was not obtainable;
(3) Documents rated Grade C in the methodological quality assessment.

3.4. Literature quality assessment

3.4.1. RCT appraisal tool

The methodological quality of included randomized controlled trials was independently assessed by two reviewers using the Joanna Briggs Institute (JBI) RCT appraisal instrument (2016 edition). The tool contains 10 items that evaluate aspects such as the randomization process, allocation concealment, blinding of participants and outcome assessors, and handling of follow-up data [25]. Trials with low risk of bias were rated Grade A; those with moderate risk were rated Grade B; trials with high risk of bias were rated Grade C. Grade-C studies were excluded.

3.4.2. Guideline appraisal tool

Clinical practice guidelines were assessed using the AGREE II instrument, which includes 23 items in six domains and two overall assessment items, each scored from 1 to 7 [26]. Domain scores were calculated independently, and standardized scores were computed as: (obtained score − minimum score) / (maximum score − minimum score) × 100%. Recommendations were then determined based on the six domain scores [26].

3.4.3. Systematic review appraisal tool

The methodological quality of included systematic reviews was independently assessed by two reviewers using the JBI systematic review appraisal checklist (2016 edition). Discrepancies were resolved through discussion with a third reviewer. The checklist comprises 11 items addressing clarity of the review question, comprehensiveness of the search strategy, rigor of data analysis, and related domains.

3.4.4. Expert-consensus appraisal tool

Included expert consensus statements were independently evaluated by two reviewers using the JBI expert consensus appraisal instrument (2016 edition). Any disagreements were resolved via discussion with a third reviewer. The appraisal tool contains eight items covering clarity of purpose, declaration of conflicts of interest, the evidentiary basis, the consensus-development process, and the clarity and feasibility of recommendations [27].

3.4.5. Clinical decision document appraisal

The quality assessment of clinical decision documents was conducted by tracing each recommendation back to its original source documents and appraising those original documents according to their respective study types.

3.5. Appraisal procedure

Two reviewers independently performed all quality assessments. Where disagreements arose, a third reviewer was consulted and consensus was reached by discussion. When conclusions from different evidence sources conflicted, inclusion and interpretation followed a hierarchy that prioritized higher-quality evidence, evidence-based documents, clinical guidelines, and, where applicable, the most recently published literature.

3.6. Evidence extraction and grading

A nursing postgraduate synthesized evidence on oral-health education for patients with diabetes [28]. Consistent and complementary evidence was integrated, independent evidence retained, and conflicting evidence resolved by prioritizing recent, high-quality sources. Evidence was graded using the JBI 2014 system, and recommendations were classified as Grade A or B [29].

3.7. Determination of expert-consultation questionnaire content

3.7.1. Literature retrieval

Following an evidence-based nursing workflow, formulating the evidence question, developing the search strategy, setting inclusion/exclusion criteria, conducting quality appraisal, and extracting and integrating evidence, the study team prepared a draft outline for a PMT-based health-education program for patients with diabetes and periodontitis.

3.7.2. Draft development

An initial PMT-based health-education program was developed with two primary dimensions, threat appraisal and coping appraisal and seven secondary indicators: perceived severity, perceived susceptibility, internal rewards, external rewards, self-efficacy, response efficacy, and response cost. The tertiary indicators addressed risk awareness, behavior correction, family support, self-management benefits, confidence building, and barrier reduction. The draft program was then discussed and revised by the research team to finalize the questionnaire content.

3.8. Implementation of expert consultation

3.8.1. Expert inclusion criteria

Experts were eligible if they met all of the following criteria:

(1) ≥ 10 years of clinical practice and/or nursing experience in diabetes and/or oral health;
(2) Familiarity with nursing and treatment relevant to diabetes complicated by periodontitis;
(3) Bachelor's degree or higher and associate senior professional title or above;
(4) High willingness to participate and voluntary engagement in this study.

3.8.2. Questionnaire development

The expert consultation (Delphi) questionnaire comprised three parts: a preface, an expert basic-information form, and the main questionnaire body [30].

(1) Preface

The questionnaire opened with a greeting, thanks, a brief introduction to the study purpose, and the return deadline. Contact information was provided for expert feedback.

(2) Expert information form

This section collected demographic data and assessed expert authority based on familiarity and judgment basis. Familiarity was rated on a 5-point Likert scale, and judgment basis included practice experience, theoretical basis, literature, and subjective judgment.

(3) Main questionnaire

Experts rated the importance of each item on a 5-point Likert scale and evaluated its relevance and wording, with space provided for suggestions on revision or deletion [16].

3.8.3. Consultation implementation

(1) Consultation timeframe

The consultation mode followed experts' preferred contact methods. A combination of e-mail and paper questionnaires was used, and questionnaires were collected within a predetermined period. To avoid memory effects, an interval of four weeks was maintained between successive rounds [31].

(2) Consultation method

A back-to-back (iterative Delphi) approach was adopted. After Round 1, experts' basic information plus item ratings and comments were collated and discussed. Criteria for retaining items were: coefficient of variation (CV) < 0.25, mean score (Mean) > 3.5, and full-score rate > 20%. Items meeting all three criteria were retained; items meeting at least one criterion were discussed by the research team to decide whether to retain; items satisfying none of the criteria were deleted. Based on these decisions, the Round-2

questionnaire was prepared. The first part of Round 2 presented a summary of Round-1 modifications for experts' reference; the second part listed the revised items and requested re-rating and further comments. This process was repeated for 2–4 rounds until expert opinion converged [32].

3.9. Result analysis

Data were analyzed using Excel and SPSS 24.0 with double entry and verification. Two researchers independently entered the data, and 20% of questionnaires were randomly checked for accuracy. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequency and percentage. Expert engagement was evaluated by response and suggestion rates; a response rate > 70% indicated good engagement. Expert authority was assessed by Cr = (Ca + Cs) / 2, with Cr > 0.8 indicating high authority.

4. Results

4.1. Literature analysis results

4.1.1. Literature screening results

The initial search retrieved 448 records. After removing 32 duplicates and screening titles and abstracts, 63 records were excluded; full-text review resulted in the exclusion of a further 256 records. Following methodological quality assessment, 19 low-quality documents were excluded. Ultimately, 22 studies were included, comprising 5 guidelines, 3 expert consensus statements, 2 systematic reviews, and 12 randomized controlled trials. The literature selection flow chart is shown in **Figure 1**. General characteristics of the included studies are presented in **Table 1**.

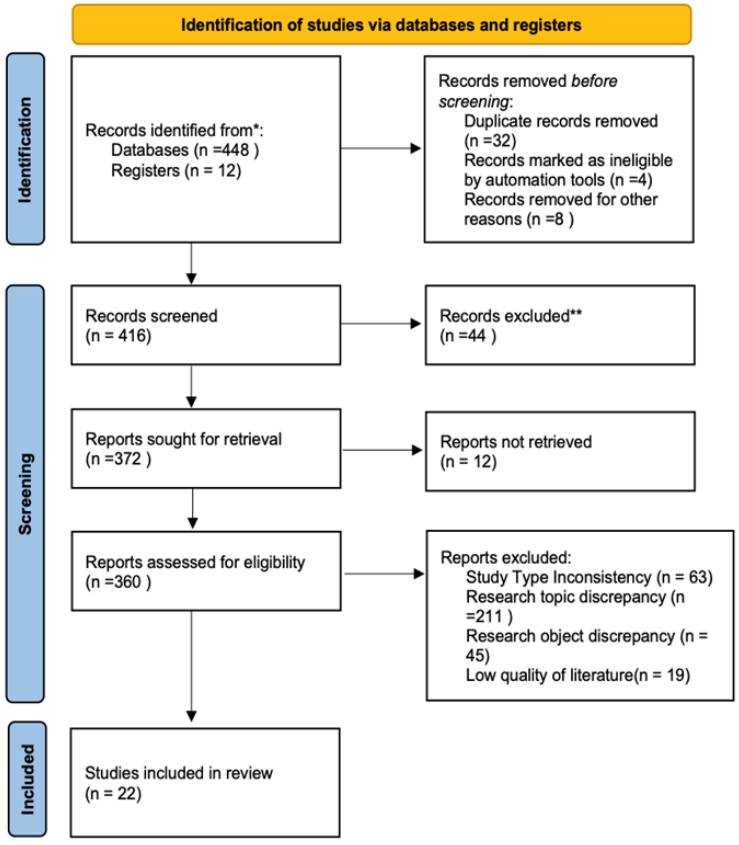


Figure 1. Flow diagram of literature screening and selection.

Table 1. Characteristics of included studies (n = 22)

Included literature	Time of publication (years)	Source of evidence	Type of evidence	Literature topics
German Society of Periodontology et al [33]	2024	National Guide Network	Guidelines	Management of Diabetes and Periodontitis
Sanz et al [34]	2018	National Guide Network	Guidelines	Scientific evidence on the links between periodontal diseases and diabetes
Scottish Dental Clinical Effectiveness Programme [35]	2024	PubMed	Guidelines	Prevention and treatment of periodontal diseases in primary care
Public Health England	2020	PubMed	Guidelines	Guidelines for oral health education
Department of Health and Social Care Welsh Government Department of Health Northern Ireland Public Health England NHS England [36]	2021	PubMed	Guidelines	In Delivering better oral health: An evidence-based toolkit for prevention
Dale et al [37]	2014	PubMed	Expert consensus	Oral management of diabetes
Ternois et al [38]	2017	PubMed	Expert consensus	Oral management of diabetes
Periodontology Committee of Chinese Stomatological Association [39]	2017	Wanfang database	Expert consensus	Nursing care of periodontitis
Gurav et al [40]	2016	PubMed	Systematic Review	Management of Diabetes and Periodontitis
Petropoulou et al [41]	2024	PubMed	Systematic Review	Health education of diabetic oral cavity
Saruta et al [42]	2014	PubMed	RCT	Effectiveness of lifestyle change plus dental care program on improving glycemic and periodontal status in the elderly with type 2 diabetes
Zhang et al [43]	2025	PubMed	RCT	Community interventions improve diabetes management and oral health in type 2 diabetes patients with chronic periodontitis
Sun Linlin et al [44]	2007	CNKI	RCT	Oral education for diabetic patients with periodontitis
Yang Xiaohui et al [45]	2017	CNKI	RCT	Health education for patients with diabetes mellitus and periodontitis
Tang Chao et al [46]	2018	Wanfang Data	RCT	Health education for patients with diabetes mellitus and periodontitis
Gong Deai et al [47]	2018	Wanfang Data	RCT	Health education for patients with diabetes mellitus and periodontitis
Qi Fengwei et al [48]	2018	Wanfang Data	RCT	Oral education in elderly patients with diabetes mellitus and periodontitis
Xu Ya et al [49]	2019	CNKI	RCT	Oral education for elderly patients with diabetes mellitus and periodontitis
Huang Qian et al [50]	2019	Wanfang Data	RCT	Oral education for elderly patients with diabetes mellitus and periodontitis
Niu Feng et al [51]	2020	CNKI	RCT	Health education for patients with diabetes mellitus and periodontitis
Lai Qizhi et al [52]	2023	Wanfang Data	RCT	Health education for diabetes mellitus with periodontitis
Liu Jingfang et al [53]	2024	Wanfang Data	RCT	Oral education in elderly patients with diabetes mellitus and periodontitis

4.2. Expert consultation

4.2.1. General characteristics of consulted experts

Fourteen experts took part in the two-round consultation; they were drawn from departments of endocrinology and stomatology. All 14 experts were female (100%). The largest group had 20–29 years of work experience (42.86%), followed by 10–19 years (28.57%) and ≥ 30 years (28.57%). All experts held a bachelor's degree or higher, with 42.86% holding a master's degree. Associate chief nurses accounted for 57.14% of the panel.

4.2.2. Expert positive coefficient (response rate)

Two rounds of expert consultations were conducted in this study. In the first round, 14 questionnaires were distributed and 14 were recovered, resulting in a response rate (positive coefficient) of 100.00%, with 71.43% of the experts providing additional suggestions. In the second round, 14 questionnaires were distributed and 14 were recovered, with a response rate of 100.00%. The effective recovery rates for both rounds were above 70%, indicating a high level of enthusiasm and engagement among the experts.

4.2.3. Expert authority coefficient (Cr)

The results of the consultation are considered reliable when the expert authority coefficient (Cr) is ≥ 0.7. In this study, the individual authority coefficients of the 14 experts ranged from 0.75 to 1.00, with an average authority coefficient of 0.87 for the expert panel. This indicates a high degree of authority among the participating experts.

4.2.4. Degree of coordination of expert opinions

The degree of coordination was measured using the Coefficient of Variation (CV) and Kendall's Coordination Coefficient (Kendall's WW). The CVCV values ranged from 0.1 to 0.3, and the Kendall's WW was 0.466 ($p < 0.01$). These results indicate a good degree of coordination among expert opinions and high consistency in the experts' evaluations of the indicators within the program.

4.3. The final version of health education program for patients with diabetes and periodontitis based on protection motivation theory

Following two rounds of expert consultation, the final version of the program was established. It consists of 7 first-level indicators and 48 second-level indicators. The detailed content is presented in **Table 2**.

Table 2. Final version of the health education program for diabetes with periodontitis based on the protection motivation theory

Intervention theme	Intervention content	Timing	Frequency	Setting
1. Perceived susceptibility	1.1 Explain the bidirectional exacerbation between uncontrolled diabetes and periodontitis. 1.2 Discuss genetic susceptibility to diabetes with periodontitis. 1.3 Use typical cases to illustrate susceptibility. 1.4 Guide patients to read the susceptibility section of the health manual. 1.5 Encourage patients to share daily unhealthy behaviors. 1.6 Analyze the link between unhealthy behaviors and susceptibility. 1.7 Conduct follow-up (phone/online) to reinforce susceptibility-related content.	1st week of admission	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology

Table 2 (Continued)

Intervention theme	Intervention content	Timing	Frequency	Setting
2. Perceived severity	2.1 Explain disease stages, progression, and complications. 2.2 Discuss adverse outcomes and impact on daily life. 2.3 Explain the economic burden and family stress caused by the disease. 2.4 Discuss the psychological burden on the patient and family. 2.5 Guide patients to read the severity section of the manual. 2.6 Provide health education videos on disease severity. 2.7 Lead discussions on the relationship between unhealthy behaviors and adverse outcomes. 2.8 Analyze the severity of unhealthy behaviors. 2.9 Conduct follow-up to reinforce severity-related content.	2nd week post-discharge	1 h Lecture, 30min Peer Discussion, 30min Q&A	Demonstration Room, Department of Endocrinology
3. Internal rewards	3.1 Discuss measures to address poor glycemic and periodontal control caused by unhealthy behaviors (e.g., poor oral hygiene, overeating). 3.2 Encourage patients to describe bad lifestyle habits (e.g., smoking, excessive drinking). 3.3 Provide guidance on how to quit unhealthy habits. 3.4 Guide patients to read the internal rewards section of the manual. 3.5 Explain the hazards of non-standard diabetes management. 3.6 Explain the hazards of improper periodontal care. 3.7 Conduct follow-up to reinforce internal rewards-related content.	3rd–4th week post-discharge	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology
4. External rewards	4.1 Explain the role and importance of family in disease management. 4.2 Guide patients on family caregiving content from the manual. 4.3 Instruct patients on how to educate family members about the disease. 4.4 Teach scientific dietary methods for the whole family. 4.5 Discuss the impact of medical expenses on the family. 4.6 Guide patients and families/friends to watch health education videos at home. 4.7 Conduct follow-up to reinforce external rewards-related content.	5th–6th week post-discharge	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology
5. Self-efficacy	5.1 Explain the positive impact of adopting healthy behaviors. 5.2 Provide guidance on standardized medication use. 5.3 Demonstrate proper periodontal care methods. 5.4 Teach daily blood glucose control methods. 5.5 Educate on scientific and healthy diet. 5.6 Instruct on scientific exercise methods. 5.7 Conduct follow-up to consolidate previous learning.	7th week post-discharge	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology
6. Response efficacy	6.1 Invite peers to share successful experiences in blood glucose control. 6.2 Present positive cases of successful glycemic control. 6.3 Present positive cases of effective periodontal care. 6.4 Explain the effectiveness of good habits in improving diabetes and periodontitis. 6.5 Conduct follow-up to consolidate previous learning.	8th week post-discharge	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology
7. Response costs	7.1 Encourage patients to share difficulties encountered during self-management. 7.2 Provide one-on-one guidance to identify barriers. 7.3 Assist patients in finding solutions to management obstacles. 7.4 Provide emotional and psychological support and affirm healthy behaviors. 7.5 Guide patients on how to utilize community resources effectively. 7.6 Conduct follow-up to consolidate the program content.	9th week post-discharge	1 h Lecture, 30 min Peer Discussion, 30 min Q&A	Demonstration Room, Department of Endocrinology

5. Discussion

5.1. Construction and innovation of an evidence-based integrated health education program

The quality of evidence included in this study exhibited stratified characteristics. Guidelines and certain systematic reviews demonstrated high quality, whereas some randomized controlled trials (RCTs) and lifestyle-related studies were of relatively lower quality. This discrepancy is closely related to the rigor of research design, the authority of evidence sources, and the degree of methodological standardization. High-quality evidence primarily originated from international authoritative guidelines and expert consensuses [34–36, 54]. These documents were typically developed using systematic evidence-based processes, strictly adhering to AGREE II or JBI evaluation criteria, and featured clear clinical question frameworks, comprehensive literature search strategies, standardized evidence grading systems, and transparent descriptions of recommendation strength. Furthermore, the development teams usually possessed multidisciplinary backgrounds with extensive clinical and research experience. The guideline development process often integrated results from multiple high-quality RCTs and systematic reviews, ensuring the scientific validity and stability of the evidence [55,56]. Additionally, guideline-related literature generally maintained high editorial independence and clear conflict-of-interest statements, enhancing the credibility and generalizability of the findings [57]. Consequently, core disease education, basic oral care measures, and multidisciplinary collaborative management were mostly categorized as Grade A (Strong Recommendation).

The innovations of this study are reflected in the following aspects: First, based on systematic retrieval and quality appraisal, fragmented research evidence was integrated and graded to form a structured health education evidence framework with clear hierarchical levels. This shifts clinical practice away from empirical education toward an evidence-based approach. Second, the content construction broke through previous single-intervention models by systematically integrating multiple dimensions, including disease cognition, oral care, lifestyle, follow-up management, social support, and psychological care, which better meets the comprehensive management needs of patients with the comorbidity of diabetes and periodontitis. Third, it emphasizes the integration of oral health education into the overall diabetes management system, highlighting the importance of synergistic management between oral health and endocrinology, thus providing a specific direction for multidisciplinary cooperation.

In contrast, the reasons for lower evidence quality mainly focused on: First, some RCTs had methodological limitations, such as small sample sizes, lack of blinding, inadequate allocation concealment, and insufficient reporting of baseline comparability. Although their results reached statistical significance, the risk of bias remained relatively high. Second, lifestyle intervention studies (e.g., diet, exercise, psychological support) often struggled to control for confounding factors, with significant variations in intervention formats and generally short follow-up periods (mostly 3–6 months), making it difficult to assess long-term effects. Third, some studies were confined to single centers or specific populations (e.g., elderly patients), limiting their representativeness and generalizability. Fourth, some literature was published in journals with lower impact factors, with variations in research design and reporting standards. Furthermore, while some expert consensuses held clinical value, they lacked transparency in conflict-of-interest statements and the level of detail in recommendations, which affected their evidence grade.

5.2. Construction and innovation of the evidence-based health education program

Systematic evidence integration reveals significant deficiencies in the current management of diabetes with periodontitis. Currently, these two conditions are often managed independently by different clinical departments, leading to a lack of integrated care pathways and making it difficult for patients to develop a systemic understanding of their health. Furthermore, health education content remains fragmented, with most studies

focusing on isolated intervention modalities, such as lectures, videos, or toothbrushing instructions, while lacking systematic frameworks and long-term follow-up mechanisms.

Previous research has generally overlooked behavioral change mechanisms; interventions have predominantly focused on knowledge transmission, paying insufficient attention to patients' self-efficacy, motivation formation, and sustained adherence. Additionally, limited sample sizes and short follow-up durations in existing studies hinder the assessment of long-term efficacy. Compared with existing literature, this study further identifies that the core issue lies not only in fragmented intervention methods but also in a profound "cognitive gap" regarding the bidirectional relationship between diabetes and periodontitis. Therefore, merely intensifying knowledge dissemination is insufficient. It is essential to construct a systematic, structured, and theoretically supported intervention program to facilitate the transition from knowledge acquisition to sustained self-management behavior.

5.3. Advantages of protection motivation theory (PMT) in the study program

Previous health education for diabetes with periodontitis has primarily relied on knowledge counseling or skill instruction. While these methods may improve short-term mastery of oral care or glycemic management, the lack of a systematic behavioral change theory often limits the impact to the cognitive level, failing to translate into stable, long-term self-management.

To address this, the present study adopted Protection Motivation Theory (PMT) as the theoretical framework, utilizing threat appraisal and coping appraisal as the core logic of the intervention. In the early stage, the intervention intensified patients' perceptions of susceptibility and severity, specifically how periodontitis affects glycemic control and increases complication risks. During the implementation phase, response efficacy and self-efficacy were enhanced through practical demonstrations, individualized guidance, interactive discussions, and weekly follow-ups. Furthermore, by addressing specific barriers identified through patient feedback, the study successfully reduced the response costs (behavioral execution costs), fostering a proactive management mindset.

In contrast to previous interventions lacking theoretical support, this study integrates evidence-based findings, behavioral theory, and multidisciplinary collaboration. This approach provides the intervention with a clear logical structure and action pathway, avoiding fragmented measures and insufficient mechanistic explanations while enhancing both sustainability and generalizability. This demonstrates that in the management of diabetes with periodontitis, knowledge transmission must be reinforced by behavioral change theories to truly achieve the transformation from cognitive improvement to behavioral maintenance.

6. Conclusion

A structured Protection Motivation Theory–based health education program for patients with diabetes and periodontitis was successfully developed. The program demonstrated a sound scientific basis and feasibility, and it provides a systematic, theory-driven, and clinically applicable framework for improving patients' knowledge, self-management behaviors, glycemic control, and periodontal health. This study offers a replicable reference for clinical health education and integrated management of diabetes with periodontitis.

Disclosure statement

The authors declare no conflict of interest.

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Efficacy of Modified Baihe Dihuang Decoction Combined with Escitalopram in Treating Depression and Its Impact on Serum Levels of 5-HT and ACTH

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Abstract: *Objective*: To evaluate the therapeutic effects of Modified Baihe Dihuang Decoction combined with Escitalopram (ESC) in treating depression. *Methods*: A total of 200 patients with depression admitted to the hospital from May 2023 to May 2025 were selected and randomly divided into two groups using a random number table. The experimental group received combined treatment with Modified Baihe Dihuang Decoction and ESC, while the control group received ESC monotherapy. The therapeutic effects of the two groups were compared. *Results*: The total effective rate of the Hamilton Depression Rating Scale (HAMD) and the total effective rate of traditional Chinese medicine (TCM) syndromes in the experimental group were higher than those in the control group ($p < 0.05$). After 6 weeks of treatment, the cortisol (Cor) level in the experimental group was lower than that in the control group. The HAMD scores after 2, 4, and 6 weeks of treatment were lower in the experimental group than in the control group. The levels of 5-hydroxytryptamine (5-HT), adrenocorticotropic hormone (ACTH), and corticotropin-releasing hormone (CRH) were better in the experimental group than in the control group, and the Treatment Emergent Symptom Scale (TESS) score was lower in the experimental group than in the control group ($p < 0.05$). *Conclusion*: Combined treatment with Modified Baihe Dihuang Decoction and ESC for patients with depression can improve clinical efficacy, alleviate TCM syndromes, reduce depressive symptoms, regulate neurotransmitter and hormone secretion, and exhibit high medication safety.

Keywords: Modified Baihe Dihuang Decoction; Escitalopram; Depression; Serum 5-HT; ACTH

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1. Introduction

Depression is a mental illness characterized by low mood and pessimism, which can have a long-term impact

on patients' physical and mental health and even lead to self-harm or suicidal tendencies. The primary treatment method for this disease is oral administration of Western medications, which can alleviate disease symptoms and reduce the incidence of adverse events [1]. ESC is a first-line antidepressant drug that can regulate neurotransmitter levels, increase 5-HT secretion, and thereby correct depressive states. However, monotherapy with this drug can only achieve relatively good short-term efficacy, with numerous adverse reactions during long-term use and a tendency to develop drug dependence, presenting certain treatment limitations. Traditional Chinese medicine believes that the pathogenesis of depression is related to the nourishment deficiency of the heart and mind as well as heart and lung deficiency. The treatment principles include nourishing the lungs and heart, clearing heat and calming the mind, among others. Modified Baihe Dihuang Decoction can be selected for treatment. Based on this, this study selected 200 patients with depression to evaluate the efficacy of combined treatment with Modified Baihe Dihuang Decoction and ESC.

2. Materials and methods

2.1. General information

A total of 200 patients with depression admitted to the hospital between May 2023 and May 2025 were selected and divided by the random number table method. The experimental group consisted of 100 cases, including 45 males and 55 females, aged 12 to 75 years, with a mean age of (45.68 ± 5.17) years. The TCM syndromes were as follows: 44 cases of liver Qi stagnation, 19 cases of Qi stagnation transforming into fire, 10 cases of Yin deficiency and fire excess, 10 cases of deficiency of both the heart and spleen, 12 cases of internal disturbance of phlegm-heat, and 5 cases of liver depression transforming into fire. The marital status was as follows: 59 married cases, 30 unmarried cases, 5 divorced cases, and 6 widowed cases. The educational levels were as follows: 14 illiterate cases, 14 primary school cases, 26 junior high school cases, 12 senior high school cases, 19 junior college cases, and 15 undergraduate cases. In the control group, there were 36 males and 64 females, aged 15–85 years, with a mean age of (46.84 ± 5.20) years. The TCM syndromes were as follows: 45 cases of liver Qi stagnation, 19 cases of Qi stagnation transforming into fire, 9 cases of Yin deficiency and fire excess, 8 cases of deficiency of both the heart and spleen, 14 cases of internal disturbance of phlegm-heat, and 5 cases of liver depression transforming into fire. The marital status was as follows: 69 married cases, 27 unmarried cases, 2 divorced cases, and 2 widowed cases. The educational levels were as follows: 14 illiterate cases, 11 primary school cases, 22 junior high school cases, 11 senior high school cases, 22 junior college cases, and 20 undergraduate cases. The basic data of the two groups were compared, with $p > 0.05$.

2.1.1. Inclusion criteria

Diagnosed with depression according to the "Expert Consensus on Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment of Depression (2020)" [2]; HAMD score between 20 and 35 points; complete basic data; highly informed about the study.

2.1.2. Exclusion criteria

Presence of eating disorders and other diseases in the past six months; concurrent schizophrenia; suicidal tendencies in the past month; electroconvulsive therapy in the past six months; allergy to the study drugs; presence of cardiovascular or cerebrovascular diseases or metabolic diseases; pregnancy or lactation.

2.2. Methods

The control group received ESC monotherapy: The initial dosage was 5 mg once daily; after one week of medication, the dosage was increased to 10 mg twice daily, and treatment was continued for 4 weeks.

The ESC treatment method in the experimental group was the same as above, combined with Modified Baihe Dihuang Decoction treatment: Granules were selected, and the drug composition was as follows: Baihe (20 g), Yujin (10 g), Shengdihuang (20 g), Chenpi (10 g), Jiangbanxia (5 g), Fushen (10 g), Chaihu (10 g), and Xiangfu (5 g). The granules were dissolved and taken after breakfast and dinner 30 minutes later, with one dose each time, and treatment was continued for 4 weeks.

2.3. Observation indicators

(1) HAMD score

The HAMD includes five categories of factors such as weight loss, cognitive impairment, and anxiety somatization, with a total of 17 items. Each item is scored from 0 to 4 points. A score below 7 indicates no depression, and the degree of depression is positively correlated with the score.

(2) Neurotransmitter and hormone levels

Before and after treatment, 2 mL of fasting venous blood was collected, centrifuged for 10 minutes at a speed of 2500 r/min and a centrifugal radius of 8 r, and the levels of 5-HT, ACTH, Cor, and CRH were evaluated using an automatic biochemical analyzer.

(3) TESS score

Before and after treatment, the TESS scale was used, which includes 33 items such as excitement and agitation, nausea and vomiting, and constipation. Each item is scored from 0 to 4 points, with a total of 132 points. If a single item score is > 2 points, it is judged as having the corresponding adverse reaction. The severity of adverse reactions is positively correlated with the score.

2.4. Efficacy evaluation criteria

HAMD efficacy: Reduction rate = (HAMD score before treatment − HAMD score after treatment) / HAMD score before treatment × 100%. Recovery is defined as a reduction rate of HAMD exceeding 75%; marked improvement as a reduction rate between 50% and 75%; improvement as a reduction rate between 25% and 49%; and no improvement as a reduction rate below 25%.

According to the TCM Syndrome Score Scale, TCM syndrome efficacy is evaluated as follows: Reduction rate = (TCM syndrome score before treatment − TCM syndrome score after treatment) / TCM syndrome score before treatment × 100%. Recovery is defined as a reduction rate of TCM syndrome score exceeding 80%; marked improvement as a reduction rate between 50% and 80%; improvement as a reduction rate between 30% and 49%; and no improvement as a reduction rate below 30%.

2.5. Statistical analysis

The data were processed using SPSS 28.0 software. Measurement data were compared using *t*-tests, and count data were compared using chi-square tests. Statistical significance was defined as $p < 0.05$.

3. Results

3.1. Comparison of HAMD scores between the two groups

At different time points after treatment, the HAMD scores in the experimental group were lower than those in the control group ($p < 0.05$). See **Table 1**.

Table 1. Comparison of HAMD scores between the two groups [$\overline{x} \pm s$, points]

Group	Number of cases	Before treatment	After 2 weeks of treatment	After 4 weeks of treatment	After 6 weeks of treatment
Experimental group	100	29.67 ± 3.22	14.88 ± 2.61	11.06 ± 1.64	10.33 ± 1.26
Reference group	100	29.94 ± 3.15	19.93 ± 2.57	15.87 ± 2.31	12.79 ± 2.05
t		0.599	13.787	16.979	10.223
p		0.550	0.000	0.000	0.000

3.2. Comparison of neurotransmitter and hormone levels between the two groups

After 6 weeks of treatment, the Cor level in the experimental group was lower than that in the control group. At different time points after treatment, the levels of other neurotransmitters and hormones in the experimental group were superior to those in the control group ($p < 0.05$). See **Table 2** and **3**.

Table 2. Comparison of neurotransmitter and hormone levels between the two groups (5-HT and ACTH) [$\overline{x} \pm s$]

Group	Number of cases	5-HT (ng/mL)				ACTH (pmol/L)			
		Before treatment	2 weeks after treatment	4 weeks after treatment	6 weeks after treatment	Before treatment	2 weeks after treatment	4 weeks after treatment	6 weeks after treatment
Experimental group	100	86.54 ± 6.14	89.02 ± 3.34	91.46 ± 3.41	95.12 ± 5.11	8.58 ± 3.86	7.10 ± 1.51	10.56 ± 0.44	10.68 ± 1.32
Reference group	100	86.51 ± 6.10	87.15 ± 3.45	89.41 ± 3.50	91.15 ± 5.06	7.59 ± 3.73	9.68 ± 1.26	10.04 ± 0.51	8.46 ± 1.27
t		0.035	3.894	4.195	5.521	1.844	13.119	7.720	0.035
p		0.972	< 0.001	< 0.001	< 0.001	0.067	< 0.001	< 0.001	0.972

Table 3. Comparison of neurotransmitter and hormone levels between the two groups (Cor and CRH) [$\overline{x} \pm s$]

Group	Number of Cases	Cor (nmol/L)				CRH (pmol/L)			
		Before treatment	2 weeks after treatment	4 weeks after treatment	6 weeks after treatment	Before treatment	2 weeks after treatment	4 weeks after treatment	6 weeks after treatment
Experimental group	100	153.92 ± 15.95	134.48 ± 5.11	121.60 ± 5.36	131.46 ± 4.17	11.07 ± 2.42	9.98 ± 1.58	9.36 ± 1.04	6.65 ± 1.43
Reference group	100	157.37 ± 15.18	133.73 ± 5.40	122.73 ± 5.30	149.12 ± 2.36	10.57 ± 2.55	11.44 ± 1.66	10.92 ± 1.10	10.03 ± 1.68
t		1.567	1.009	1.499	36.857	1.422	6.371	10.305	15.320
p		0.119	0.314	0.135	< 0.001	0.157	< 0.001	< 0.001	< 0.001

3.3. Comparison of TESS scores between the two groups

At different time points after treatment, the TESS scores in the experimental group were all lower than those in the control group ($p < 0.05$). See **Table 4**.

Table 4. Comparison of TESS scores between the two groups [$\overline{x} \pm s$, points]

Group	Number of cases	2 weeks after treatment	4 weeks after treatment	6 weeks after treatment
Experimental group	100	13.65 ± 2.74	14.53 ± 2.85	16.12 ± 2.91
Control group	100	19.22 ± 3.45	20.56 ± 3.74	22.04 ± 3.42
t		12.643	12.824	13.183
p		0.000	0.000	0.000

3.4. Comparison of HAMD therapeutic efficacy between the two groups

The total effective rate of HAMD in the experimental group was higher than that in the control group ($p < 0.05$). See **Table 5**.

Table 5. Comparison of HAMD therapeutic efficacy between the two groups [n/%]

Group	Number of cases	Recovery	Markedly effective	Effective	Ineffective	Total effective
Test group	100	46	34	16	4	96.00% (96/100)
Reference group	100	42	30	16	12	88.00% (88/100)
χ^2						4.348
p						0.037

3.5. Comparison of therapeutic efficacy for TCM syndromes between the two groups

The total effective rate for TCM syndromes in the experimental group was higher than that in the control group ($p < 0.05$). See **Table 6**.

Table 6. Comparison of therapeutic efficacy for TCM syndromes between the two groups [n/%]

Group	Number of cases	Cure	Markedly effective	Effective	Ineffective	Total effective
Experimental group	100	45	38	14	3	97.00 (97/100)
Reference group	100	41	36	13	10	90.00 (90/100)
χ^2						4.031
p						0.045

4. Discussion

The main symptoms of depression include decreased energy, low mood, etc. The continuous progression of the condition can lead to severe symptoms such as delusions and hallucinations, thereby reducing the patient's quality of life [3]. The pathogenesis of this disease is relatively complex, involving disorders such as hypothalamic-pituitary-adrenal axis dysfunction, gut microbiota imbalance, and neuroinflammatory

responses. The primary treatment approach involves oral administration of Western medications, with ESC being a commonly used drug. Derived from cyclic hydrophtalide, ESC is an isomer of citalopram. It exerts a long-lasting blocking effect on the reuptake of 5-HT within central neurons and has low sensitivity to neurotransmitters such as dopamine, making it less likely to cause severe side effects after administration [4]. However, the long-term efficacy of ESC monotherapy is suboptimal, necessitating combination with traditional Chinese medicine (TCM) treatments.

According to TCM, depression is located in the liver and is a relatively common disease affecting the mind and orifices. Its causes include insufficient kidney Yang, brain dysfunction, and emotional stimuli, while its pathogenesis involves nourishment deficiency of the mind's residence and stagnation of phlegm, blood stasis, and Qi. Symptomatic treatments such as clearing heat and reducing fire, opening the orifices and resolving phlegm, and calming the mind and nourishing the heart are required [5]. Lily Bulb and *Rehmannia* Decoction (modified) is a classic formula for this disease, with lily bulb and fresh *rehmannia* root as the sovereign herbs. Lily bulb has the effects of clearing the heart and calming the mind, moistening the lungs and nourishing Yin, etc.; fresh *rehmannia* root has the effects of nourishing Yin and promoting saliva production, nourishing the lungs and supplementing Qi, and clearing heat and cooling the blood, etc. [6]. The ministerial herbs are turmeric tuber, *poria* with hostwood, *bupleurum* root, and *cyperus rhizome*. Turmeric tuber can relieve depression and move Qi, open the orifices and clear the heart; poria with hostwood can calm the mind and soothe the nerves; *bupleurum* root and *cyperus rhizome* can open the orifices, soothe the liver and relieve depression. The assistant herbs are dried tangerine peel and *pinellia* tuber prepared with ginger. The former has the effects of drying dampness and resolving phlegm, strengthening the spleen and regulating Qi, etc.; the latter has the effect of resolving phlegm and stopping vomiting. The combined use of these herbs can exert therapeutic mechanisms such as calming the mind, relieving depression, and nourishing Yin [7].

The results showed that at different time points after treatment, the HAMD scores of the experimental group were lower than those of the reference group; after 6 weeks of treatment, the Cor levels of the experimental group were lower than those of the reference group, and the levels of other neurotransmitters and hormones in the experimental group were superior to those of the reference group at different time points after treatment ($p < 0.05$). The analysis suggests that lily bulb is rich in alkaloids and lily bulb polysaccharides, which can exert antidepressant, neuroprotective, and sedative effects; fresh *rehmannia* root contains catalpol and other components, which have a long-lasting antidepressant effect; bupleurum root can act on multiple signaling pathways and regulate the secretion of various hormones such as Cor and CRH; turmeric tuber can act on multiple signaling pathways such as calcium ions and cyclic adenosine monophosphate, thereby regulating the secretion level of 5-HT; *cyperus rhizome* can act on the depressive metabolic pathway and has a strong regulatory mechanism on the release process of neurotransmitters [8]. Combined with ESC, it can enhance the antidepressant effect, allowing normal secretion of neurotransmitters and various hormones in patients [9]. At different time points after treatment, the TESS scores of the experimental group were lower than those of the reference group ($p < 0.05$). The analysis suggests that integrated traditional Chinese and Western medicine treatment can reduce the dosage of ESC, prevent the accumulation of drug components, and thereby alleviate adverse reactions after medication. In addition, Lily Bulb and *Rehmannia* Decoction is a pure TCM preparation with low drug toxicity. It can eliminate the pathogenesis in a relatively short time, thereby shortening the course of treatment and reducing treatment side effects [10]. The HAMD efficacy and TCM syndrome efficacy of the experimental group were higher than those of the reference group ($p < 0.05$). The analysis suggests that Lily

Bulb and *Rehmannia* Decoction (modified) have a long-lasting antidepressant effect, can accelerate the speed of nerve regeneration, protect brain neurons, regulate the secretion level of neurotransmitters, prevent the massive apoptosis of dopaminergic neurons, improve the patient's neurological function, and thereby promote the improvement of the condition [11]. Combined with Western medications, it can exert a synergistic mechanism and act on brain neurons through multiple targets, thereby enhancing the efficacy and significantly improving the overall treatment response rate of patients.

5. Conclusion

In conclusion, the combined treatment of Lily Bulb and *Rehmannia* Decoction (modified) and ESC for patients with depression has a good effect. It can improve the secretion status of 5-HT and ACTH, effectively exert an antidepressant effect, and have few side effects after treatment. It can be used as a common treatment plan for patients with this disease.

Disclosure statement

The authors declare no conflict of interest.

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Research Progress on Functional Exercise Nursing Interventions for Elderly Patients with Alzheimer's Disease

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Abstract: Alzheimer's Disease (AD) is a degenerative disorder of the central nervous system characterized primarily by progressive cognitive decline, behavioral abnormalities, and a decrease in daily living abilities. It is predominantly observed in the elderly population, with its incidence rising annually alongside the aging demographic, posing a significant public health threat to the physical and mental well-being and quality of life of older adults. Currently, clinical treatment primarily relies on pharmacological interventions to alleviate symptoms, whereas functional exercise nursing interventions, as a core non-pharmacological approach, can effectively delay cognitive decline, improve physical motor function, enhance self-care abilities in daily life, and reduce the caregiving burden on families and society. This article systematically reviews the main types, implementation methods, influencing factors, and intervention effects of functional exercise nursing interventions for elderly patients with AD, aiming to provide theoretical foundations and practical references for the clinical implementation of standardized and individualized functional exercise nursing interventions.

Keywords: Elderly Alzheimer's disease; Functional exercise; Nursing intervention; Cognitive function

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1. Introduction

As the global population continues to age, the incidence and prevalence of Alzheimer's Disease (AD) exhibit an annual upward trend. According to the "China Report on the Development of Aging Undertakings (2025)", by the end of 2024, the population aged 60 and above in China reached 321 million, accounting for 22.8% of the total population, while those aged 65 and above numbered 217 million, representing 15.4%. The vast elderly population base poses severe challenges to AD prevention and control [1,2]. The pathological changes of AD are insidious and progressive, with early manifestations primarily including memory impairment, language dysfunction, and other cognitive impairments, leading to a decline in patients' daily living abilities and the emergence of abnormal mental behaviors, thereby imposing a heavy burden on individuals, families, and society [3]. Currently, clinical treatment for AD still predominantly relies on pharmacological interventions, which can temporarily slow down the rate of

cognitive decline but cannot reverse the pathological process and may result in adverse reactions with long-term use. Against this backdrop, non-pharmacological interventions have gradually garnered widespread attention. The "Chinese Guidelines for Non-Pharmacological Prevention of Cognitive Impairment in the Elderly" explicitly state that regular physical exercise, cognitive training, and other functional exercises are core non-pharmacological means for AD prevention and intervention (Grade A recommendation, Level 2a evidence) [4]. Due to their advantages of being easy to operate, safe, effective, and free from adverse reactions, they have become an important component of comprehensive management for AD patients. Functional exercise nursing interventions, through targeted physical exercises, cognitive training, and daily living skills training, can improve patients' physical function, delay cognitive decline, enhance quality of life, and simultaneously alleviate the burden on caregivers [5]. Therefore, it is necessary to study the research progress in functional exercise nursing interventions for elderly AD patients.

2. Main types and implementation methods

2.1. Physical function exercise

The core objective of physical function exercise is to maintain the physical activity capabilities of elderly AD patients, prevent complications such as muscle atrophy, joint stiffness, and pressure sores, improve balance and gait, and reduce the risk of falls. The implementation methods should be carried out in different grades according to the physical functional status of the patients:

For mild AD patients with largely normal physical function, moderate-intensity aerobic exercises combined with muscle strength training are recommended. Research by Han Conglin and others indicates that individuals aged 65 and above should engage in at least 150 minutes of moderate-intensity aerobic exercise or 75 minutes of vigorous-intensity aerobic exercise per week, with each session lasting over 10 minutes, and perform strength training for major muscle groups at least two days a week [6]. Active exercises such as walking, Tai Chi, square dancing, and dumbbell exercises can be conducted. Walking is the simplest and most feasible form of exercise; adhering to 30-60 minutes daily at a comfortable pace for the patient can effectively improve cardiopulmonary function, promote blood circulation, and delay physical function decline. Tai Chi, with its gentle movements and slow rhythm, emphasizes the coordination of breath and movements, improving patients' balance and physical flexibility while alleviating negative emotions such as anxiety and depression. Studies have shown that engaging in Tai Chi exercises three times a week for 60 minutes each session over 12 weeks can significantly improve gait stability and balance in mild AD patients [7]. Square dancing, combining music and dance, can stimulate patients' interest and improve exercise adherence while enhancing physical coordination and endurance, making it suitable for mild AD patients.

Guo Yuhong points out that moderate to severe AD patients experience a significant decline in physical function, often accompanied by symptoms such as balance disorders and limb stiffness, necessitating passive and assisted exercises under the assistance of nursing staff or caregivers [8]. Passive exercises mainly include joint flexion and extension and muscle massages, conducted 2–3 times daily for 15–20 minutes each session, focusing on massaging the muscles and joints of the limbs to prevent muscle atrophy and joint stiffness. Assisted exercises include walking with support, leg lifts in a seated position, and grip strength training, with nursing staff or caregivers providing full accompaniment to ensure patient safety and prevent accidents such as falls.

2.2. Cognitive function exercise

Cognitive decline is a core symptom of AD patients, primarily manifesting as a decline in memory, attention, language ability, and thinking ability [9]. Cognitive function exercises can stimulate the activity of brain nerve cells, delay cognitive decline, and maintain patients' cognitive levels. Implementation methods should be tailored to the patient's cognitive function status, emphasizing fun and practicality while avoiding overly complex training content.

Research indicates that strictly memory-based training interventions are more effective than interventions targeting multiple cognitive domains in improving cognitive abilities in elderly individuals with cognitive impairment [10]. Memory training mainly includes short-term memory training, long-term memory training, and episodic memory training [11]. Short-term memory training can be conducted through methods such as digit memory, word memory, and picture memory. Long-term memory training can be carried out by recalling past events, browsing old photographs, and narrating personal experiences to stimulate patients' remote memory.

Attention and thinking ability training can be conducted through activities such as jigsaw puzzles, chess, calligraphy, and painting [12]. Jigsaw puzzles and chess can exercise patients' attention and logical thinking abilities; choose puzzles and chess pieces of moderate difficulty and guide patients to complete them under the guidance of nursing staff, gradually increasing the difficulty. Calligraphy and painting can cultivate patients' concentration while exercising fine hand movements and alleviating cognitive decline. Studies have shown that engaging in calligraphy or painting training 2–3 times a week for 8 weeks can significantly improve attention and thinking abilities in AD patients [13]. Language ability training primarily targets AD patients with language impairments, exercising their language expression and comprehension abilities through methods such as reading aloud, conversation, and picture description.

2.3. Daily living skills exercise

A decline in daily living skills is one of the primary manifestations of elderly AD patients and an important factor affecting their quality of life. The goal of daily living skills exercise is to help patients maintain basic self-care abilities and reduce dependence on others.

Dressing training should be tailored to the patient's condition; mild AD patients can be allowed to choose their own clothes and dress independently, with nursing staff providing guidance and assistance only when necessary; moderate to severe AD patients require nursing staff to assist in preparing clothes and guide them through dressing actions. Eating training should focus on dietary safety and nutritional balance; mild AD patients can eat independently, with nursing staff guiding them on proper utensil use and chewing slowly; moderate to severe AD patients may experience difficulties eating and choking, requiring nursing staff to assist in feeding and choose easily swallowable and digestible foods to prevent choking and aspiration. Grooming and toilet training should be conducted under the guidance of nursing staff, enabling patients to master the basic steps of grooming and toileting and gradually improving their daily living self-care abilities.

3. Influencing factors

3.1. Patient-related factors

Patient-related factors are the core determinants influencing the effectiveness of functional exercise nursing interventions. The severity of the condition directly affects the patient's exercise capacity and intervention outcomes.

Patients with mild AD, who possess relatively intact cognitive and physical functions, can actively participate in exercises, leading to significant intervention effects [14]. Conversely, patients with moderate to severe AD experience severe cognitive decline and physical impairments, making it difficult for them to cooperate with exercises and resulting in relatively poor intervention outcomes. As age increases, patients' physical functions deteriorate, with more pronounced declines in physical activity and cognitive abilities, increasing the difficulty of exercises and affecting intervention outcomes. Gender also plays a role, with female AD patients demonstrating higher exercise compliance and better intervention outcomes compared to males. Additionally, patients' physical conditions, such as the presence of comorbidities like hypertension, diabetes, and osteoporosis, can influence the implementation and effectiveness of exercises. Patients with comorbidities face increased exercise challenges and require tailored exercises under medical guidance. Exercise compliance is a key factor affecting intervention outcomes; AD patients may forget or refuse to exercise due to cognitive decline, leading to suboptimal intervention effects [15].

3.2. Caregiver factors

Caregivers are the primary implementers of functional exercise nursing interventions for elderly AD patients, and their caregiving abilities, cognitive levels, and participation enthusiasm directly influence intervention outcomes. Insufficient caregiving abilities hinder caregivers from providing scientific exercise guidance, preventing the effective implementation of intervention plans. Low cognitive levels among caregivers regarding AD may lead them to believe that functional exercises are ineffective in improving patients' conditions, reducing their participation enthusiasm and even resulting in refusal to cooperate with functional exercises. Furthermore, caregivers' psychological states also affect intervention outcomes. Long-term caregiving for AD patients can induce adverse emotions such as anxiety, depression, and fatigue in caregivers, leading to a decline in caregiving quality and affecting the implementation of functional exercises [16].

3.3. Environmental factors

Environmental factors, encompassing both home and hospital environments, can enhance patients' exercise compliance and strengthen intervention outcomes [17]. A clean, spacious, and safe home environment provides patients with a suitable space for exercises, while the availability of necessary exercise equipment, such as walkers, dumbbells, and puzzles, facilitates exercise participation. In hospital settings, a well-organized ward layout, complete facilities, designated exercise areas, and the presence of professional nursing staff and rehabilitation therapists offer patients scientific exercise guidance and safety assurance. Additionally, the social environment influences intervention outcomes. Insufficient societal attention to AD patients and a lack of professional caregiving institutions and rehabilitation resources can limit the implementation of functional exercise nursing interventions.

4. Intervention outcomes

4.1. Improvement in cognitive function

Cognitive decline is a core symptom of AD patients. Functional exercise nursing interventions can stimulate brain neuronal activity, promote neurotransmitter secretion, and delay cognitive decline [18]. Research by Fu Xiaoxiao and others demonstrates that a 12-week multi-sensory stimulation training program based on cognitive remodeling for mild AD patients, including memory training, concentration training, and arithmetic and logical thinking ability training, significantly improves patients' MMSE and WGOQOL-BREF scores, effectively reducing psychiatric

symptoms and agitation levels while enhancing cognitive function and quality of life [19]. Another study shows that combining physical and cognitive exercises significantly enhances cognitive levels and self-care abilities in patients with moderate to severe AD [20]. Furthermore, novel cognitive exercise methods such as digital nostalgia therapy and virtual reality training can further improve intervention outcomes by activating the brain's default mode network and delaying hippocampal atrophy.

4.2. Improvement in physical function

Physical dysfunction is a common complication in elderly AD patients. Functional exercise nursing interventions can effectively maintain patients' physical activity capabilities, prevent muscle atrophy and joint stiffness, and improve balance and gait. An 8-week program of passive and assisted exercises for patients with moderate to severe AD significantly expands their range of physical motion, enhances muscle strength, and alleviates joint stiffness. Practicing Tai Chi three times a week for 12 weeks significantly improves balance and gait stability in mild AD patients, reducing the risk of falls. Additionally, 150 minutes of aerobic exercise per week can elevate brain-derived neurotrophic factor (BDNF) levels, further improving physical and cognitive functions [21].

4.3. Enhancement of daily living abilities

A decline in daily living abilities significantly impacts the quality of life of elderly AD patients. Functional exercise nursing interventions, through targeted daily living skills training, can help patients maintain basic self-care abilities and reduce dependence on others [22]. Research indicates that a 6-month daily living skills training program for AD patients, including dressing, eating, grooming, and toileting, significantly improves their ADL scores and self-care abilities [23]. After systematic daily living skills training, patients with moderate to severe AD can complete basic life activities with the assistance of nursing staff or caregivers, alleviating the burden on caregivers. Moreover, integrating eating into thought-stimulating scenarios, such as guiding plate arrangement under the pretext of "preparing a snack break", can enhance eating interest through "food associations", further improving patients' daily living abilities.

4.4. Alleviation of adverse emotions and improvement in quality of life

Elderly AD patients are prone to adverse emotions such as anxiety, depression, and loneliness due to cognitive decline and physical impairments, affecting their quality of life [24]. Functional exercise nursing interventions can alleviate these adverse emotions and improve quality of life through physical activity and social interaction. For example, collective exercise methods like square dancing and group walks increase patients' social opportunities, reduce loneliness, and alleviate anxiety and depression. Exercise methods such as calligraphy and painting provide patients with a sense of accomplishment, boosting their confidence and improving their psychological state. Furthermore, functional exercises can reduce the burden on caregivers, with a significant decrease in the Zarit Burden Interview (ZBI) scores, further enhancing patients' caregiving quality and quality of life.

5. Conclusion

Elderly Alzheimer's Disease is a degenerative condition that severely threatens the physical and mental health of the elderly. Functional exercise nursing interventions, as a core non-pharmacological approach, can effectively delay cognitive decline, improve physical function, enhance daily living abilities, alleviate adverse emotions, and

reduce the caregiving burden on families and society. In the future, it is essential to further strengthen related research, develop standardized intervention guidelines, innovate intervention methods, enhance caregiver training, increase investment in rehabilitation resources, and continuously improve the functional exercise nursing intervention system to achieve standardized, individualized, and scientific interventions.

Disclosure statement

The authors declare no conflict of interest.

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Observation on the Therapeutic Effect of Modified Major Bupleurum Decoction in Treating Elderly Patients with Type 2 Diabetes Mellitus Complicated by Constipation

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Abstract: *Objective*: To observe the clinical effect of modified Major Bupleurum Decoction in treating elderly patients with type 2 diabetes mellitus (T2DM) complicated by constipation, particularly its role in alleviating constipation symptoms. *Methods*: A clinical study was conducted on 60 elderly patients with T2DM complicated by constipation who were hospitalized in the geriatrics department of our hospital from January 2024 to December 2025. The patients were divided into groups based on the order of their visits. The control group (n = 30) received Western medicine treatment, while the treatment group (n = 30) received a combination of Western medicine and modified Major Bupleurum Decoction. Differences in traditional Chinese medicine (TCM) syndrome scores, constipation scale scores, glycemic and lipid metabolism indicators, treatment efficacy, and the incidence of adverse reactions were compared between the two groups before and after treatment. *Results*: Compared with the control group, the treatment group showed a significant reduction in TCM syndrome scores and CCS scores after treatment, along with an increase in treatment efficacy, with statistically significant differences ($p < 0.05$). Compared with the control group, the treatment group also demonstrated a significant reduction in glycemic and lipid metabolism indicators after treatment, with statistically significant differences ($p < 0.05$). *Conclusion*: Modified Major Bupleurum Decoction can actively improve constipation symptoms in elderly patients with T2DM complicated by constipation, with a definite therapeutic effect. Additionally, it exerts a certain auxiliary regulatory effect on the glycemic and lipid metabolism health of patients.

Keywords: Elderly patients; Type 2 diabetes mellitus; Functional constipation; Modified Major Bupleurum Decoction

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1. Introduction

Type 2 diabetes mellitus (T2DM), as a common chronic metabolic disease in clinical practice, has a complex pathogenesis and a high incidence rate among the elderly population. It can damage the functional health of multi-

ple organ systems through long-term blood glucose fluctuations after onset, exacerbating the impact of the disease on patients' health [1].

Gastrointestinal dysfunction, a common manifestation of digestive system dysfunction in elderly T2DM patients, primarily presents as functional constipation. Blood glucose fluctuations can cause nerve and functional damage to the human anorectal structure, thereby exacerbating constipation symptoms. Prolonged constipation not only affects patients' quality of life but also increases the risk of hemorrhagic stroke in patients with comorbid hypertension. Therefore, it is crucial to alleviate constipation symptoms in relevant patients [2,3].

Based on a summary of previous treatment experiences for elderly T2DM patients with constipation, while the use of laxatives can provide some relief from constipation, it fails to address the root cause. Combining other therapeutic techniques may optimize the actual treatment outcomes for patients [4]. Therefore, to observe the clinical effects of modified Dachaihu Decoction on elderly T2DM patients with constipation and its role in alleviating constipation symptoms, a study was conducted, with details as follows.

2. Materials and methods

2.1. Clinical data

Sixty elderly patients with T2DM and constipation who were hospitalized in the geriatrics department of our hospital from January 2024 to December 2025 were selected for this clinical study. They were divided into a control group and a treatment group based on the order of admission, with 30 patients in each group.

In the control group, the gender ratio (male/female) was 17/13, with ages ranging from 67 to 86 years (76.54 ± 5.12 years), a T2DM duration of 2 to 11 years (6.58 ± 1.04 years), and a constipation duration of 3 to 9 weeks (6.12 ± 0.73 weeks). In the treatment group, the gender ratio (male/female) was 16/14, with ages ranging from 68 to 84 years (76.28 ± 5.07 years), a T2DM duration of 3 to 9 years (6.25 ± 1.02 years), and a constipation duration of 3 to 10 weeks (6.51 ± 1.08 weeks). There were no statistically significant differences in gender ratio, age, or disease duration between the groups ($p > 0.05$), indicating comparability.

2.1.1. Inclusion criteria

(1) Meeting the clinical diagnostic criteria for T2DM and functional constipation;
(2) Traditional Chinese medicine (TCM) syndrome differentiation indicating liver-stomach heat stagnation syndrome;
(3) Age > 65 years, with intact cognitive and language communication abilities and clear expression of autonomous will;
(4) No history of stroke or mobility impairment, capable of cooperating with clinical treatment.

2.1.2. Exclusion criteria

(1) Definite gastrointestinal organic lesions;
(2) Presence of alternating constipation and diarrhea symptoms within the previous 12 weeks;
(3) Comorbid severe liver, kidney, or other organ diseases or diabetic complications;
(4) Comorbid psychiatric disorders;
(5) Allergic constitution or a clear history of allergy to the study drugs;
(6) Comorbid psychiatric disorders (repeated for emphasis, should be removed in actual text);

(7) Withdrawal or active exit from the study during the research period.

2.2. Methods

All patients received constipation treatment based on individualized blood glucose control, treatment of underlying diseases, and health guidance on lifestyle factors such as diet and exercise.

2.2.1. Control group

Western medicine treatment.

(1) Lactulose

Administered orally with warm water before meals, 15 mL per dose, for 14 consecutive days of treatment;

(2) Glycerin enema

If the patient has not defecated for three consecutive days during treatment, glycerin enema should be administered through the anus for bowel evacuation.

2.2.2. Treatment group

(1) Western medicine treatment was the same as that in the control group;

(2) Modified Dachaihu Decoction treatment

The decoction consisted of 24 g of *Bupleurum*, 15 g of White Peony Root, 12 g of *Scutellaria*, and 10 g each of *Pinellia*, Immature Bitter Orange, Ginger, and Jujube, along with 5 g of Raw Rhubarb. The herbs were decocted twice over a gentle flame to obtain 400 mL of juice, which was taken in the morning and evening, one dose per day, for 14 consecutive days of treatment. If the stool was dry and hard, 20 g of *Scrophularia* and 12 g of *Rehmannia* could be added; if defecation was weak, 20 g each of *Codonopsis* and *Astragalus* could be added.

2.3. Observation indicators

(1) TCM syndrome scores

Based on the syndromes related to diabetes with liver-stomach heat stagnation and functional constipation, the main symptoms (dry stool, difficult defecation) and secondary symptoms (abdominal distension, red face and bitter mouth) were evaluated before and after treatment. The main symptom scores ranged from 0 to 6 points, and the secondary symptom scores ranged from 0 to 3 points. Higher scores indicated more severe syndrome manifestations [5].

(2) Constipation scale scores

The Cleveland Constipation Scale (CCS) was used for evaluation, including eight items such as defecation frequency, abdominal pain, difficult defecation, and incomplete evacuation. The total score ranged from 0 to 30 points. A score ≥ 15 indicated constipation, with higher scores indicating more severe constipation [6].

(3) Glucose and lipid metabolism indicators

Fasting peripheral venous blood samples and postprandial 2-hour peripheral venous blood samples were collected. The clinical laboratory performed tests for fasting blood glucose (FBG), postprandial 2-hour blood glucose (2hPG), total cholesterol (TC), triglycerides (TG), and low-density lipoprotein cholesterol (LDL-C) as needed.

(4) Treatment effectiveness rate

Based on the improvement in constipation symptoms and TCM syndrome scores after treatment, the treatment effect was evaluated as follows: markedly effective (constipation symptoms disappeared or significantly improved after treatment, with a total TCM syndrome score reduction of ≥ 70% compared to before treatment), effective (constipation symptoms improved after treatment, with a total TCM syndrome score reduction of ≥ 30% compared to before treatment), and ineffective (not meeting the above evaluation criteria). The total effectiveness rate = (markedly effective + effective) / n × 100%.

(5) Incidence of adverse reactions

The total incidence of drug-related adverse reactions in each group was statistically analyzed, including dizziness, nausea, gastrointestinal reactions, and skin reactions.

2.4. Statistical methods

Data were analyzed using SPSS 25.0 statistical software. Count data were expressed as [number (%)], and constituent ratio data were tested using the χ^2 test. Measurement data conforming to a normal distribution were expressed as ($\overline{x} \pm s$), with independent sample *t*-tests used for intergroup comparisons and paired *t*-tests used for intragroup comparisons. A *p*-value < 0.05 indicated a statistically significant difference.

3. Results

3.1. Comparison of TCM syndrome scores

There was no statistically significant difference in TCM syndrome scores between the groups before treatment ($p > 0.05$). After treatment, the scores for dry stool, difficult defecation, abdominal distension, and red face and bitter mouth decreased compared to before treatment, with the treatment group having lower scores than the control group ($p < 0.05$), as shown in **Table 1**.

Table 1. Comparison of TCM syndrome scores ($\overline{x} \pm s$)

Group/n	Dry stool (score)		Difficult defecation (score)		Abdominal distension (score)		Facial flushing and bitter taste (score)	
	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Control group / 30	4.35 ± 0.32	2.47 ± 0.41*	4.28 ± 0.35	2.42 ± 0.21*	1.87 ± 0.38	1.17 ± 0.22*	1.82 ± 0.28	1.02 ± 0.23*
Treatment group / 30	4.28 ± 0.38	1.52 ± 0.25*	4.31 ± 0.32	1.45 ± 0.18*	1.89 ± 0.36	0.79 ± 0.18*	1.84 ± 0.31	0.85 ± 0.22*
t	0.772	10.836	0.356	19.209	0.209	7.322	0.262	2.926
p	0.443	< 0.001	0.730	< 0.001	0.835	< 0.001	0.794	0.005

Note: A statistically significant difference was observed compared to before treatment, *$p < 0.05$.

3.2. Comparison of constipation scale scores

There was no statistically significant difference in CCS scores between the two groups before treatment ($p > 0.05$). After treatment, CCS scores in both groups decreased compared with those before treatment, and the scores in the treatment group were lower than those in the control group ($p < 0.05$). See **Table 2**.

Table 2. Comparison of constipation scale scores ($\overline{x} \pm s$)

Group (n)	Before treatment (points)	After 7 days of treatment (points)	After 14 days of treatment (points)
Control group / 30	14.24 ± 2.78	10.85 ± 2.21*	9.15 ± 1.79*
Treatment group / 30	14.21 ± 2.83	9.24 ± 2.15*	7.21 ± 1.25*
t	0.041	2.860	4.867
p	0.967	0.006	< 0.001

Note: A statistically significant difference was observed compared to pre-treatment values, *$p < 0.05$.

3.3. Comparison of glycemic and lipid metabolism indicators

There was no statistically significant difference in glycemic and lipid metabolism indicators between the groups before treatment ($p > 0.05$). After treatment, FBG, 2hPG, TC, TG, and LDL-C levels decreased compared to pre-treatment values, with the treatment group showing lower levels than the control group ($p < 0.05$). See **Table 3** and **4**.

Table 3. Comparison of glycemic and lipid metabolism indicators (FBG and 2hPG) ($\overline{x} \pm s$)

Group / n	FBG (mmol/L)		2hPG (mmol/L)	
	Before treatment	After treatment	Before treatment	After treatment
Control group / 30	12.85 ± 2.21	8.97 ± 2.24*	15.72 ± 3.45	11.45 ± 2.87*
Treatment group / 30	12.94 ± 2.16	7.05 ± 1.65*	15.68 ± 3.52	9.15 ± 2.15*
t	0.159	3.779	0.044	3.513
p	0.874	< 0.001	0.965	0.001

Table 4. Comparison of glycemic and lipid metabolism indicators (TC, TG and LDL-C) ($\overline{x} \pm s$)

Group (n)	TC (mmol/L)		TG (mmol/L)		LDL-C (mmol/L)	
	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Control group (n = 30)	5.98 ± 1.24	5.45 ± 0.79	4.79 ± 1.25	4.05 ± 0.82*	3.41 ± 0.97	3.02 ± 0.67*
Treatment group (n = 30)	6.01 ± 1.26	4.97 ± 0.62*	4.81 ± 1.22	3.24 ± 0.78*	3.43 ± 0.92	2.34 ± 0.58*
t	0.093	2.618	0.063	3.920	0.082	4.203
p	0.926	0.011	0.950	< 0.001	0.935	< 0.001

Note: There is a statistically significant difference compared to before treatment, *$p < 0.05$.

3.4. Comparison of treatment effectiveness rate and incidence of adverse reactions

There was no statistically significant difference in the incidence of drug-related adverse reactions between the groups ($p > 0.05$). The treatment effectiveness rate in the treatment group was higher than that in the control group ($p < 0.05$). See **Table 5**.

Table 5. Comparison of treatment effectiveness rate and incidence of adverse reactions (n, %)

Group (n)	Treatment effectiveness rate	Adverse reaction incidence rate
Control group (30)	25 (83.33)	1 (3.33)
Treatment group (40)	30 (100.00)	3 (10.00)
χ^2	5.455	1.071
p	0.019	0.301

4. Discussion

Digestive system diseases, as a category where traditional Chinese medicine (TCM) demonstrates significant therapeutic advantages, have shown definite clinical efficacy in treating various types of diseases. After conducting a syndrome differentiation analysis of the symptoms and pathogenesis in patients with type 2 diabetes mellitus (T2DM) complicated by constipation, it is considered that their condition falls within the scope of "diabetes" and "constipation". Based on diabetes, the pathogenesis of "fullness in the middle and internal heat" leads to internal dryness and heat accumulation, as well as impaired large intestine function. Alternatively, diabetes can cause damage to both Qi and Yin, internal retention of damp turbidity, or blood stasis obstructing the collaterals, resulting in insufficient intestinal lubrication as the primary pathogenic mechanism of constipation. The primary pathological sites are the gastrointestinal tract, which can also affect the lungs, spleen, liver, and kidneys. Therefore, a differential treatment approach can be adopted, utilizing methods such as clearing heat and promoting blood circulation, soothing the liver and relieving depression, and strengthening the spleen and harmonizing the stomach [7].

Major Bupleurum Decoction, originating from Treatise on Febrile Diseases, has the effects of purging heat and promoting bowel movement, as well as soothing the liver and regulating Qi. The formula uses *bupleurum* as the principal herb, which can soothe the liver and relieve depression, clear heat, and elevate Yang. *Rhubarb*, *scutellaria*, and immature bitter orange serve as the deputy herbs, which can clear heat and reduce fire, dry dampness, and break Qi to eliminate accumulation. Supplemented with white peony root to soften and restrain the liver and suppress liver Yang, and *pinellia* to dry dampness and resolve phlegm, eliminate fullness, the overall formula, through the combined effects of its individual herbs, can regulate the functions of the stomach, intestines, spleen, liver, and other organs, address the pathogenic mechanisms, and enhance the efficacy of laxatives in alleviating constipation symptoms in patients [8,9]. These conclusions are consistent with the findings of this study. Compared with the control group, the treatment group showed reduced TCM syndrome scores and CCS scores after treatment, along with an increased treatment efficacy, with statistically significant differences ($p < 0.05$).

Moreover, this study indicates that, compared with the control group, the treatment group demonstrated reduced glycemic and lipid metabolism indicators after treatment, with statistically significant differences ($p < 0.05$). Analysis suggests that the biological polysaccharides and poly glycosides contained in bupleurum in Major Bupleurum Decoction have a certain regulatory effect on human lipid metabolism levels and possess anti-inflammatory properties. The biological components in *scutellaria* can inhibit the activity of inflammatory cytokines, while those in immature bitter orange significantly improve human lipid metabolism and glucose tolerance. Therefore, under the combined effects of these components, they can assist in promoting the improvement of glycemic and lipid metabolism health in patients after treatment and optimize the clinical treatment outcomes of T2DM [10].

5. Conclusion

In summary, the treatment with modified Major Bupleurum Decoction can actively improve constipation symptoms in elderly patients with T2DM complicated by constipation, with definite therapeutic effects, and also has a certain auxiliary regulatory effect on the glycemic and lipid metabolism health of patients.

Disclosure statement

The author declares no conflict of interest.

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Discussion on the Current Situation and Implementation Models of Pharmaceutical Science Popularization Communication in China

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Abstract: At present, the general public has limited knowledge of pharmaceutical products, which to a certain extent increases the risk of medication. Strengthening pharmaceutical science popularization education is particularly important for promoting rational drug use, reducing medication risks, and improving national health literacy. Based on this, this paper analyzes the current situation and main implementation models of pharmaceutical science popularization communication in China, reveals the prominent challenges faced, and explores specific countermeasures on this basis. It is expected to provide useful references for the high-quality development of China's pharmaceutical science popularization cause and contribute to the construction of Healthy China.

Keywords: Pharmaceutical science popularization; Communication current situation; Implementation models; Rational drug use; New media communication

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1. Introduction

The national Healthy China Action (2019–2030) clearly includes rational drug use popularization in the key tasks of health promotion, and the Three-Year Action Plan for Improving National Health Literacy (2024–2027) further incorporates pharmaceutical science popularization into the core content of healthy promotion hospital construction. In 2025, the national residents' health literacy level reached 33.69%, but the problem of irrational drug use is still prominent. Drugs are one of the most basic intervention methods for chronic disease treatment. Data from the World Health Organization shows that about 50% of patients worldwide have irrational drug use behaviors, posing a serious threat to their own health. Drugs are powerful tools to protect health, but incorrect medication or improper prescriptions will instead cause secondary harm to patients. Therefore, the popularization of pharmaceutical knowledge is of great significance for improving public health literacy, reducing drug abuse and misuse, saving medical resources, and promoting social harmony and development. This paper briefly sorts out the current situation characteristics and mainstream implementation models of pharmaceutical science popularization

communication in China, analyzes the current challenges, and proposes optimization paths to provide references for the high-quality development of the pharmaceutical science popularization cause.

2. Current situation characteristics of pharmaceutical science popularization communication in China

2.1. Online-offline integrated communication form, with new media as the main carrier

At present, the development of pharmaceutical science popularization in China has made considerable progress. The publicity forms are no longer limited to traditional lectures and distribution of promotional materials; new media platforms such as Weibo, WeChat, Douyin, and Xiaohongshu have become the main carriers [1]. For example, WeChat, a social software with a large user base, can spread information in a timely manner, and many hospitals or pharmaceutical departments take it as the main position for pharmaceutical science popularization; numerous doctors and experts have also settled on short video platforms, using their professional knowledge and clinical experience to create concise and easy-to-understand popular science works.

Although more and more people obtain health knowledge through online platforms, offline communication still plays an irreplaceable role, especially for the elderly. For them, online information is complex and inconvenient to operate, and they need more offline popular science services. Offline forms such as hospital pharmaceutical consultation windows, community popular science lectures, campus education, home pharmacist home visits, and popular science exhibitions are still important carriers of pharmaceutical science popularization [2]. Online popular science allows users to obtain health knowledge more quickly and can drive more people to participate in consultations, free clinics and other activities; offline lectures and activities can expand the coverage of popular science and improve its pertinence.

2.2. Communication content focuses on practical needs, with continuously expanding coverage scenarios

In the past, pharmaceutical science popularization content mainly focused on explaining the dosage and usage of drugs to the public. Now, it mainly centers on the public's high-frequency medication needs, becoming more diversified and refined. In particular, the physiological, biochemical and pathological mechanisms of the elderly, children, pregnant and lactating women and other groups are different from ordinary people, with different pharmacokinetic and pharmacodynamic characteristics, so medication safety needs more focused attention. In recent years, traditional Chinese medicine (TCM) popularization and the communication of knowledge on the homology of medicine and food have become increasingly popular. Some hospitals interpret TCM prescriptions through allusions, legends, animations, etc., correcting some misunderstandings about TCM [3]. For example, Pingyi County Traditional Chinese Medicine Hospital has created a column of TCM culture stories, telling the origin of drug names such as "Liujinu" and allusions like "Jujing Quanxiang"; Shanghai Seventh People's Hospital has produced the animation series *Zhizi Seeks Medical Advice* to popularize TCM knowledge.

2.3. Pharmacists as the main communication subject, with a preliminary formation of a diversified participation pattern

Pharmacists are the main force for rational drug use and the core subject of pharmaceutical science popularization. They participate in popular science work by writing popular science articles, making videos, and giving lectures.

The pharmacy department of hospitals is the core force of popular science organizations. Many hospitals have set up full-time publicity teams to release popular science content, or cooperate with TV stations, universities and other institutions to improve the professionalism and communication power of popular science works [4].

In addition to medical institutions, pharmaceutical associations, pharmaceutical enterprises, universities and other subjects also actively participate. For example, the Guangdong Pharmaceutical Association hosts AI application training to improve pharmacists' popular science skills; the PSM Guangdong Pharmaceutical Science Popularization Research Fund supports the development of popular science projects such as stroke prevention and treatment. However, the construction of the popular science talent team still needs to be strengthened. Many pharmacists lack relevant popular science training, as well as skills such as new media operation and video production, which affects the quality of popular science [5].

2.4. Differences in communication effects, with overall efficiency to be improved

Nowadays, pharmaceutical science popularization communication has achieved certain results and attracted widespread attention. However, there are obvious differences in the effects of popular science communication. Urban residents have a higher level of understanding, trust and practice of popular science content than rural residents; people with high educational levels have significantly higher health literacy than those with low educational levels; groups such as the elderly and rural residents have more limited channels to obtain popular science knowledge [6]. On platforms, for example, WeChat official accounts rely on fan bases for communication, and their exposure will decrease over time; although platforms like Bilibili can achieve continuous communication through algorithm recommendations, differences in user preferences on the platform will lead to differentiated communication effects.

3. Main implementation models of pharmaceutical science popularization communication in China

3.1. New media matrix linkage model

The so-called new media matrix linkage model relies on multiple media platforms to build a differentiated communication matrix and expand the coverage of popular science. It mainly uses the attributes and user characteristics of different media to formulate adaptive content [7]. WeChat official accounts usually publish graphic content to conduct popular science in the form of pictures and texts. Douyin is usually used to release fast-paced short videos to attract users. Bilibili is more suitable for creating long video popular science series and designing interactive narrative structures to guide bullet screen comments.

3.2. AI-enabled full-process model

Artificial intelligence can optimize links such as popular science creation and production, improve the efficiency and quality of popular science, and is an innovative direction of pharmaceutical science popularization in recent years. AI tools can be used to assist topic selection, generate scripts, and produce videos. AI tools such as DeepSeek and Doubao can sort out hot demand and create vertical content, parallel content, and hot topic integration content [8]. Inputting structured prompts can generate initial scripts. In the production stage, Tencent Zhiying is used to create digital humans, and JianYing's voice cloning and AI subtitle functions are used to reduce production costs and shorten the cycle. Before the release of works, AI tools can also be used to screen

the scientificity of the content and check for sensitive words, and professional review can be carried out by the medical team.

3.3. Diversified integrated service model

The diversified service model aims to break the single boundary between online and offline, inside and outside the hospital, and provide the public with popular science services in various popular science forms. It mainly includes three dimensions: in-hospital popular science, community extension, and home services. In-hospital popular science is based on pharmaceutical consultation windows, promotional electronic screens, and pharmaceutical clinics to provide timely and professional medication guidance; community extension sinks services to the grassroots through popular science lectures, free clinics, and health record establishment; home services rely on family pharmacist teams to provide personalized services such as home visits and medication monitoring for key groups such as chronic disease patients and the elderly [9].

3.4. Professional team operation model

The development of popular science work requires a professional team. Therefore, a professional popular science team composed of pharmacists, clinicians, new media operators, designers, etc. can be established, responsible for content planning, professional review, production and communication and other links. Team members need to learn knowledge such as popular science creation processes and relevant laws and regulations, and also review the scientificity, professionalism and compliance of popular science works [10]. The operation of a professional team can effectively solve problems such as scattered popular science creation and uneven quality, and is an important guarantee for the output of high-quality popular science works.

3.5. Demand-oriented dynamic adjustment model

This model aims to take public demand as the core and timely adjust the content and form of popular science through data monitoring, extensive research, clinical feedback and other methods. For example, design personalized popular science content for needs, formulate healthy recipes for office workers, and produce chronic disease medication guidance for middle-aged and elderly groups; evaluate the communication effect through indicators such as the number of views, interaction rate, and knowledge awareness rate of works on various platforms, and adjust and improve the popular science content [11].

4. Main challenges faced by pharmaceutical science popularization communication in China

4.1. Insufficient resources and capabilities of professional personnel

Professional pharmaceutical personnel have limited time and energy, and their daily work tasks are already heavy, which compresses the time for popular science creation. In addition, a prominent problem is that the ability of popular science talents needs to be improved. Many medical personnel have not received popular science training and do not have skills such as script creation, video editing, and platform operation.

4.2. Prominent contradiction between homogenization and adaptability of popular science content

A large number of popular science contents have poured into the online space, but problems such as repetitive

themes, lack of innovation, and serious homogenization of works will make the public tired. It is necessary to design targeted content and forms based on the preferences of users on different platforms and the differences in the knowledge levels of different groups, which is currently insufficient [12]. The spread of pseudo-science and false information has disrupted the normal popular science order. Misleading content such as health preservation rumors and folk remedies is also spreading rapidly with the help of new media. Some members of the public delay treatment due to blind following, while the public's ability to distinguish popular science information is weak, which further aggravates the communication chaos.

4.3. Imperfect guarantee mechanisms and supervision

The incentive mechanism is not perfect. The evaluation standards for popular science contributions vary in different regions, and a fair and unified professional title evaluation and performance appraisal system has not been formed. The weight of popular science achievements in professional title promotion and selection of excellent employees is low, making it difficult to fully mobilize the enthusiasm of pharmaceutical practitioners. Some platforms lack professional review processes, leading to the proliferation of unprofessional and unscientific content. Popular science work lacks unified guiding standards and evaluation systems. The quality of popular science activities carried out by various regions and institutions is uneven, making it difficult to conduct effective supervision and effect evaluation [13].

4.4. Imbalanced allocation and accessibility of popular science resources

There is an obvious problem of uneven regional allocation of pharmaceutical popular science resources in China. Popular science resources are particularly scarce in underdeveloped areas and rural areas, making it difficult to meet the popular science needs of local people. At the same time, the personalized popular science needs of special groups have not been fully considered, and the targeted popular science supply for groups such as the elderly, children, pregnant and lactating women is insufficient. Among them, the elderly and rural residents are limited by access channels and find it difficult to easily obtain high-quality pharmaceutical popular science knowledge, which further widens the health literacy gap between different groups and is not conducive to the realization of the goal of universal coverage of pharmaceutical popular science.

5. Countermeasure suggestions for optimizing pharmaceutical science popularization communication in China

5.1. Improve guarantee mechanisms and strengthen policy support

Improve the incentive system, and incorporate popular science works and activities into the performance evaluation of health professional and technical talents. For example, medical institutions can clearly specify that popular science works and popular science awards can be used as the basis for professional title promotion, establish quantitative assessment indicators for popular science work, and link them with performance rewards. At the same time, encourage cooperation among multiple subjects such as medical institutions, pharmaceutical associations, and enterprises to integrate funds, technology, and talent resources to form a joint force for popular science. Establish unified standards, formulate unified norms for the creation, review, and communication of popular science content, and build a relatively complete evaluation system to improve the standardization level of popular science work.

5.2. Strengthen capacity building and improve popular science quality

Construct a hierarchical training system, carry out special training on popular science creation, new media operation, AI tool application, etc. for medical personnel, and establish an internal training mechanism to expand the coverage of training. Cultivate professional teams, support medical institutions to set up full-time popular science teams, absorb diverse talents such as pharmacists, clinicians, and new media operators, and clarify the division of labor and cooperation [14]. Promote the application of AI, and use AI technology to improve the accuracy of topic selection, production efficiency, and review quality.

5.3. Optimize the communication system and improve coverage efficiency

Improve the new media matrix, and customize content according to the characteristics of different platforms. For example, WeChat official accounts focus on pictures, texts and long videos, Douyin and Kuaishou focus on short, flat and practical content, and Bilibili creates serialized long videos. Promote resource sinking, establish an inter-regional popular science cooperation mechanism, and extend high-quality popular science resources to underdeveloped areas and rural areas through the "Internet + popular science" model [15]. Carry out activities such as "popular science entering campuses, communities, and villages", and combine offline lectures, free clinics, and promotional brochures to improve the accessibility of popular science for special groups and grass-roots people. With the help of big data analysis, push personalized popular science content for different groups and different disease types. Provide aging-friendly popular science products for the elderly and people with low educational levels, such as simplified video instructions and audio popular science.

5.4. Improve supervision mechanisms and purify the communication environment

Strengthen review and management, use AI tools for preliminary scientific verification and sensitive word screening, conduct re-review by the medical professional team, and review compliance by new media operators. Crack down on the spread of pseudo-science, strengthen cooperation with cyberspace administration, market supervision and other departments, and severely deal with behaviors that spread misleading medication information. Improve the public's ability to distinguish, incorporate popular science information discrimination skills into pharmaceutical popular science content, guide the public to obtain medication knowledge through authoritative channels, and cultivate scientific health concepts.

6. Conclusion

With the in-depth advancement of the Healthy China strategy and the rapid development of digital technology, China's pharmaceutical science popularization communication is moving towards intelligence, precision, and universalization. AI technology will be further integrated into the popular science process, playing a role in topic selection, production, distribution, review and other links. Popular science models will be more diversified, and personalized and scenario-based popular science content will become the mainstream. However, pharmaceutical science popularization has a long way to go and requires the joint participation of the whole society. Based on science, oriented by demand, and driven by innovation, we will make rational drug use knowledge deeply rooted in the hearts of the people and protect the medication safety and health of the whole people.

Disclosure statement

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In Adults with Type 1 Diabetes, is the Artificial Pancreas System More Effective than Open-loop Systems in Controlling Blood Glucose?

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Abstract: ***Background*:** Despite advances in continuous glucose monitoring (CGM) and insulin pump therapy, many adults with type 1 diabetes (T1D) do not consistently achieve recommended glycemic targets. Automated insulin delivery (AID), often referred to as the artificial pancreas (AP), integrates CGM, an insulin pump, and a control algorithm to adjust insulin delivery in real time. ***Objective*:** To summarize contemporary evidence comparing AP/AID (closed-loop or hybrid closed-loop) with open-loop approaches (e.g., sensor-augmented pump therapy or user-directed insulin dosing) for glycemic control in adults with T1D. ***Methods*:** We synthesized evidence from recent randomized controlled trials (RCTs) and meta-analyses in adults with T1D, focusing on clinically meaningful CGM-derived metrics (time in range [TIR], time below range), HbA1c, and safety outcomes. Reporting principles align with PRISMA 2020 where applicable. ***Results*:** Across modern RCTs and meta-analyses, AP/AID consistently improves TIR and reduces hyperglycemia compared with open-loop strategies, without increasing hypoglycemia. Key trials in older adults show clinically relevant gains in TIR with closed-loop systems versus sensor-augmented pump therapy. Meta-analytic evidence supports improved TIR and modest HbA1c reductions with closed-loop compared with open-loop approaches. ***Conclusion*:** In adults with T1D, AP/AID systems are more effective than open-loop regimens in improving glycemic control, offering better TIR and comparable or improved hypoglycemia safety profiles.

Keywords: Type 1 diabetes; Artificial pancreas; Automated insulin delivery; Closed-loop; Hybrid closed-loop; Sensor-augmented pump; Time in range; Continuous glucose monitoring.

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1. Background

Type 1 diabetes is a chronic autoimmune condition characterized by pancreatic β-cell destruction and lifelong insulin dependence. Although it represents a smaller proportion of global diabetes burden, the number of people living with T1D is substantial and projected to increase [1]. Achieving and sustaining near-target glycaemia reduces the risk of microvascular and macrovascular complications and improves quality of life; however, daily self-

management remains complex, particularly in the setting of variable meals, exercise, illness, and stress.

Open-loop therapy, whether via multiple daily injections or pump therapy guided by user decisions has improved substantially with real-time CGM and sensor-augmented pumps. Yet, persistent glycemic variability, nocturnal dysglycemia, and fear of hypoglycemia continues to limit target attainment for many adults. Recent data also suggest that severe hypoglycemia and impaired awareness can persist even among technology users, highlighting the unmet need for safer, more stable glucose control strategies [2].

The artificial pancreas (AP), more broadly conceptualized as automated insulin delivery (AID), combines CGM, an insulin pump, and an algorithm that automatically adjusts insulin delivery. Most commercially available systems are hybrid closed-loop: they automate basal adjustments and may provide automated corrections, but still require user-initiated meal boluses. Contemporary clinical evidence indicates that these systems can increase TIR, reduce hyperglycemia, and maintain or reduce hypoglycemia compared with open-loop regimens [3].

2. Methods

This publication-form synthesis focuses on adult populations (≥ 18 years) with T1D and compares AP/AID (closed-loop or hybrid closed-loop) to open-loop strategies (e.g., sensor-augmented pump therapy or user-directed insulin dosing). This study prioritized evidence from:

(1) Randomized controlled trials conducted under free-living/outpatient conditions; and

(2) Systematic reviews/meta-analyses evaluating closed-loop versus open-loop approaches in adults with T1D.

Primary outcomes of interest were CGM-derived metrics, particularly TIR (typically 70–180 mg/dL [3.9–10.0 mmol/L]), time above range, and time below range, as well as HbA1c and safety outcomes (severe hypoglycemia, diabetic ketoacidosis, device-related adverse events). Reporting and synthesis principles follow PRISMA 2020 guidance when applicable [4].

3. Results

3.1. Glycemic effectiveness

Across contemporary RCTs in adults, AP/AID improves glycemic control compared with open-loop strategies, with the most consistent benefits observed in TIR. In a randomized crossover trial in older adults with long-duration T1D (ORACL), closed-loop insulin delivery improved CGM TIR compared with sensor-augmented pump therapy, while maintaining a favorable safety profile [5]. Findings from an open-label, multicenter randomized crossover study in older adults similarly demonstrated superior glycemic outcomes with hybrid closed-loop versus sensor-augmented pump therapy, achieved without an increased risk of hypoglycemia [6].

These trial-level findings align with meta-analytic evidence. A systematic review and meta-analysis of RCTs in adults reported that closed-loop systems increase TIR and reduce HbA1c relative to sensor-augmented pump therapy, with no excess hypoglycemia [7]. Collectively, the evidence supports a clinically meaningful improvement in daily glucose stability, commonly expressed as greater time spent within target range and less time spent above range, when insulin delivery is partially automated by an algorithm.

3.2. Hypoglycemia and safety

A critical question for AP/AID is whether tighter control increases hypoglycemia risk. Across recent RCTs, closed-loop strategies generally do not increase time below range and may reduce exposure to hypoglycemia due to predictive low-glucose management and automated insulin modulation [5,6]. The safety signals reported in these trials are reassuring, with low rates of severe hypoglycemia and no clear increase in ketoacidosis in the controlled trial settings.

At a population level, severe hypoglycemia and impaired awareness remain clinically relevant challenges for adults with T1D, including technology users, reinforcing the importance of solutions that improve control without trading off safety [2]. The available trial evidence indicates that AP/AID can deliver this balance for many adults, though outcomes depend on user training, device wear adherence, and appropriate system settings.

3.3. Patient-centered outcomes and implementation considerations

Beyond glycemic endpoints, treatment burden and user experience influence real-world effectiveness. Observational and follow-up studies suggest that advanced hybrid closed-loop use can be associated with improvements in quality-of-life domains among adults, including those previously naïve to advanced diabetes technology [8]. These patient-centered outcomes are consistent with the conceptual promise of AID: reducing cognitive load associated with continuous self-management while improving glucose stability.

Health-system factors, including training, follow-up support, and telemedicine-enabled workflows, may further influence outcomes. Telemedicine interventions in T1D have been associated with improvements in diabetes-related outcomes in systematic review evidence, supporting the plausibility that structured remote support could complement AP/AID adoption, particularly during initiation and optimization phases [9].

4. Discussion

The current evidence base indicates that AP/AID systems provide superior glycemic control compared with open-loop regimens in adults with T1D, primarily via improvements in TIR and reductions in hyperglycemia, without increasing hypoglycemia [5–7]. These benefits have been demonstrated in free-living conditions and in higher-risk groups such as older adults, who may be particularly vulnerable to severe hypoglycemia and its consequences [5,6].

Several considerations are important for interpretation. First, many technology trials are open-label by necessity, which may affect subjective outcomes; however, primary glycemic endpoints are typically derived from CGM data and are objective. Second, trial populations may be more motivated and supported than typical real-world cohorts, potentially inflating adherence and outcomes. Third, systems vary (algorithm features, automation level, correction boluses, usability), so effect sizes may differ across devices and settings [10]. Comprehensive clinical reviews highlight rapid device evolution and increasing automation, which may further enhance effectiveness over time [3].

From an implementation standpoint, the observed advantages of AP/AID strengthen the argument for broader access, particularly for adults who remain above target despite optimized open-loop therapy, those with problematic hypoglycemia, and individuals with high day-to-day glycemic variability. Nevertheless, persistent severe hypoglycemia risk in some technology users underscores that device adoption alone may be insufficient; structured education, follow-up and telemedicine-enabled optimization may be required to maximize benefit [2,9].

5. Conclusion

In adults with type 1 diabetes, artificial pancreas/automated insulin delivery systems are more effective than open-loop approaches for controlling blood glucose. Contemporary RCT and meta-analytic evidence shows consistent improvements in time in range and reductions in hyperglycemia without increased hypoglycemia, supporting AP/AID as an important therapeutic advancement in adult T1D management.

Disclosure statement

The author declares no conflict of interest.

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Gut Microbiota and Liver Health: The Role of Resistant Starch in Ameliorating Metabolic Dysfunction-Associated Fatty Liver Disease

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Abstract: With lifestyle changes, the prevalence of metabolic dysfunction-associated fatty liver disease (MAFLD), which accompanied by obesity, has been steadily increasing rising and has become the most common chronic liver disease. MAFLD is a multisystem condition that heightens the risk of liver disease and is concomitantly linked to an increased risk of other metabolic disorders, including cardiovascular and renal diseases. Research indicates that resistant starch (RS), a natural compound, influences MAFLD by dietary intervention, regulation of blood glucose and lipids, and reduction of inflammation. These studies augment our comprehension of the processes through which RS ameliorates MAFLD related disorders. This article examines recent research on the role of gut microbiota in enhancing the condition and progression of MAFLD, along with the therapeutic effects of RS. This study also analyzes the prospective advantages and obstacles of employing RS to treat MAFLD patients. Overall, the available evidence suggests that RS significantly improves MAFLD via the gut microbiota. However, these effects vary depending on the type of RS, the patient population, and gender. We recommend that future studies refine RS classification and usage conditions to optimize its application in MAFLD treatment.

Keywords: Metabolic dysfunction-associated fatty liver disease; Resistant starch; Gut microbiota; Metabolomics; Non-alcoholic fatty liver disease

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1. Introduction

Metabolic Dysfunction-Associated Fatty Liver Disease (MAFLD), previously referred to as non-alcoholic fatty liver disease (NAFLD). In early 2020, a panel of 30 experts from 22 countries reached a consensus on a new definition for MAFLD. This statement delineated precise diagnostic criteria for MAFLD, shifting NAFLD from an

exclusionary to an inclusionary diagnosis [1]. The definition of MAFLD underscores the crucial role of metabolic variables in the development of fatty liver disease. A diagnosis of MAFLD can be established if a patient with fatty liver disease has type 2 diabetes, is overweight or obese, or exhibits at least two additional metabolic variables. MAFLD is a global public health issue, with a current worldwide prevalence as high as 30% and continuing to rise [2]. The disease spectrum of MAFLD ranges from simple steatosis to metabolic dysfunction-associated steatohepatitis (MASH) and liver fibrosis, with potential progression to cirrhosis and hepatocellular carcinoma [3]. It increases the risk of liver disease and is also linked to a heightened risk of other metabolic disorders, including cardiovascular disease and kidney disease [4,5]. Furthermore, given the substantial economic burden associated with this disease, there is an urgent need to enhance public awareness of MAFLD and to implement strategies at both local and global levels to mitigate its detrimental effects [6]. The latest clinical practice guidelines for MAFLD, jointly published by the European Association for the Study of the Liver, the European Association for the Study of Diabetes, and the European Association for the Study of Obesity, recommend non-pharmacological measures for the general population to prevent the occurrence and complications of MAFLD, with an emphasis on strengthening preventive strategies for high-risk groups [7]. In 2024, the U.S. Food and Drug Administration approved the first drug for MASH, Resmetirom [8]. This medication is not yet available in the Chinese market, and dietary adjustments and exercise remain the cornerstones of clinical management for MAFLD. Among these, resistant starch (RS) has been reported to improve hepatic steatosis in MAFLD patients in clinical applications and is gaining increasing attention. RS, as a type of dietary fiber, passes through the small intestine undigested and enters the colon. Its structure or processing renders it “resistant” within the human digestive system. For a long time, the benefits of RS for MAFLD have been recognized [9–11]. This review examines the biological properties of RS, its association with gut microbiota, and its impact on MAFLD via the modulation of gut microbiota, emphasizing gut microbiota as a crucial mechanism by which RS enhances MAFLD conditions. It examines the mechanisms of action of RS and the outcomes from randomized controlled trials, providing a theoretical foundation and direction for clinical therapies in patients with MAFLD.

2. Biological characteristics of RS

Starch is a glucose polymer composed of amylose and amylopectin [12]. Starch provides over 25% of caloric intake in many traditional diets. The human body metabolizes it into glucose for absorption via a variety of enzymes, including amylase and glucosidase [13]. In everyday life, RS dietary fiber is crucial, predominantly located in plant-derived foods including unripe bananas, potatoes, cereals, legumes, and nuts [14]. RS demonstrates exceptional resistance to α-amylase digestion, experiencing no enzyme-mediated hydrolysis and remaining intact in the small intestine. It ultimately arrives at the large intestine unaltered, where it is fermented by the gut microbiota [15]. The initial identification of these compounds transpired in 1982, when Englyst et al. noted that, following the enzymatic breakdown of non-starch polysaccharides in vitro, residual starch persisted in the culture medium [16]. There are five commonly recognized categories of RS: RS1 through RS5. These encompass RS types 1 to 5: RS1 (physically inaccessible starch); RS2 (RS granules); RS3 (retrograded starch); RS4 (chemically modified starch); and RS5 (starch-lipid complex). RS1 is challenging to extract and purify, whereas commercial RS5 products have not yet been launched [17]. Thus, contemporary research on the active constituents and effects of RS predominantly concentrates on the remaining three categories.

3. The relationship between gut microbiota and MAFLD

The gut microbiota comprises a diverse collection of microorganisms residing in the human intestinal tract. This intricate community, consisting of bacteria, viruses, fungi, and other microorganisms, is essential for nutrient absorption, regulation of immune function, and the prevention of harmful pathogen invasion [18–20]. Due to its immense scale and vital role in maintaining health, the gut microbiome is regarded as a "new organ" within the human body [21]. The gut microbiota consists mainly of six fundamental bacterial phyla: *Firmicutes*, *Bacteroidetes*, *Actinobacteria*, *Proteobacteria*, *Verrucomicrobia*, and *Fusobacteria*. Gut dysbiosis is significantly linked to multiple metabolic disorders, such as obesity, metabolic syndrome, diabetes, and liver disease. When gut microbiota dysbiosis occurs, it leads to reduced short-chain fatty acids (SCFAs), impaired intestinal barrier function, and increased intestinal permeability. This allows bacterial components to enter the bloodstream, travel to the liver via the portal vein system, and subsequently trigger or exacerbate inflammatory responses and metabolic disorders in the liver [22]. Research indicates that patients with MAFLD exhibit significant gut dysbiosis, characterized by an increased abundance of pro-inflammatory Proteobacteria and a disrupted balance between the Firmicutes and Bacteroidetes phyla, alongside a reduction in specific beneficial bacteria [23–25]. This dysregulation leads to reduced expression of tight junction proteins, directly impairing intestinal barrier function. This allows harmful microorganisms and their metabolic byproducts to breach the intestinal barrier, stimulating the immune system and inducing inflammatory responses, ultimately accelerating the progression of MAFLD and liver fibrosis [26,27].

4. Regulatory effects of RS on gut microbiota

4.1. Gut microbial degradation of RS

Ruminococcus bromii and *Bifidobacterium adolescentis* are acknowledged as the principal degraders of RS. *Ruminococcus bromii*, a prominent member of the human gut microbiota, features a distinctive amylase structure that enables the formation of multi-enzyme complexes adhering to the cell surface, rendering it a crucial species for RS breakdown [28]. The sugars and acetic acid released by ruminal rumen bacteria during RS degradation serve as substrates for other gut microorganisms lacking RS-degrading capabilities, thereby enabling RS to exert beneficial effects [29,30]. *Bifidobacterium adolescentis* and *Brucella rumenis* exhibit similar functions, capable of degrading RS to produce lactic acid and sugars [31].

4.2. Gut microbiota metabolizes RS into beneficial metabolites

SCFAs are produced by certain gut bacteria through the fermentation of carbohydrates. By diminishing lipid synthesis and enhancing the production of hormones such as PYY and GLP-1 in the intestine, they contribute to the regulation of systemic energy metabolism and foster overall metabolic health [32–34]. Gut microbiota degrades RS to produce SCFAs, primarily acetate, propionate, and butyrate, which are the main end products of RS fermentation in the intestine [35]. The promotion of butyrate production by the RS demonstrates considerable individual variation, which may be associated with initial gut microbiota composition, host genetic background, or dietary patterns [36]. RS dietary supplements positively affect the gut flora by creating a prebiotic effect, hence alleviating symptoms related to metabolic diseases [37–39].

4.3. Clinical research on RS regulation of gut microbiota

The regulating impact of RS on gut microbiota has attracted growing interest. Numerous randomized controlled

trials have shown that RS, irrespective of its origin or dosage, influences its prebiotic physiological effects by affecting the makeup of gut bacteria (**Table 1**). A randomized, double-blind, placebo-controlled clinical experiment assessed the impact of daily doses of 3.5 g and 7 g of Solnul resistant potato starch on beneficial gut microbiota and stool consistency over a duration of 4 weeks. Analysis indicated that, relative to the placebo group, the administration of Solnul resistant potato starch at a daily dosage of 3.5 g over a period of 4 weeks had prebiotic effects, promoting an increase in health-promoting beneficial bacteria while diminishing bowel motions linked to diarrhea and constipation [40]. A randomized placebo-controlled crossover trial involving 37 overweight or obese participants demonstrated that supplementation with RS enhanced outcomes related to obesity. The research demonstrated that gut microbiota plays a crucial role in this effect, with the enrichment of *B.adolescentis* through RS being a significant factor associated with the observed weight loss [41]. Additionally, studies have directly compared the effects of different types of RS (RS2, RS3, and RS5) on the gut microbiota of aged mice. Results indicate that RS5 demonstrates superior efficacy in regulating microbiota and promoting health compared to RS2 or RS3, suggesting it may represent a superior functional ingredient for health maintenance [42]. Overall, RS holds significant value as a functional food ingredient for promoting gut health and preventing metabolic diseases.

Table 1. Regulatory effect of RS on intestinal flora

Resistant starch type	Exist in	Increased abundance	Reduced abundance	Effects on metabolism	Ref
RS1	Found in grains and legumes	*Clostridium* and *Butyricicoccus*	*Bacteroides*, *Lactobacillus*, and *Ruminococcus*	Significant reduction in appetite and decreased postprandial blood glucose levels	[43]
RS2	Found in raw potatoes, green bananas, and raw peas	*Bifidobacterium* and *Ruminococcus*, as well as *Faecalibacterium prausnitzii*, *Roseburia faecis*, and *Akkermansia muciniphila*.	*Bacteroides*, *Odoribacter*, *Dorea*, *Lachnospira*, *Rumi nococcus*, and *Eubacterium*	Reduction of postprandial glucose and leptin, improvement of fasting blood glucose and insulin levels and insulin sensitivity, and reduction of serum total cholesterol and low-density cholesterol	[41,44,45]
RS3	Found in cold rice, bread, and fried foods	*Bifidobacterium*, *Prevotella*, *Ruminococcus*, *Blautia*, *Clostridium*, *Veillonella*, and *Coprococcus*.	*Firmicutes*/*Bacteroidetes ratio*, *Clostridium*, *Enterococcus*, *Streptococcus*, *Leuconostoc*, and *Bacillus*	Reduction of body weight, food intake, total cholesterol, triglyceride, low-density lipoprotein cholesterol levels, and liver fat in mice	[46,47]
RS4	Foods using modified starch (e.g., bread, cakes)	*Clostridia*, *Rothbaryomycetes*, and *Brautobacteria*	*Firmicutes*, and the *Firmicutes/ Bacteroidetes ratio*	Reduces blood sugar and insulin resistance, reduces hunger	[48,49]
RS5	Starch-lipid complexes	*Dialister, Collinsella* , *Megamonas*, *Blauti a*, butyrate-producing bacteria such as *Co prococcus*, *Rosebur ia*, *Bifidobacterium*, and *Butyricicoccus*.	*Bacteroidetes* and *Lactobacillus*	Controls fat deposition in the liver, reduces body weight, and lowers blood sugar and lipid levels	[50]

* RS: Resistant Starch

5. The improvement of MAFLD by RS through the gut microbiota

A healthy diet can reduce the likelihood of obesity and fatty liver disease [51]. Currently, the ketogenic diet, Med-

iterranean diet, and intermittent fasting are all being utilized to improve MAFLD [52–54]. RS is increasingly recognized as an important dietary component, not only for its direct impact on gut health but also for its broader metabolic effects, particularly in relation to metabolic syndrome [55]. Given the critical role of dietary therapy in MAFLD, the corresponding role of RS in MAFLD has also garnered increasing attention (**Table 2**). A review of the literature reveals that alterations in gut microbiota may play a pivotal role in RS-mediated improvement of MAFLD. By increasing beneficial bacteria and reducing harmful bacteria, RS exerts positive effects on MAFLD. Therefore, gut microbiota can be considered a key target for RS in improving MAFLD.

Table 2. Effects of RS on MAFLD-related parameters: evidence from a randomized controlled trial

Types of resistant starch	Subject of intervention	Control subjects	Intervention time	Impact on MAFLD-related indicators	Ref
RS 2	200 participants with NAFLD	Taking control of starch with equal energy supply (CS)	4 months	Absolute reduction in intrahepatic triglyceride content and decreased abundance of *Bacteroides merdae*.	[56]
RS	37 overweight or obese participants	Study participants were randomized into two groups: RS-eluting-CS or CS-eluting-RS	8 weeks	Weight reduction, increased abundance of *Ruminococcus* and *Bifidobacterium*, and decreased abundance of *Bacteroides vulgatus*, *Odoribacter splanchnicus*, *Parabacteroides merdae*, and *Bacteroides vulgatus*.	[41]
RS3	115 patients with hyperlipidemia	Preparation of an identical placebo containing plantain taro natural starch, Ce-NS	12 weeks	Significant reductions in total cholesterol, low-density lipoprotein cholesterol, and non-high-density lipoprotein cholesterol levels.	[57]
RS3	High-fat diet Kunming mice	The negative control group was fed a normal standardized laboratory animal diet, while the blank control group was fed a high-fat diet supplemented with an additional 100 g/kg lard and 10 g/kg cholesterol	4 weeks	Significant reduction in serum total cholesterol, triglycerides, low-density lipoprotein cholesterol and liver fat levels.	[58]
RS5	Mice fed a high-fat diet	Control group 1: received rice starch treated with moist heat; Control 2: received untreated rice starch	8 weeks	Serum oxidative stress levels were significantly improved, and the levels of alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase were reduced	[59]
Natural corn starch (65% RS content)	Rats on a high-fat diet	Received a high-fat diet without added resistant starch	36 weeks	Reduction in total cholesterol, triglyceride, and low-density lipoprotein cholesterol levels, as well as an increase in high-density lipoprotein cholesterol levels	[60]

* RS = Resistant Starch; CS = Control Starch

5.1. The effect of RS on obesity via the gut microbiota

The increasing prevalence and severity of MAFLD are associated with the rising trend of obesity [61]. Because the early stages of MAFLD typically present no obvious symptoms, the prevalence of obesity-driven MAFLD and its subsequent incidence can be considered one of the major health crises of the coming decade [62,63]. Several strains have been demonstrated to exert positive effects in reducing obesity, body weight, and energy intake. *Bifidobacterium* and *Lactobacillus* are the most common probiotic species exhibiting these characteristics [64]. Research indi-

cates that under RS intervention, the abundance of *Lactobacillus* and *Bifidobacterium* increases [65,66]. These lactic acid-producing bacterial communities support the growth and metabolic activity of butyrate-producing bacteria by increasing lactic acid availability, thereby promoting SCFA production to improve obesity and MAFLD [67]. Studies conducted among obese populations indicate that the intake level and intervention duration of high-amylose cornstarch (HA-MRS 2) in the diet are key factors influencing its efficacy. Higher intake levels combined with longer intervention periods yield greater reductions in abdominal fat, more significant weight loss, and improved outcomes in other obesity-related metabolic indicators. An animal study similarly confirmed the dose-response effect of RS: Obese mice were fed potato RS at varying concentrations (5%, 15%, and 25%) for 12 weeks. Results demonstrated that RS alleviated high-fat diet-induced metabolic syndrome in a dose-dependent manner; Its mechanisms include reducing the *Firmicutes*/*Bacteroidetes* (F/B) ratio, regulating the relative abundance of gut microbiota such as *Bifidobacterium*, *Ruminococcus*, *Bacteroides*, and *Faecalibacterium*, and promoting the production of beneficial microbial metabolites like propionic acid and acetic acid [68].

5.2. The effect of RS on liver lipid metabolism via the gut microbiota

The liver is the central regulator of serum cholesterol and triglycerides [69]. When lipid intake exceeds the liver's metabolic capacity, it disrupts triglyceride and cholesterol metabolism, leading to fatty degeneration and lipotoxicity. This promotes the development of metabolic disorders such as MAFLD and hypercholesterolemia [70,71]. Research indicates that RS significantly influences lipid metabolism factors via the gut microbiota, thereby preventing and controlling hyperlipidemia, affecting hepatic lipid metabolism, and improving MAFLD. A recent clinical study first applied RS in MAFLD patients. Over 4 months, RS intake positively impacted hepatic triglyceride levels in MAFLD patients through gut microbiome regulation. Following HAM-RS2 intake by 200 MAFLD patients, an absolute reduction in hepatic triglyceride levels and decreased fecal Bacteroides abundance were observed. This improvement was independent of weight loss [56]. Animal studies also provide compelling mechanistic evidence. In an investigation examining the effects of lotus seed RS on hyperlipidemic mice induced by a high-fat diet and its potential mechanisms, RS intervention significantly reduced weight gain and fat index in high-fat diet mice. It also markedly lowered serum levels of total cholesterol, triglycerides, and LDL-cholesterol while increasing HDL-cholesterol levels. Mechanistic investigations revealed that RS significantly modulated genes associated with fatty acid degradation, fatty acid elongation, and triglyceride metabolism [72]. In another study using a high-fat diet rat model, 36 weeks of intake of a RS-rich corn starch (containing 65% RS) improved serum lipid profiles by reducing total cholesterol, triglycerides, and LDL-cholesterol, and by increasing HDL-cholesterol. Concomitantly, this treatment modulated the gut microbiota, increasing Firmicutes and maintaining Bacteroidetes abundance [60].

5.3. RS modulates hepatic inflammatory responses via the gut microbiota

Reactive oxygen species (ROS) and oxidative stress induced by inflammatory responses are key mechanisms causing hepatocyte damage [73]. Excessive hepatic lipids induce alterations in cellular redox status and accumulation of oxidative damage to biomolecules [74]. Subsequently, excessive ROS production suppresses the capacity of other antioxidant defense systems in MAFLD, leading to further oxidative damage [75]. Compared to healthy individuals, MAFLD is characterized by a reduction in beneficial anti-inflammatory microbes (*Ruminococcus* and *Faecalibacterium*) and an increase in the abundance of harmful pro-inflammatory microbes (*Fusobacterium* and *Escherichia*) [67,76–78]. These alterations indicate that gut microbiota dysbiosis may trigger inflammatory responses in the liver, thereby influencing the progression of MAFLD. Animal studies confirm that RS2 intervention reduces

the abundance of multiple obesity- and inflammation-associated pathogens in mice, such as *Desulfovibrio* and *Ruminiclostridium* 9, demonstrating its potential to antagonize inflammation by regulating the microbiota [79].

5.4. RS maintains stable blood glucose levels through the gut microbiota

Due to its slow absorption rate, RS regulates glucose and insulin levels by lowering fasting and postprandial blood glucose and enhancing insulin sensitivity, thereby promoting glucose homeostasis in the body. In the liver, smaller β-glycogen granules can aggregate into larger composite α-granules. In diabetic mouse models, these hepatic glycogen granules exhibit fragility at the molecular level. A high-RS diet can prevent the fragility of hepatic glycogen α-granules, thereby contributing to blood glucose control. Beyond directly regulating blood glucose, RS can also indirectly influence metabolism through fermentation by gut microbiota. *Clostridium butyricum*, a bacterium that degrades RS, can grow on various types and sources of RS, producing large amounts of butyrate during the degradation process. Butyrate improves insulin sensitivity by enhancing energy expenditure and fat oxidation in the colon. Additionally, research indicates that RS, when fermented by gut microbiota, produces SCFAs that stimulate the release of anorexigenic hormones such as peptide YY (PYY) and glucagon-like peptide-1, thereby increasing satiety and reducing calorie intake. Existing studies have demonstrated the positive effects of adjusting dietary RS intake on glycemic control, insulin sensitivity, and gut health. Human studies also provide direct evidence: In a study involving 37 overweight or obese participants, the effects of RS as a dietary supplement on obesity-related outcomes were examined. Results indicated that RS improves hepatic steatosis and increases insulin sensitivity by modulating the gut microbiota to enhance secondary bile acid production [41].

6. Limitations of RS in MAFLD applications

Despite the significant potential of RS in improving MAFLD, its clinical application remains limited. A cohort study of Korean adults revealed gender-specific associations between RS intake and metabolic syndrome: high RS intake significantly reduced the risk of metabolic syndrome in men, whereas no similar association was observed in women [5]. Furthermore, the mechanism of action of RS is highly dependent on the reconstitution of the gut microbiota. The substantial individual variation in patients' baseline gut microbiome composition is the primary reason for the inconsistent therapeutic efficacy. Patients with more severe gut dysbiosis may require longer intervention periods to observe significant improvement. This suggests that the efficacy of RS intervention may vary depending on gender and individual microbiome characteristics, and future studies should further explore its mechanisms. Current research primarily focuses on patients with mild to moderate MAFLD [56]. Its intervention effects are evident during the simple fatty liver stage. For patients who have progressed to non-alcoholic steatohepatitis (NASH) or liver fibrosis, there is currently insufficient evidence to determine whether resistant starch can reverse liver damage. Overall, while RS represents an innovative intervention strategy for MAFLD, further development of personalized gut microbiota modulation approaches and expanded efficacy assessments in advanced-stage patients are needed to enhance its clinical applicability.

7. Conclusions

The gut microbiota is essential for our health. In the therapy of MAFLD, preserving gut microbiota equilibrium is crucial for hepatic health. Studies demonstrate that dysbiosis is significantly linked to the initiation and advance-

ment of MAFLD. A decline in beneficial bacteria and an increase in pathogenic bacteria may incite inflammatory responses, compromise liver function, and ultimately facilitate the onset of MAFLD. Consequently, modifying and improving gut microbiota composition by RS presents considerable potential for the prevention and treatment of MAFLD. The European Food Safety Authority and the U.S. Food and Drug Administration have both sanctioned health claims for RS in diabetes control, endorsing its application in diabetic treatment. This validates the beneficial impact of RS on metabolic diseases. Nevertheless, investigations of RS in MAFLD, a metabolic disorder similar to diabetes, are limited, a situation that necessitates thorough examination. Nonetheless, current research provides initial insights. Numerous studies suggest that the consumption of RS products beneficially affects fatty liver diseases via gut flora. Significantly, RS encounters difficulties in the treatment of MAFLD. Diverse RS varieties have distinct impacts on gut flora, and individual and gender variations may considerably affect RS responsiveness. Future study requires additional cohort studies focused on specific patient populations, meticulously structured clinical trials, and a comprehensive investigation of RS's molecular processes and therapeutic effectiveness. These investigations will provide a more accurate assessment of appropriate RS intake amounts and varieties, elucidate its function as a viable therapeutic strategy, and yield tailored, evidence-based therapy regimens for MAFLD patients, while guaranteeing the safety and efficacy of RS-based therapies.

Disclosure statement

The authors declare no conflict of interest.

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Design and Application of a New Four-party Collaborative Management Model in the Intelligent Scheduling System for Operating Room

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Abstract: This study targets issues in traditional manual operating room scheduling, including unbalanced resource use, low efficiency, poor inter-departmental communication, and ignored nursing staff personal needs. It developed an integrated surgical scheduling platform to achieve refined, intelligent operating room management while balancing medical quality and humanistic care. Built on the existing Hospital Information System (HIS) with Caché database and Vue + .Net B/S three-tier architecture, the platform integrates five core functions: standardized surgical application, intelligent scheduling, staff rostering, dynamic dispatching, and information collaboration. It combines multi-objective optimization algorithms and Answer Set Programming (ASP) for precise matching of personnel, procedures, time and demands. Comparative analysis was conducted between 66,300 manually scheduled surgeries in 2024 (observation group) and 79,000 surgeries under intelligent scheduling in 2025 (control group). Results showed significant improvements: elective surgery scheduling time reduced by 78.1%, operating room golden time utilization increased by 31.18%, nursing workload balance rose by 27%, nursing emotional exhaustion positive rate decreased by 23%, and nursing turnover reached 0, with enhanced patient experience and staff satisfaction ($p < 0.05$). The platform forms a four-party collaborative management system, realizing efficient resource allocation and providing replicable experience for intelligent operating room management in tertiary hospitals.

Keywords: Intelligent surgical scheduling; Four-party collaboration; Integrated scheduling platform; Data decision-making; Refined management of operating room

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1. Introduction

The operating room is a core diagnosis and treatment unit with high investment and high output in hospitals, and its operational efficiency directly affects the quality of medical services, patient safety and the overall efficiency of hospitals [1–3]. At present, the surgical volume of most large Grade A tertiary hospitals is increasing year by year.

The traditional manual scheduling mode has problems such as uneven human resource allocation, low accuracy of specialist matching, low scheduling efficiency, information asymmetry, and difficulty in taking into account the personalized needs of nursing staff, leading to low utilization efficiency of operating room resources and prominent occupational burnout of nursing staff, which is difficult to adapt to the high-intensity and high-complexity surgical operation needs [4–8].

The Action Plan for Further Improving Nursing Services (2023–2025) issued by the National Health Commission of the People's Republic of China clearly proposes to "promote the informatization construction of nursing and optimize the allocation of nursing resources", which provides a policy basis for the construction of an intelligent scheduling system for operating room [9]. To solve the problems of traditional management and meet the trend of high-quality hospital development and policy requirements, our hospital, as a large Grade A tertiary hospital with more than 3000 beds, launched the construction project of an integrated surgical scheduling platform in 2024, and innovatively constructed a new four-party collaborative management model of "surgical scheduling-human resource allocation-quality supervision-humanistic care". Through technological innovation and process reengineering, we realized the intelligent surgical scheduling, accurate human resource allocation and refined operation management, providing practical reference for the management upgrading of operating room in large Grade A tertiary hospitals.

2. Demand analysis and system design

2.1. System design objectives and demand analysis

2.1.1. Design objectives

Focusing on the pain points of operating room operation and management, the system set four core design objectives:

(1) Improve scheduling efficiency

Replace manual scheduling with automated and intelligent means, reduce tedious operations and human errors, and shorten scheduling time and emergency response time;

(2) Optimize resource allocation

Realize dynamic matching of operating room, nursing staff and surgical needs, and improve the utilization rate of operating room resources and the balance rate of human resource load;

(3) Ensure medical quality

Improve the accuracy of specialist matching, reduce the rate of surgical delay and the incidence of adverse nursing events, and strengthen the whole-process quality supervision of surgeries;

(4) Highlight humanistic care

Take into account the personalized scheduling needs of nursing staff, reduce overtime hours, alleviate occupational burnout, and improve the occupational satisfaction and team stability of nursing staff.

2.1.2. Demand analysis

Combined with the actual clinical operation needs, the system needs to meet four core demands:

(1) Standardization of surgical application

Establish a standardized application process and verification mechanism, reduce invalid surgical preparation, and improve the accuracy of application information;

(2) Intelligence of scheduling algorithm

Integrate multi-dimensional data to build an optimization algorithm, realize the automatic generation of surgical scheduling and staff rostering, and support flexible manual adjustment;

(3) Dynamization of dispatching process

Real-time collection of surgical status information, realize the visualization of surgical process, and improve the response speed of emergency dispatching;

(4) Collaboration of information interaction

Break the information isolated islands of multiple departments, realize the real-time information sharing among doctors, nurses and managers, and reduce communication costs;

(5) Humanization of scheduling management

Support nursing staff's application for desired shifts and shift adjustment, and establish a working load control mechanism to meet personalized needs.

2.2. System development and architecture design

2.2.1. Development tools and technologies

(1) Development tools

Caché database; System mode: B/S structure (Browser/Server); Development architecture: Vue + .Net front-end and back-end separation mode, building a three-tier architecture with separate client-server-database.

(2) System docking

Realize data intercommunication with the hospital's existing information systems such as HIS, Laboratory Information System (LIS) and surgical anesthesia information management system, and complete the extraction, cleaning and fusion of multi-source data through ETL tools;

(3) Terminal support

Compatible with multi-terminal access such as computers, mobile phones, operating room announcement large screens and mobile ward-round PDAs to meet the use needs of different clinical scenarios.

2.2.2. Overall system architecture

The architecture of the intelligent surgical scheduling system is divided into four layers, and each layer collaborates and links to realize the whole-process flow of data and the efficient implementation of functions. The architecture is as follows:

(1) Data source layer

Provides basic data support for system operation, integrates multi-dimensional data such as basic patient information, surgical plans, clinical surgical pathways, surgical risk levels, nursing staff qualifications, specialist capabilities and scheduling wishes, and realizes unified data collection and storage;

(2) Data middle platform layer

As the core data processing unit of the system, it is responsible for data cleaning, verification, fusion and security control, builds a dynamically updated surgical duration prediction database and staff capability database, and provides high-quality data services for upper-layer applications through standardized processing;

(3) System application layer

The core function implementation unit of the system, including five core modules: standardized surgical application, intelligent scheduling, staff rostering, dynamic dispatching and information collaboration. It

integrates surgical management rules and multi-objective optimization algorithms to realize the intelligent operation of various business functions;

(4) Terminal equipment layer

Responsible for the terminal display of system functions and data, supports real-time multi-terminal access and operation, and realizes the multi-channel release and real-time query of surgical scheduling information, staff rostering information and surgical process information.

2.2.3. Design of core function modules

Centering on the new four-party collaborative management model, the system developed five core function modules, which are connected with each other to form a whole-process surgical operation management system of "application-scheduling-dispatching-collaboration-supervision".

(1) Standardized surgical application module

A standardized surgical application process was established, with clear rules such as no application for elective surgeries after 13:00 and no repeated surgical applications on the same day; A real-name reminder and mandatory cancellation mechanism for non-real-name (NA) surgeries was added, with SMS reminders for unreal-named surgeries at 15:30 and automatic cancellation of surgeries with incomplete information at 17:30 to improve the real-name rate of surgeries; Based on the hospital's 3-year surgical historical data, the median reference value was provided for the filling of estimated surgical duration, the surgical adaptability was automatically verified combined with surgical admission criteria, the filling of surgical remark information was standardized, and the invalid surgical preparation and cross-department communication costs were reduced.

(2) Intelligent scheduling module

Integrated 12 types of core data in four dimensions: surgical scheduling, nursing staff qualifications, surgical types, surgical risk levels and humanistic needs, and built a multi-objective optimization algorithm model, taking into account the four objectives of "load balance, specialist matching, optimal efficiency and humanistic care"; Based on Answer Set Programming (ASP) technology, the qualifications, specialist capabilities and personalized needs of nursing staff were converted into logical constraints to realize the automatic generation and optimization of scheduling schemes. The core functions include: ① Automatic main schedule arrangement, arrange main schedule surgeries with one click according to specialist allocation rules, surgical duration prediction data and surgical priority, and automatically generate a waiting queue for non-main schedule surgeries; ② Automatic follow-up schedule arrangement, distinguish follow-up schedule surgeries with color markers, support one-click multiple automatic follow-up schedule arrangements, control the interval between follow-up schedules within 60 minutes, and make full use of the golden time of operating room; ③ Surgical duration prediction, take surgical type, attending surgeon, patient age and other factors as characteristic variables, build a prediction model with random forest algorithm, the prediction accuracy is 40% higher than that of traditional empirical estimation, and realize the preview of surgical process and balanced allocation of resources.

(3) Staff rostering module

It includes two functions: monthly scheduling and daily scheduling, integrating ASP technology and humanized design to realize the accurate and personalized rostering of nursing staff: ① Monthly scheduling, supporting the arrangement of regular shifts, on-call shifts and leave such as parental leave,

home leave and breastfeeding leave, and can automatically generate the next month's staff grouping and shift cycle, solving the problems of difficult sharing of scheduling information and hard to find historical data; ② Daily scheduling, integrating information such as nurses' rotating specialist, capability level, recent shifts and consecutive working hours, automatically arranging suitable nurses first, supporting interface-based fine adjustment, and eliminating missed scheduling; ③ Personalized application, adding the function of applying for shift adjustment and desired shifts, realizing the online submission and approval of nursing staff's scheduling needs, and improving the demand satisfaction rate; ④ Load control, establishing a nurse's consecutive working hours management mechanism, automatically calculating consecutive working hours, and giving red warnings for high-intensity work events exceeding 5 hours to prevent occupational burnout.

(4) Dynamic dispatching module

Realize the whole-process dynamic management of surgeries, and improve the emergency dispatching capacity and quality supervision level: ① Real-time ward round, collect surgical status information in real time through the mobile ward round function, shorten ward round time and reduce the number of ward rounds; ② Process visualization, present the estimated end time and actual process of surgery in the form of Gantt chart, providing accurate data support for emergency operations such as adding, canceling and adjusting surgical schedules; ③ Efficient handover, release handover arrangement information with one click, shorten handover time and improve work efficiency; ④ Risk early warning, the system automatically reminds risk information such as abnormal infection screening and abnormal patient physical signs, and realizes early warning of surgical risks combined with the Clinical Decision Support System (CDSS) to reduce the surgical cancellation rate.

(5) Information collaboration module

Construct an information release system with multi-department linkage including operating room, clinical departments and nursing department, realizing a high degree of consistency of information among doctors, nurses and managers: ① Operating room announcement large screen, displaying surgical staff rostering information, shift color distinction and yesterday's consecutive working hours warning in real time, facilitating the chief nurse's overall dispatching; ② WeChat Work push, medical staff can query surgical arrangements, processes and handover information online at any time, reduce the number of inquiries out of the operating room, and improve work concentration; ③ Nursing management system sharing, nurse shift information and consecutive working hours are transmitted back to the nursing management system with one click, reducing the workload of manual statistics and improving management efficiency. Through multi-channel information collaboration, the cross-department communication time is greatly shortened and the coordination efficiency is improved.

2.3. System implementation guarantee

2.3.1. Organizational guarantee

A "1 + 4 + N" management model was adopted to ensure the implementation of the system: the vice president of the hospital served as the leader to coordinate project planning and resource allocation; Four core groups were set up, including a technical R&D group (Information Department + software engineers), a clinical implementation group (operating room scheduling group), a quality evaluation group (department quality control group) and a humanistic care group (nurse representatives at all levels), responsible for system development, clinical testing,

effect evaluation and personalized demand guarantee respectively; Linkage with N collaborative departments such as Information Data Processing Center, Medical Engineering Department and Medical Affairs Department to form a multi-department linkage mechanism.

2.3.2. System and fund guarantee

Formulated the Implementation Plan of AI Intelligent Scheduling System for Operating Room and Specifications for System Data Security Management, established a system of "weekly review, monthly evaluation and quarterly summary", and timely collected clinical feedback to optimize system functions; The hospital allocated special funds covering the whole process of AI algorithm development, hardware upgrading and staff training to ensure the orderly progress of the project.

2.3.3. Phased implementation

A three-stage implementation strategy of "pilot-promotion-optimization" was adopted:

(1) Pilot stage (January-March), selected 2 specialist operating room in the Department of General Surgery to carry out the pilot, focusing on verifying the adaptability and system stability of surgical scheduling, and collecting clinical feedback to iterate the system version;

(2) Promotion stage (April-June), carried out general training in 3 batches, covering all chief nurses of surgical scheduling, and established a "system communication group" to provide real-time technical support;

(3) Optimization stage (July to present), dynamically adjusted algorithm parameters based on system operation data, incorporated nursing staff's professional title promotion needs and specialist development wishes into scheduling considerations, and continuously improved system functions.

3. Results

3.1. Research data

The integrated surgical scheduling platform was fully and officially put into operation in our hospital in January 2025, and the system operated stably. The data of 66,300 manually scheduled surgeries in the operating room of our hospital from January to December 2024 were selected as the observation group, and the data of 79,000 intelligently scheduled surgeries after the system application in 2025 were selected as the control group. There were no significant differences in baseline data such as the number of operating room (58), the scale of nursing staff and the distribution of surgical departments between the two groups ($p > 0.05$), which were comparable.

3.2. Evaluation indicators

14 evaluation indicators in 4 categories including surgical scheduling efficiency, resource utilization efficiency, nursing human resources and quality, and humanistic care and team stability were selected to comprehensively evaluate the application effect of the system:

(1) Surgical scheduling efficiency indicators

Scheduling time of elective surgeries, emergency response time for adjusting/adding surgical schedules, surgical delay rate, standardized rate of surgical application;

(2) Resource utilization efficiency indicators

Average daily surgical volume per operating room, total surgical volume of operating room, utilization

rate of golden time in operating room, standard deviation of operating room usage time;

(3) Nursing human resources and quality indicators
Balance rate of nursing human resource load, accuracy of specialist matching;

(4) Humanistic care and team stability indicators
Satisfaction rate of nursing staff's desired shifts, average daily overtime hours of nursing staff, positive rate of emotional exhaustion of nursing staff, turnover rate of nursing staff.

3.3. Statistical analysis

SPSS AU software was used for statistical analysis. Measurement data were expressed as ($\overline{x} \pm s$) and tested by *t*-test; Count data were expressed as rate (%) and tested by χ^2 test. $p < 0.05$ was considered statistically significant.

3.4. System application effect

After the application of the integrated surgical scheduling platform, all evaluation indicators were significantly improved compared with before the application, realizing the dual improvement of surgical scheduling efficiency and resource utilization efficiency, and at the same time greatly optimizing the allocation of nursing human resources, enhancing humanistic care and team stability. The differences between the two groups in all indicators were statistically significant ($p < 0.05$). The specific results are shown in **Table 1**.

Table 1. Comparison of various evaluation indicators of operating room operation and management between the two groups

Indicator category	Specific indicator	Before system application (2024)	After system application (2025)	Improvement effect
Surgical scheduling efficiency	Scheduling time of elective surgeries	410 min	90 min	78.1% efficiency improvement
	Emergency response time for adjusting/adding surgical schedules	30 min	10 min	66.7% response speed improvement
	Surgical delay rate	3.50%	0.80%	2.7% reduction
	Standardized rate of surgical application	58%	89%	31% improvement
Resource utilization efficiency	Average daily surgical volume per operating room	4.55 cases/room	4.76 cases/room	0.21 cases/room increase
	Total surgical volume of operating room	66,300 cases	79,000 cases	19.15% growth
	Utilization rate of golden time in operating room	60.86%	92.04%	31.18% improvement
	Standard deviation of operating room usage time	2.81 h	2.13 h	0.68 h reduction
Nursing human resources and quality	Balance rate of nursing human resource load	65%	92%	27% improvement
	Accuracy of specialist matching	85%	98%	13% improvement
Humanistic care and team stability	Satisfaction rate of nursing staff's desired shifts	65%	88%	23% improvement
	Average daily overtime hours of nursing staff	4.2 h	3.5 h	0.7 h reduction
	Positive rate of emotional exhaustion of nursing staff	45%	22%	23% reduction
	Turnover rate of nursing staff	1.38%	0	Zero turnover achieved

After the application of the system, the operation and management of the operating room in our hospital has realized three major transformations: ① Transformation from empirical decision-making to data-driven decision-

making, managers can monitor indicators such as nursing human resource load, surgical efficiency and quality safety in real time, and optimize the allocation of operating room and nursing staff training plans based on data; ② Transformation from decentralized resources to collaborative sharing, breaking the information isolated islands of multiple departments and realizing the intensification, common use and sharing of operating room resources; ③ Transformation from efficiency priority to both efficiency and humanism, while improving operational efficiency, fully meeting the personalized needs of nursing staff and alleviating occupational burnout.

In addition, through the optimal allocation of human resources and efficiency improvement, our hospital has reduced the additional costs such as repeated disinfection of instruments and overtime subsidies caused by surgical delays and personnel mismatches, saving more than one million yuan in annual operating costs; This project won the second prize in the 2025 Annual Excellent Case Collection Activity for Improving Nursing Services of Guangdong Nursing Association, attracted 24 hospitals to conduct research and study, and formed 4 hospital internal standards which were incorporated into the hospital operation management system.

4. Discussion

4.1. System innovation points

The core innovation of the integrated surgical scheduling platform constructed in this study is to create a new four-party collaborative management model of "surgical scheduling-human resource allocation-quality supervision-humanistic care", which breaks through the limitations of the traditional intelligent scheduling system of "emphasizing efficiency, neglecting quality and lacking humanism", and realizes the all-round upgrading of operating room operation and management. The main innovations are reflected in three aspects:

(1) Algorithm and technological innovation

Integrate multi-objective optimization algorithm and machine learning technology, build an algorithm model covering 12 types of core data, break through the limitations of traditional single-objective algorithms, and realize the four objectives of efficiency, quality, fairness and humanism at the same time; Combine ASP technology to convert the personalized needs of nursing staff into algorithm constraints, realize the accurate matching of "person-procedure-time-demand", and improve the scientificity and humanization of scheduling.

(2) Management model innovation

Incorporate quality supervision and humanistic care into the whole-process management of operating room scheduling, build a new four-party collaborative management ecosystem, and break the traditional management barriers of operating room of "emphasizing scheduling, neglecting supervision and ignoring humanism"; Establish a mechanism of "nursing staff participating in scheduling decision-making", realize the transformation of nursing staff from "passively accepting scheduling" to "actively participating in management", and enhance team sense of belonging and cohesion.

(3) Value realization innovation

Realize a win-win situation for patients, nursing staff and hospitals. At the patient level, the surgical delay rate is significantly reduced, the surgical process is more controllable, and the patients' medical experience and surgical safety are greatly improved; At the nursing staff level, the work load is more balanced, personalized needs are met, occupational burnout is alleviated, and team stability is significantly enhanced; At the hospital level, without increasing hardware investment such as operating room, the

surgical undertaking capacity is greatly improved, the operating cost is reduced, and a replicable and promotable refined management model is formed.

4.2. Application experience

(1) High-quality data is the basis for the accurate operation of the system

The intelligent operation of the system relies on multi-dimensional and high-quality basic data. In clinical application, it is necessary to establish a standardized data collection and verification mechanism, standardize the entry of information such as surgical name, surgical duration and staff qualifications to ensure the accuracy and integrity of data; At the same time, establish a dynamic data update mechanism, timely incorporate the latest surgical data and staff information, and improve the prediction accuracy and adaptability of the algorithm model.

(2) Humanistic care is the key to the sustainable operation of the system

Nursing staff in the operating room have high work intensity, and personalized scheduling needs are an important factor to improve their occupational satisfaction. In the design and operation of the system, while pursuing operational efficiency, it is necessary to fully consider the needs of nursing staff for desired shifts, shift adjustment and work load, and balance clinical operation needs and personal wishes through humanized function design to realize the organic unity of efficiency and humanism.

(3) Multi-department linkage is the guarantee for the implementation of the system

The intelligent surgical scheduling system involves multiple departments such as operating room, Information Department, Nursing Department and clinical departments. The construction and operation of the system need to clarify the responsibilities of each department, establish an efficient cross-department communication and data sharing mechanism, break information isolated islands, and ensure the smooth connection of the whole process of surgical application, scheduling, dispatching and execution.

(4) Regular optimization is the core of the system's adaptive development

Medical needs and hospital operation environment are constantly changing. The system needs to establish a regular iteration mechanism of "clinical feedback-data evaluation-function optimization", dynamically adjust algorithm parameters and improve function modules according to the actual clinical operation situation to ensure that the system is always adapted to the needs of the hospital's high-quality development.

4.3. Limitations and prospects

This study has certain limitations: First, the research data are all from a single center of our hospital, the sample has geographical and case type limitations, and the adaptability of the system and algorithm model in other types of hospitals still needs to be further verified; Second, the system is currently mainly aimed at the scheduling optimization of elective surgeries, the scheduling of emergency surgeries still needs partial manual intervention, and the intelligent level of emergency scheduling needs to be improved.

In the future, our hospital will optimize and expand the system from three aspects: ① Improve the emergency surgical scheduling algorithm, combine factors such as the severity of patients' condition, surgical priority and real-time status of operating room resources, build an intelligent emergency scheduling model for emergency surgeries, and improve the resource allocation capacity in emergency situations; ② Realize the whole-process closed-loop management, develop the integrated function of scheduling and appointment, deeply link the

system with the patient's pre-operative examination appointment system, realize the whole-process closed-loop management of patients' pre-operative examination, surgical appointment, scheduling and execution, and further improve the patients' medical experience; ③ Expand the application scope of the system, promote the scheduling logic and management concept of this system to other hospital operation links such as outpatient appointment and bed dispatching, and realize the optimal allocation of the whole hospital's resources; At the same time, refine the classification of nurses' specialist proficiency, improve the function of specialist capability map, and realize a more accurate matching between nursing staff and surgical types.

In addition, we will carry out multi-center research in conjunction with other hospitals of different grades and types to verify the universality and adaptability of the system, further optimize the algorithm model, and provide more universal practical experience for the refined and intelligent management of operating room in hospitals at all levels across the country.

5. Conclusion

Through technological innovation and process reengineering, the integrated surgical scheduling platform integrates surgical management concepts and multi-objective optimization algorithms, and constructs a new four-party collaborative management model of "surgical scheduling-human resource allocation-quality supervision-humanistic care", which effectively solves the pain points of unbalanced resource utilization, low scheduling efficiency, prominent communication barriers and insufficient humanistic care under the traditional manual scheduling mode. After the application of the system, the scheduling efficiency and resource utilization efficiency of the operating room are significantly improved, the accurate allocation of nursing human resources is realized, the medical quality supervision is strengthened, and at the same time, humanistic care is highlighted, the occupational satisfaction and team stability of nursing staff are improved, and the transformation of operating room operation management from experience-driven to data-driven is realized. The platform provides a feasible path and practical experience for the refined and intelligent management of operating room in large Grade A tertiary hospitals, and has important promotion and application value.

Disclosure statement

The authors declare no conflict of interest.

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Preliminary Experience on the Safety and Efficacy of Laparoscopic Choledochojejunostomy Reconstruction for Anastomotic Stenosis After Choledochojejunostomy

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Abstract: *Objective*: To evaluate the safety, feasibility, and key surgical techniques of laparoscopic choledochojejunostomy reconstruction for anastomotic stenosis following biliary-enteric internal drainage surgery. *Methods*: The clinical data of 5 patients with anastomotic stenosis after biliary-enteric internal drainage surgery, admitted to The First Affiliated Hospital of Hunan Normal University between March 2025 and August 2025, were retrospectively reviewed and analyzed. All patients provided written informed consent, and the study was conducted in compliance with medical ethics standards. There were 3 males and 2 females, with an age range of 10–45 years and a median age of 17 years. Outcome measures included operation time, intraoperative blood loss, postoperative anal exhaust time, postoperative hospital stay, and perioperative complications. *Results*: All 5 patients successfully underwent laparoscopic choledochojejunostomy reconstruction without conversion to open surgery. The operation time ranged from 220 to 380 minutes (median, 235 minutes), and the intraoperative blood loss was 20–80 mL (median, 50 mL), with no blood transfusion required in any case. T-tube drainage was performed in 2 patients. The postoperative anal exhaust time was 1–2 days (median, 2 days), and the postoperative hospital stay was 5–7 days (median, 6 days). No perioperative complications occurred in any patient. *Conclusion*: Laparoscopic choledochojejunostomy reconstruction is a safe and feasible surgical approach for anastomotic stenosis after biliary-enteric internal drainage surgery, offering advantages of minimal invasiveness and a low incidence of perioperative complications.

Keywords: Laparoscope; Biliary-enteric anastomotic stricture; Biliary-enteric anastomotic reconstruction

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1. Introduction

As a commonly used clinical procedure, biliary-enteric drainage plays a key role in the treatment of diseases such

as liver and bile duct stones, common bile duct cysts, bile duct injuries, and reflux cholangitis [1]. It can effectively improve bile drainage and prolong patient survival. However, anastomotic stenosis is a common complication after surgery, which not only leads to recurrent biliary obstruction, but also can cause cholangitis, biliary cirrhosis, and even liver failure, seriously affecting the quality of life and long-term prognosis of patients [2]. The existing treatment methods include endoscopic or percutaneous dilation and stent placement, open anastomosis reconstruction, etc [3,4]. Although endoscopic and interventional procedures have minimal trauma, the recurrence rate is relatively high and the duration of patency maintenance is limited [5]. Although open surgery can achieve long-lasting patency, the surgical trauma is large, postoperative recovery is slow, and the difficulty of reoperation often increases due to abdominal adhesions. How to reduce surgical trauma while ensuring therapeutic efficacy remains a clinical challenge.

With the development and popularization of minimally invasive techniques, the application of laparoscopic surgery in biliary reconstruction has gradually attracted attention. It has the advantages of enlarging the field of view, clear anatomy, and minimal trauma, which can improve surgical safety and reduce patient recovery time while ensuring surgical effectiveness [6]. At present, there are several large clinical diagnosis and treatment centers in China that have accumulated rich experience and are proficient in using laparoscopic technology to perform anastomotic reconstruction surgery for patients with biliary-enteric anastomotic stenosis who have undergone two or more surgeries [7]. In this study, laparoscopic cholestochojejunostomy reconstruction was performed on 5 cases of bile intestinal anastomosis stenosis, achieving good clinical efficacy. The summary report is as follows.

2. Data and methods

2.1. General information

Retrospective analysis of clinical data of 5 patients admitted to the Hepatobiliary Surgery Department of the First Affiliated Hospital of Hunan Normal University (Hunan Provincial People's Hospital) from March 2025 to August 2025 who underwent laparoscopic cholestochojejunostomy reconstruction due to bile intestinal anastomosis stenosis. Among them, there were 3 males and 2 females; The age range is 10–45 years old, with a median age of 17 years old. The cause and surgery of the first biliary-enteric anastomosis: 2 cases of liver and bile duct stones, underwent biliary exploration and stone removal combined with biliary-enteric drainage surgery; Three cases of congenital choledochal cyst were treated with choledochal cystectomy combined with biliary-enteric drainage. The time interval between the first anastomosis and narrow reconstruction was 16–126 months, with a median time of 61 months. General information is detailed in **Table 1**. Diagnostic criteria for biliary-enteric anastomotic stenosis: A history of biliary-enteric drainage surgery and the following conditions:

(1) The patient has recurrent symptoms such as abdominal pain, chills, fever, jaundice, and imaging examinations such as CT, magnetic resonance cholangiopancreatography (MRCP), and percutaneous transhepatic cholangiography (PTC) suggest anastomotic stenosis [8].

(2) During the operation, it was found that the bile duct anastomotic site was narrow, resembling a needle tip, and the bile duct was dilated at or above [9].

Table 1. General information of five patients

Sequence	Gender	Age (Year)	BM (kg/m^2)	Basic disease	Preoperative CT/MR	First surgery	Time interval between two surgeries (Month)
1	Male	37	25.3	None	Anastomotic stenosis	Intrahepatic bile duct stone extraction, Choledochojejunostomy	38
2	Male	45	23.6	None	Anastomotic stenosis, Bile duct stones	Intrahepatic bile duct stone extraction, Choledochojejunostomy	16
3	Male	12	19.4	None	Anastomotic stenosis, Bile duct stones	Congenital Dilated Bile Duct Resection Choledochojejunostomy	126
4	Female	17	22.6	None	Anastomotic stenosis, Bile duct stones	Congenital Dilated Bile Duct Resection Choledochojejunostomy	118
5	Female	10	18.2	None	Anastomotic stenosis	Congenital Dilated Bile Duct Resection Choledochojejunostomy	61

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Diagnosed with biliary anastomotic stenosis and laparoscopic choledochojeunostomy reconstruction;
(2) Previously underwent biliary-enteric drainage surgery;
(3) The general condition is good and the patient can tolerate surgery;
(4) Clinical and follow-up data are complete.

2.2.2. Exclusion criteria

(1) Choledochojejunostomy reconstruction under laparoscopy due to other factors such as intestinal obstruction and perforation;
(2) The general condition is good and the patient cannot tolerate surgery;
(3) Lost to follow-up or incomplete clinical data.

2.3. Surgical methods

Under general anesthesia, adopt a supine split leg position, with the head high and feet low, and a five hole layout (see **Figure 1** for details). Place a 12 mm puncture sheath on the navel. After the construction of pneumoperitoneum is completed, the principle is to first place a puncture sheath in the left non adhesive area (in this case, a 12 mm puncture sheath is placed under the rib margin of the left clavicle midline); Place a 12 mm puncture sheath above the navel on the midline of the left clavicle, and use an ultrasonic knife combined with scissors to release the adhesion between the abdominal wall, omentum, and intestinal tract. After the separation of abdominal wall adhesion, a right puncture sheath is inserted (in this case, a 5 mm puncture sheath is placed below the rib margin of the right clavicle midline); Place a 5 mm puncture sheath above the navel on the right axillary line. Adhering from the right edge of the liver towards the hepatic hilum (**Figure 2a**), residual hepatic circular ligament is exposed, and the hepatic hilum is exposed along the hepatic circular ligament approach. Finally, the enlarged biliary-enteric anastomosis and dilated bile duct are revealed (**Figure 2b**); Open the biliary-enteric anastomosis, use an 11Fr cholangioscopy to explore the bile duct, take stones from the stone basket and

exclude intrahepatic bile duct stenosis (**Figure 2c**, **d**), further free the extrahepatic bile duct, cut off scar bile duct tissue with scissors (**Figure 2e**), extend the incision along the longitudinal axis of the anterior wall of the common hepatic duct, and expose the left and right hepatic duct openings as much as possible in the lumen; Free the input loop and check the intestinal anastomosis to ensure that the length of the input loop intestinal tube is sufficient and the tension is appropriate. Then, use a 4-0PDS suture to reconstruct the biliary intestinal anastomosis (**Figure 2f**). For patients who may have residual stones, the diameter of the reconstructed anastomosis is still relatively small, and the inflammation of the tube wall is severe, which increases the possibility of anastomotic leakage after surgery. Place a T tube at the anastomosis site. Finally, fix the end of the intestinal ring onto the circular ligament of the liver to reduce anastomotic tension.

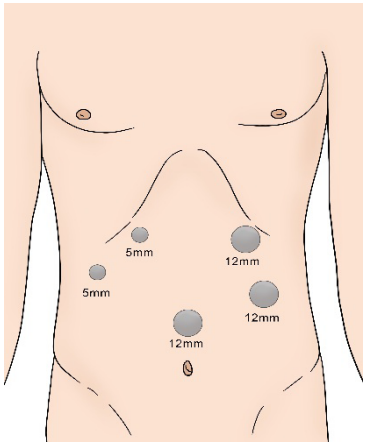
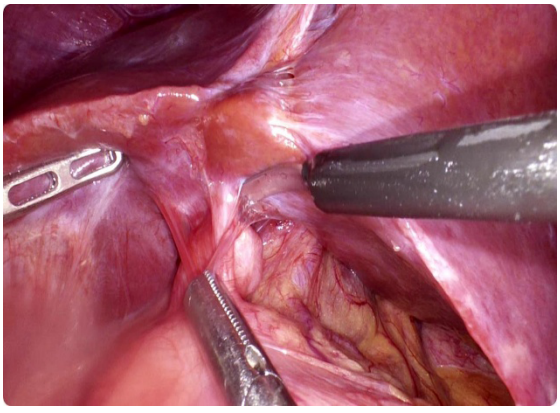
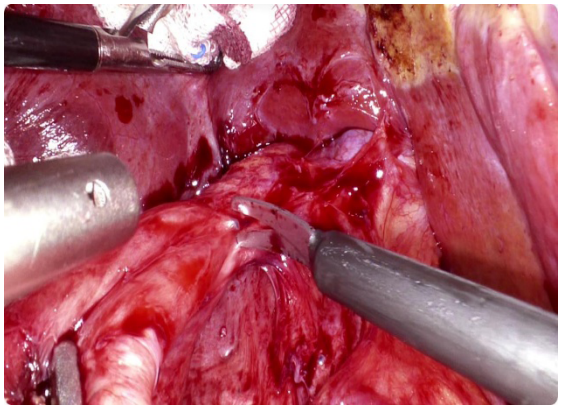


Figure 1. Distribution of surgical puncture sheaths in sequence two patients.



a



b

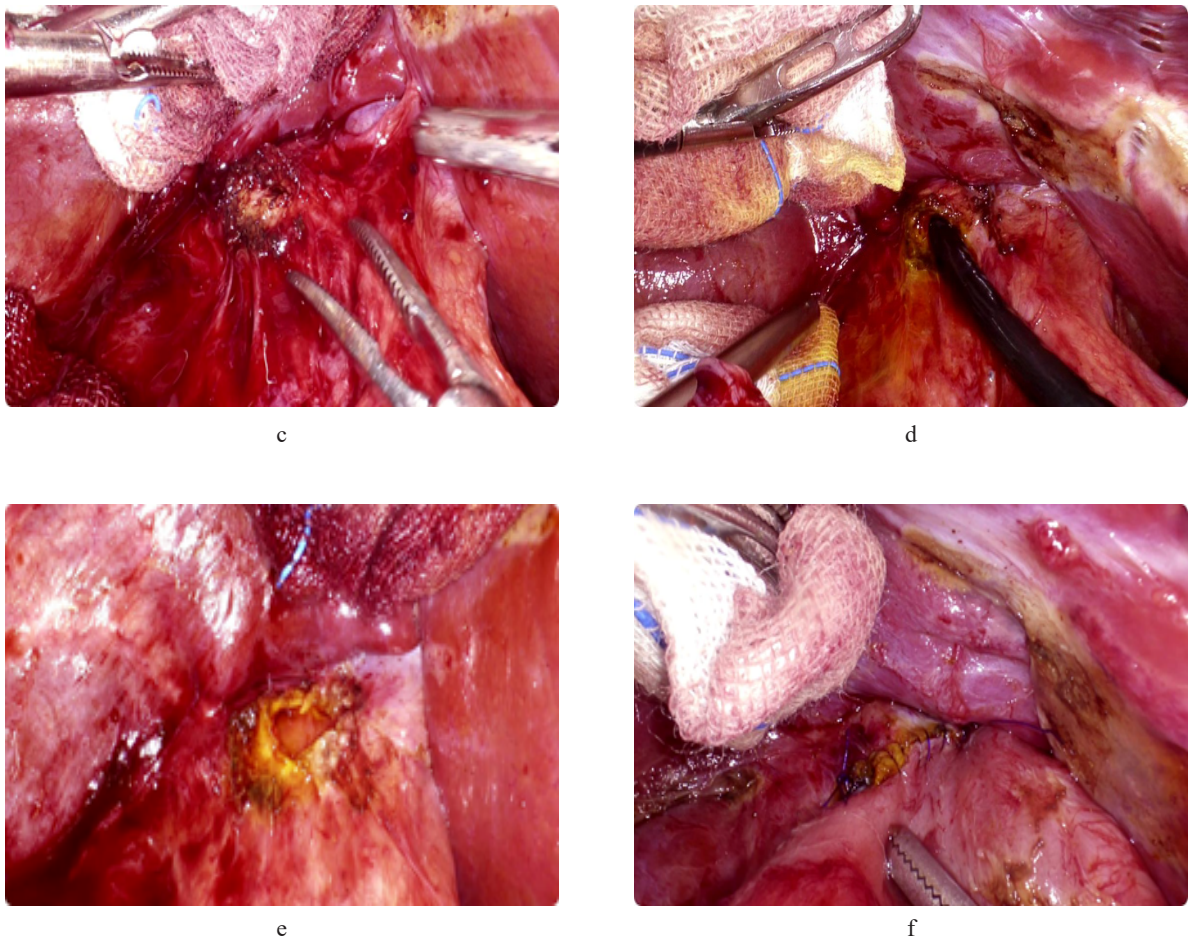


Figure 2. Schematic diagram of laparoscopic choledochojejunostomy reconstruction surgery performed on patient 2 in sequence.

Note: a represents the separation of intestinal tract and liver adhesions; B is to expose the original biliary-enteric anastomosis; C shows a narrow biliary-enteric anastomosis when the anastomotic site is opened; D is for cholangioscopy exploration and stone extraction; E is to dilate the mouth and open it for intestinal anastomosis; F is for reconstruction of biliary intestinal anastomosis.

2.4. Observation indicators

Intraoperative conditions include surgical time and intraoperative bleeding volume. Postoperative conditions include postoperative anal exhaust time, postoperative hospital stay, and postoperative complications (bleeding, bile leakage, intestinal leakage, infection, secondary surgery). Recent therapeutic effects include clinical recurrence of cholangitis, antibiotic use, and re intervention rate during postoperative follow-up; Biochemical changes: alkaline phosphatase (ALP), glutamine transferase (GGT), total bilirubin, and trend of direct bilirubin ratio (TB/DB); All patients received follow-up after surgery, with a follow-up period of 4–9 months.

3. Results

3.1. Surgery and recovery

All 5 patients underwent laparoscopic reconstruction of the biliary-enteric anastomosis and none were converted

to open surgery. The operation time was 220–380 minutes, with a median time of 235 minutes; The intraoperative bleeding volume was 20–80 mL, with a median bleeding volume of 50 mL, and no blood transfusion was administered. Among them, 2 patients were placed with a T-tube, and the postoperative anal exhaust time was 1–2 days, with a median time of 2 days. The postoperative hospitalization time was 5–7 days, with a median time of 6 days. All 5 patients did not experience perioperative complications, Including readmission within 30 days, bile leakage, infection, intestinal fistula, intra-abdominal abscess, bleeding re intervention, etc. The specific patient information is shown in **Table 2,3,4**.

Table 2. Perioperative situation of five patients

Sequence	Operation time (min)	Intraoperative blood loss (mL)	Retain T tube	Postoperative anal exhaust time (d)	Complication	Postoperative hospitalization time (d)
1	235	50	No	2	None	5
2	380	80	No	2	None	6
3	230	50	Yes	1	None	7
4	220	20	Yes	1	None	6
5	260	20	No	2	None	7

Table 3. Biochemical indicators during the perioperative period and follow-up of five patients

Sequence / Indicator	Alkaline phosphatase (ALP)			Glutamine transferase (GGT)			Total bilirubin/Direct bilirubin (TB/DB)		
	Preoperative value (U/L)	Postoperative value (U/L)	After follow-up (U/L)	Preoperative value (U/L)	Postoperative value (U/L)	After follow-up (U/L)	Preoperative value	Postoperative value	After follow-up
1	246	182	106	120	96	72	2.63	2.65	2.62
2	136	140	98	66	74	50	3.74	2.51	2.47
3	375	328	100	180	172	58	1.27	1.42	2.03
4	184	190	76	112	106	42	3.14	4.12	3.84
5	120	134	86	68	82	32	2.16	1.83	1.96

Table 4. Postoperative complications and recent efficacy of five patients

Sequence	Recurrence of cholangitis	Application of antibiotics	reintervention rate	Narrowing again	Smooth anastomosis	30-day readmission
1	None	None	None	None	Yes	No
2	None	None	None	None	Yes	No
3	None	None	None	None	Yes	No
4	None	None	None	None	Yes	No
5	None	None	None	None	Yes	No

4. Discussion

Bile intestinal anastomosis stenosis is one of the most challenging complications after biliary reconstruction surgery. Previous treatments include endoscopic dilation, stent placement, interventional therapy, and open

surgery, but these methods have limitations such as high recurrence rates, decreased quality of life, or significant surgical trauma. In contrast, laparoscopy not only has curative effects, but also has minimally invasive advantages, which can reduce patient pain and recovery time while ensuring therapeutic efficacy. The results of this study are consistent with previous reports, further verifying the feasibility of laparoscopy in clinical applications [10]. This study combines case data and surgical experience to explore the causes of anastomotic stenosis and precautions for laparoscopic surgery.

4.1. Analysis of the causes of stenosis at the biliary-enteric anastomosis site

Technical defects in anastomosis:

(1) Excessive tension at the anastomotic site

Insufficient free length of bile duct or jejunum can lead to sustained local tension after anastomosis, resulting in tissue ischemia, poor healing, and ultimately causing fibrosis.

(2) Improper stitching

Suture that is too tight (causing ischemic necrosis due to tissue compression), too sparse (inflammation induced by bile leakage), or misaligned bile duct and jejunal mucosa (compensatory hypertrophy of scar tissue during healing).

(3) The initial diameter of the anastomotic site is too small

Excessive trimming of bile duct and jejunal stump (such as short bile duct stump or narrow jejunal opening) can further narrow the lumen during postoperative healing.

(4) Suture selection

When using non absorbable sutures, the sutures remain at the anastomotic site for a long time, continuously stimulating local tissues and causing chronic inflammation, ultimately leading to fibrous wrapping and narrowing.

(5) Insufficient blood supply

The main source of blood supply to the bile duct comes from the branches of the hepatic artery (especially in the 3 and 9 o'clock directions of the bile duct). If the outer membrane is excessively peeled off during the separation of the bile duct during surgery, or if the nourishing blood vessels are damaged during suturing, it can lead to blood supply disorders in the anastomotic area, a decrease in tissue repair ability, and a higher risk of scar hyperplasia and anastomotic leakage.

Anastomotic inflammation and infection factors:

(1) Early postoperative biliary fistula or infection

Leakage at the bile intestinal anastomosis can cause continuous stimulation of the abdominal cavity and surrounding tissues by bile. If combined with bacterial infection, it can further aggravate tissue damage and fill the lumen with a large amount of fibrous tissue during healing.

(2) Anti reflux mechanism

If an effective anti reflux structure is not constructed during surgery and the input loop is too short, it can lead to reflux cholangitis. Long term repeated stimulation of the anastomotic site can form a vicious cycle of "inflammation repair scar", ultimately resulting in stenosis.

4.2. Surgical experience summary

Laparoscopic feasibility: Currently, it is believed that the separation of abdominal adhesions is one of the main

difficulties in laparoscopic biliary-enteric drainage reconstruction surgery. For patients who undergo surgery again, extensive adhesions in the abdominal cavity and adhesions in the hepatic portal area are often more severe. In addition, due to the limited operating space and large angle of laparoscopic surgery, if the adhesion situation is severe and the anatomical structure is unclear, a backup plan of "conversion to open surgery" must be developed in advance to prevent intestinal and vascular damage during forced separation.

Anastomotic positioning: In the process of exploring the biliary-enteric anastomosis, the surface of the liver is first separated and exposed, and then gradually separated to the left along the right edge of the liver until reaching the first porta hepatis area. At this point, the common hepatic duct is usually exposed, and the specific location of the biliary-enteric anastomosis can be easily determined. Using this separation method can effectively reduce the risk of hepatic artery damage. Alternatively, one can first search for the bridge loop of the biliary-enteric anastomosis, and then search for the anastomosis along the intestinal tract. Patients with anastomotic stenosis and stones often have severe anastomotic dilation and bile duct dilation, which can also be used to help locate the narrowed anastomotic site during surgery; In addition, if the location of the biliary-enteric anastomosis cannot be determined, fine needle puncture can be used in suspicious areas to clarify the position of the biliary-enteric anastomosis. All cases in this group were separated from the right edge of the liver towards the hepatic hilum, revealing the anastomotic site. Among them, case 5 determined the position of the anastomotic site by puncturing bile from a suspicious area. Cases 3 and 4 had large stones embedded in the anastomotic site, causing swelling at the upper end of the anastomotic site, which helped to locate the anastomotic site.

Biliary duct plastic surgery: Inflammation, hyperplasia, and scar formation at the anastomotic site are important pathological mechanisms of anastomotic stenosis, and can even induce cancer under repeated chronic inflammation stimulation; During surgery, scar bile ducts should be removed as much as possible, and attention should be paid to protecting the arteries that run longitudinally in the 3 and 9 o'clock directions of the bile duct to ensure blood supply to the bile duct. Generally, the incision should be extended along the longitudinal axis of the anterior wall of the common hepatic duct, and the incision should not exceed the confluence of the left and right hepatic ducts, fully exposing the openings of the left and right hepatic ducts in the lumen. In order to facilitate the reconstruction of the anastomotic site and reduce the occurrence of anastomotic stenosis.

Intestinal anastomosis examination: The reconstruction of the biliary intestinal anastomosis requires ensuring a suitable length of the input loop intestinal tube, preferably 40–60 cm. A reasonable length of the input loop jejunum is one of the key strategies to prevent biliary intestinal reflux, and excessive length can cause poor bile drainage and lead to bile stasis.

Reconstruction of biliary-enteric anastomosis: Based on our experience, the margin of suture during biliary-enteric anastomosis is approximately 2 mm on the bile duct side and 3 mm on the jejunum side, with a needle spacing of about 2–3 mm. Attention should be paid to uniform needle insertion and ensuring the closure of the entire bile duct and jejunum layer. Currently, the selection of sutures mostly uses 4-0 or 5-0 PDS absorbable sutures. For larger bile duct diameters, continuous suturing of the anterior and posterior walls can effectively reduce anastomosis time and avoid knot retention in the anastomotic cavity; For small bile duct diameters, continuous suturing of the posterior wall and intermittent suturing of the anterior wall are often used for anastomosis. The reason is that laparoscopic surgery is limited by space, such as when the diameter of the bile duct is small, in the last few stitches of continuous suturing of the anterior wall, the suturing space is greatly reduced due to the tightening and completion of the anterior knot, making it difficult to identify the lumen and resulting in suturing errors. After confirming the absence of bile leakage and ischemia at the anastomotic site, the end of the intestinal

ring can be fixed on the circular ligament of the liver to reduce anastomotic tension. In addition, for patients with stones that cannot be completely removed, small anastomotic diameter, severe inflammation of the tube wall, and a high possibility of anastomotic leakage after surgery, it is recommended to place a T-tube. In this group of cases 1, 2, and 5, the anastomotic site was sutured continuously with 4-0PDS absorbable suture to the anterior and posterior walls. Cases 3 and 4 were sutured continuously with 4-0PDS absorbable suture to the posterior wall, intermittently suturing the anterior wall, and placing a T-tube.

5. Conclusion

In summary, for mature surgical teams, laparoscopic reconstruction of the biliary-enteric anastomosis is safe and effective in treating biliary-enteric anastomotic stenosis after biliary-enteric drainage surgery. Laparoscopy has a natural magnifying effect, which can further reduce surgical risks, accelerate postoperative recovery, and reduce the occurrence of postoperative complications through fine adhesion separation, proper bile duct shaping, and appropriate anastomosis strategies. It should be pointed out that laparoscopic reconstruction of the bile intestinal anastomosis is difficult, and there are relatively few such patients, so the sample size is small. Our center will expand the number of patients participating in the study and increase follow-up time to further confirm the safety and effectiveness of laparoscopic reconstruction of the biliary-enteric anastomosis for patients with anastomotic stenosis after biliary-enteric drainage surgery.

Disclosure statement

The authors declare no conflict of interest.

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Clinical Application of Guizhi Longgu Muli Decoction Combined with Traditional Chinese Medicine Foot Bath and Five-Tone Therapy in the Treatment of Insomnia

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Abstract: *Objective*: To evaluate the therapeutic effect of Guizhi Longgu Muli Decoction combined with traditional Chinese medicine (TCM) foot bath and five-tone therapy on insomnia. *Methods*: A total of 99 patients with insomnia admitted to the hospital from October 2023 to October 2025 were selected and equally divided using a random number table. Group A received Guizhi Longgu Muli Decoction treatment, Group B received Guizhi Longgu Muli Decoction combined with TCM foot bath treatment, and Group C received Guizhi Longgu Muli Decoction combined with TCM foot bath and five-tone therapy. The therapeutic effects among the groups were compared. *Results*: The total effective rate in Group C was higher than that in Groups A and B. The sleep quality score and TCM syndrome score after treatment in Group C were lower than those in Groups A and B, and the scores in Group B were lower than those in Group A ($p < 0.05$). There was no significant difference in the adverse reaction rates among the three groups ($p > 0.05$). *Conclusion*: Administering Guizhi Longgu Muli Decoction combined with TCM foot bath and five-tone therapy to patients with insomnia can improve insomnia symptoms, enhance sleep quality, and demonstrate high treatment safety and definite efficacy.

Keywords: Guizhi Longgu Muli Decoction; Traditional Chinese medicine foot bath; Five-tone therapy; Insomnia

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1. Introduction

With advancements in technology and changes in lifestyle, the incidence of insomnia has been continuously rising, becoming one of the significant factors affecting human health. Concurrently, the number of patients with psychological disorders due to insomnia is also increasing. In ancient TCM literature, insomnia is primarily named as "insomnia, inability to lie down, inability to close eyes", etc. TCM believes that normal sleep depends on the balance of Yin and Yang energies in the human body. "When Yang enters Yin, one sleeps; when Yang exits Yin, one wakes". If this process of "Yang entering Yin" is interrupted, it leads to insomnia [1].

Western medicine is a common treatment for this condition, which can improve insomnia symptoms but has strong drug dependence and poor long-term medication safety. Guizhi Longgu Muli Decoction combined with TCM foot bath and five-tone therapy is a comprehensive treatment for this condition. Through the integrated TCM approach of "treating both internally and externally, nourishing both body and spirit, and combining medication and music", it aims to re-establish the physiological state of "Yang entering Yin". The core mechanism of this combined therapy lies in simultaneous intervention at three levels: physiological (TCM), meridian (foot bath), and psychological (five-tone), collectively correcting the core pathogenesis of insomnia: disharmony between Yin and Yang and Yang failing to enter Yin. These three interventions do not simply add up but produce a synergistic effect of "1 + 1 + 1 > 3", aligning with the holistic concept of TCM and the idea of "treating the same disease differently", as well as fitting with the multi-target regulation of modern medicine. Based on this, this study selected 99 patients with insomnia to evaluate the therapeutic effect of Guizhi Longgu Muli Decoction combined with TCM foot bath and five-tone therapy.

2. Materials and methods

2.1. General information

A total of 99 patients with insomnia admitted for treatment between October 2023 and October 2025 were selected and randomly divided into three equal groups using a random number table. Group A consisted of 33 patients, including 21 males and 12 females, aged between 35 and 74 years with a mean age of (52.31 ± 4.18) years, and a disease duration ranging from 6 to 37 months with a mean duration of (17.59 ± 3.17) months. Group B also had 33 patients, with 20 males and 13 females, aged between 31 and 78 years with a mean age of (52.64 ± 4.27) years, and a disease duration ranging from 5 to 39 months with a mean duration of (17.98 ± 3.54) months. Group C had 33 patients, including 18 males and 15 females, aged between 30 and 75 years with a mean age of (52.58 ± 4.41) years, and a disease duration ranging from 7 to 38 months with a mean duration of (18.06 ± 3.76) months. Comparisons of baseline data between groups showed no significant differences ($p > 0.05$).

2.1.1. Inclusion criteria

Diagnosed with insomnia based on clinical symptoms and laboratory tests; disease duration longer than 1 month; complete basic information; normal communication ability; informed consent for the study.

2.1.2. Exclusion criteria

Pregnant or lactating; concurrent dementia, delirium, or other diseases; abnormal heart, liver, or kidney function; acute infectious diseases; mental disorders; foot ulcers; withdrawal from the study midway.

2.2. Methods

Group A received treatment with Guizhi Longgu Muli Decoction: 9 g of cassia twig, 12 g of white peony root, 6 g of roasted licorice, 3 slices of ginger, 5 jujubes, 30 g of calcined dragon bone (decocted first), 30 g of oyster (decocted first), 15 g of sour jujube seeds, 9 g of polygala root, 12 g of *atractylodes macrocephala*, and 15 g of *poria*. The herbs were decocted in water, and one dose was taken every night before bedtime for 4 consecutive weeks.

Group B received Guizhi Longgu Muli Decoction combined with traditional Chinese medicine foot bath therapy: The herbal formula was the same as above, and the foot bath formula consisted of 15 g of mugwort leaf, 6 g of cinna-

mon bark, 6 g of safflower, and 12 g of albizia bark. The foot bath herbal package was decocted starting at 9 PM, with the water temperature maintained at 40–42 °C. The foot bath was performed once daily for 4 consecutive weeks.

Group C received Guizhi Longgu Muli Decoction combined with traditional Chinese medicine foot bath and five-tone therapy: The foot bath treatment method was the same as above. In a quiet environment with soft lighting, selected Yue-mode music was played at a low volume for 20–30 minutes. After the foot bath, the warm Guizhi Longgu Muli Decoction was taken, followed by going to bed to prepare for sleep, avoiding the use of electronic devices such as mobile phones. The above treatments were continued for 4 consecutive weeks.

2.3. Observation indicators

(1) Overall response rate

No sleep disturbances and nighttime sleep exceeding 6 hours indicated a significant response; mild sleep disturbances and nighttime sleep between 3 and 6 hours indicated a preliminary response; severe sleep disturbances and nighttime sleep shorter than 3 hours indicated no response.

(2) Sleep quality score

The Pittsburgh Sleep Quality Index (PSQI) was used, including 7 items such as sleep duration and sleep quality, each scored from 0 to 3, with a total score of 21. Sleep quality was negatively scored.

(3) Traditional Chinese medicine syndrome score

Before and after treatment, a 5-grade scoring method was used, including symptoms such as dreaminess and easy awakening, dizziness and blurred vision, fatigue, and palpitations and easy fright, each scored from 0 to 4, with symptom severity positively scored.

(4) Adverse reaction rate

The incidence of appetite loss, drowsiness, dizziness, fatigue, and other adverse reactions was recorded.

2.4. Statistical analysis

Data processing was performed using SPSS 28.0. Count data were analyzed using the χ^2 test, and measurement data were tested for normal distribution using the K-S method. Comparisons between groups were performed using the *F* test. A p-value < 0.05 indicated a statistically significant difference.

3. Results

3.1. Comparison of overall response rates among the three groups

The overall response rate in Group C was higher than that in Groups A and B, and Group B had a higher response rate than Group A ($p < 0.05$). See **Table 1**.

Table 1. Comparison of overall response rates among the three groups (n/%)

Group	Number of cases	Significant efficacy	Initial efficacy	No efficacy	Total effective rate (%)
Group A	33	14 (42.42)	11 (33.33)	8 (24.24)	75.76 (25/33)
Group B	33	16 (48.48)	11 (33.33)	6 (18.18)	81.82 (27/33)
Group C	33	19 (57.58)	13 (39.39)	1 (3.03)	96.97 (32/33)
χ^2					7.741
p					0.021

3.2. Comparison of sleep quality scores among the three groups

The sleep quality score in Group C after treatment was lower than that in Groups A and B, and Group B had a lower score than Group A ($p < 0.05$). See **Table 2**.

Table 2. Comparison of sleep quality scores among the three groups ($\overline{x} \pm s$, points)

Group	Number of cases	Sleep duration		Sleep quality		Sleep disturbance		Time to fall asleep	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Group A	33	2.14 ± 0.47	1.63 ± 0.52	2.09 ± 0.63	1.59 ± 0.56	2.08 ± 0.44	1.61 ± 0.48	2.11 ± 0.69	1.66 ± 0.41
Group B	33	2.11 ± 0.41	1.37 ± 0.49	2.06 ± 0.58	1.22 ± 0.51	2.11 ± 0.48	1.38 ± 0.44	2.17 ± 0.71	1.39 ± 0.47
Group C	33	2.18 ± 0.49	1.01 ± 0.44	2.03 ± 0.61	1.04 ± 0.47	2.05 ± 0.51	1.02 ± 0.39	2.14 ± 0.66	1.03 ± 0.38
F		0.194	13.629	0.081	9.797	0.130	15.197	0.063	18.542
P		0.824	0.000	0.923	0.000	0.878	0.000	0.939	0.000

Group	Number of cases	Daytime function		Hypnotic medication use		Sleep efficiency	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Group A	33	2.12 ± 0.43	1.54 ± 0.64	1.87 ± 0.62	1.22 ± 0.38	2.08 ± 0.57	1.43 ± 0.42
Group B	33	2.08 ± 0.48	1.28 ± 0.59	1.83 ± 0.68	1.06 ± 0.31	2.11 ± 0.51	1.21 ± 0.37
Group C	33	2.15 ± 0.51	1.01 ± 0.42	1.79 ± 0.65	0.89 ± 0.22	2.04 ± 0.53	1.07 ± 0.31
F		0.181	7.444	0.125	9.332	0.141	5.844
p		0.835	0.001	0.883	< 0.001	0.869	0.004

3.3. Comparison of traditional Chinese medicine syndrome scores among the three groups

The traditional Chinese medicine syndrome scores in Group C after treatment were lower than those in Groups A and B, and Group B had lower scores than Group A ($p < 0.05$). See **Table 3**.

Table 3. Comparison of traditional Chinese medicine syndrome scores among the three groups ($\overline{x} \pm s$, points)

Group	Number of cases	Frequent dreaming and easy awakening		Dizziness		Mental fatigue and lack of strength		Palpitations and easy startling	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Group A	33	3.02 ± 0.48	2.21 ± 0.39	2.87 ± 0.61	2.28 ± 0.53	3.04 ± 0.53	2.57 ± 0.46	2.76 ± 0.41	2.29 ± 0.32
Group B	33	3.04 ± 0.51	2.02 ± 0.36	2.91 ± 0.67	2.03 ± 0.49	3.09 ± 0.59	2.21 ± 0.41	2.81 ± 0.46	2.04 ± 0.37
Group C	33	3.05 ± 0.54	1.83 ± 0.41	2.84 ± 0.63	1.76 ± 0.44	2.99 ± 0.56	2.04 ± 0.37	2.73 ± 0.49	1.88 ± 0.24
F		0.030	7.946	0.100	9.370	0.263	14.034	0.261	14.238
p		0.971	0.001	0.905	0.000	0.770	0.000	0.771	0.000

3.4. Comparison of adverse reaction rates among the three groups

The adverse reaction rates among the three groups were relatively similar ($p > 0.05$). See **Table 4**.

Table 4. Comparison of adverse reaction rates among the three groups (n/%)

Group	Number of cases	Loss of appetite	Drowsiness	Dizziness	Fatigue	Incidence rate (%)
Group A	33	1 (3.03)	1 (3.03)	1 (3.03)	2 (6.06)	15.15 (5/33)
Group B	33	2 (6.06)	0	1 (3.03)	1 (3.03)	12.12 (4/33)
Group C	33	1 (3.03)	0	0	1 (3.03)	6.06 (2/33)
χ^2 value	-	-	-	-	-	1.432
p value	-	-	-	-	-	0.489

4. Discussion

Insomnia has a high incidence rate, with its causes including a decline in immunity, poor living habits, and noisy environments, among others. It can adversely affect patients' sleep quality over the long term and even lead to adverse events such as memory decline and psychological issues [2]. Traditional Chinese Medicine (TCM) considers insomnia to fall under the category of "insomnia" (sleeplessness), with its pathogenesis involving disharmony of Qi and blood and insufficient nourishment of the mind, necessitating the adoption of comprehensive TCM therapies.

The core mechanism of Guizhi Longgu Muli Decoction is to harmonize Yin and Yang and calm the mind and spirit. The core herbal pair in the decoction is "Guizhi (Cassia Twig) + Baishao (White Peony Root). Guizhi, with its pungent and sweet properties, transforms Yang and assists the defensive Qi, while Baishao, with its sour and sweet properties, transforms Yin and nourishes the nutrient blood. Together, they disperse and astringe, harmonizing the Yin and Yang Qi and blood on the body's surface and interior, creating basic conditions for "Yang entering Yin" [3]. "Longgu (Dragon Bone) + Muli (Oyster Shell)" is another core component of the decoction. Both are heavy and descending, capable of subduing the floating and hyperactive fire of the heart and liver (deficient Yang) and converging the dissipated mind and Yin fluid, directly targeting symptoms of mental restlessness such as insomnia, palpitations, fluttering of the heart, excessive dreaming, and night sweats. The auxiliary mechanism of TCM foot bath is to warm and unblock meridians and guide fire back to its origin. The feet are the convergence point of the three Yin and three Yang meridians of the foot, housing several important acupoints such as Yongquan, Taixi, Sanyinjiao, Yangqiao, and Yinqiao. Through stimulation by warm medicinal liquid, it can unblock meridian Qi and blood and remove obstacles in the pathway for "Yang entering Yin". Addressing the pathogenesis of "upper heat and lower cold", the warming effect of the foot bath can guide the deficient fire from the head and face downward, returning it to the kidneys, thereby balancing the cold and heat of the upper and lower jiao. Additionally, TCM foot bath can improve microcirculation, enabling "blood to nourish the heart" and calming the mind [4]. The regulatory mechanism of five-tone therapy is to harmonize emotions and resonate with the viscera. TCM theory posits that the five tones (Jue, Zhi, Gong, Shang, Yu) correspond to the five viscera (liver, heart, spleen, lungs, kidneys) and five emotions (anger, joy, contemplation, worry, fear). For insomnia patients commonly experiencing anxiety (hyperactivity of liver wood), overthinking (stagnation of spleen earth), and fear (deficiency of kidney water), corresponding music can be selected, such as soothing Yu tone to nourish kidney water and peaceful Gong tone to strengthen the spleen and stomach; this can dredge disordered Qi movement, calm overexcited emotions, and enable the "mind to stay in its abode".

The results showed that the total effective rate in Group C was higher than that in Groups A and B, and the sleep quality score after treatment was lower than that in Groups A and B, with Group B outperforming Group A in these indicators ($p < 0.05$). The reasons for analysis are as follows: Guizhi Longgu Muli Decoction can upregulate

the levels of inhibitory neurotransmitters in the brain, such as gamma-aminobutyric acid (GABA) and 5-hydroxytryptamine (5-HT), while simultaneously reducing the activity of excitatory neurotransmitters like norepinephrine (NE) and dopamine (DA), thereby restoring the balance between brain excitation and inhibition. Chronic stress, an important cause of insomnia, leads to hyperactivity of the hypothalamic-pituitary-adrenal (HPA) axis and elevated cortisol (stress hormone) levels. This decoction has been shown to inhibit excessive HPA axis excitation, reduce nocturnal cortisol levels, and promote bodily relaxation [5]. Furthermore, the decoction can enhance parasympathetic nerve activity and inhibit sympathetic nerve activity, slowing the heart rate, stabilizing breathing, and preparing the body for sleep. The warming effect of TCM foot bath can rapidly dilate blood vessels in the lower limbs and improve blood circulation. This moderate increase in body surface temperature helps initiate the core body temperature decline process (a crucial physiological signal for falling asleep), reshaping the normal sleep-wake rhythm. The skin of the feet can absorb active ingredients from the medicinal liquid (such as volatile oils from *Artemisiae Argyi Folium* and glycosides from *Carthami Flos*), producing mild systemic pharmacological effects. Simultaneously, thermal stimulation is transmitted to the cerebral cortex through nerve reflexes, inducing it into an inhibitory state and producing a sedative effect. The comfortable warming sensation itself is a powerful relaxation stimulus that can significantly reduce anxiety levels and prepare the mind for sleep [6]. Five-tone therapy utilizes soothing, rhythmically stable music (typically with a frequency of 60–80 beats per minute) to guide brain waves from active beta waves to relaxed alpha waves and even induce sleep theta and delta waves, directly promoting sleep. Similar to Guizhi Longgu Muli Decoction, five-tone therapy has also been shown to effectively reduce plasma cortisol and adrenaline levels, alleviating the stress response. Performing foot baths and listening to specific music at a fixed time and in a fixed environment every night before bedtime can form a powerful behavioral conditioned reflex. After long-term adherence, once this "ritual" is initiated, the body and brain automatically enter a "prepare for sleep" mode [7]. The TCM syndrome score after treatment in Group C was lower than that in Groups A and B, with Group B having a lower score than Group C ($p < 0.05$). The reasons for analysis are as follows: The internal administration of the decoction harmonizes the nutrient and defensive Qi, and the subduing and converging nature of Longgu and Muli converges the floating Yang Qi. Combined with the warming stimulation and musical relaxation, it significantly reduces pre-sleep anxiety levels and sympathetic nerve tension, creating a favorable "preparatory state" for sleep [8]. The combined use of the three treatment methods demonstrates obvious synergistic effects, mainly manifested in the following aspects:

(1) Guiding fire back to its origin

The descending Yang (Longgu and Muli) of the internal decoction, the downward guidance of fire by the foot bath (*Cinnamomi Cortex* and *Artemisiae Argyi Folium*), and the nourishing of water and containing of wood by the music (Yu tone) all work in the same direction, collectively addressing the core issue of "disharmony between the heart and kidneys".

(2) Simultaneously nourishing the heart, spleen, and kidneys

The internal decoction strengthens the spleen and calms the mind (*Atractylodis Macrocephalae Rhizoma*, *Poria*, *Ziziphi Spinosae Semen*), the foot bath warms and unblocks meridians, and the music strengthens the spleen (Gong tone) and benefits the kidneys (Yu tone). These three approaches consolidate the acquired foundation (spleen) and innate foundation (kidneys), gradually replenishing Qi and blood and nourishing the mind [9].

(3) Establishing conditioned reflexes

The pre-sleep ritual of "foot bath + music" has formed a powerful behavioral suggestion, automatically inducing the body into a relaxation mode upon entering this scenario. The three methods simultaneously

improve circulation, neurotransmitters, the endocrine system, emotions, and behavioral patterns, which is unparalleled by a single therapy.

The adverse reaction rates among the three groups were similar ($p > 0.05$). The reasons for analysis are as follows: The three methods are all characteristic TCM therapies with no obvious side effects and high safety for long-term treatment. They aim to restore the body's natural sleep rhythm without the risk of addiction [10]. The excellence of this combined regimen lies in its multi-dimensional and synchronized intervention strategy.

(1) Spatiotemporal synchronicity

Approximately one hour before bedtime, patients simultaneously undergo a foot bath and listen to music, followed by taking the decoction. This process creates a highly synergistic "treatment time window", enabling physiological and psychological regulatory effects to peak within the same time frame [11].

(2) Target point complementarity

The decoction corrects neuroendocrine and neurotransmitter imbalances from within, the foot bath improves circulation and body temperature rhythm from the body surface and unblocks meridians, and the five-tone therapy regulates the advanced central nervous system functions from the emotional level. These three approaches respectively target the biological basis, physiological rhythm, and psychological inducement of insomnia, forming a perfect complement.

(3) Synergistic effect with reduced side effects

This non-pharmacological integrated therapy avoids the addictive, tolerant, and next-day drowsiness side effects of benzodiazepines and other sleeping pills, making it particularly suitable for long-term conditioning and elderly patients [12].

Clinical application of this regimen also requires attention to the following points:

(1) Accurate syndrome differentiation is the prerequisite

The success of this regimen hinges on accurately differentiating the syndrome as "disharmony between the heart and kidneys and deficiency of both spleen and kidneys", thereby formulating a highly consistent regimen for internal administration, external treatment, and music therapy.

(2) Advantages of integrated therapy

Combining immediate effects with long-term conditioning: The foot bath and music can rapidly alleviate symptoms and enhance patients' confidence in falling asleep; the decoction, on the other hand, deeply conditions the constitution and addresses the root cause [13].

(3) Individualized application

The choice of foot bath formula and music is closely tied to the core pathogenesis of "cold" and "deficiency" in patients. If a patient has insomnia due to hyperactivity of liver fire, a foot bath formula to clear liver fire and a Jue tone music to soothe the liver should be selected, and the regimen should be tailored to the individual.

This case fully demonstrates the unique advantages and immense potential of the TCM concept of "treating both internally and externally and nourishing both body and spirit" in treating complex insomnia.

5. Conclusion

In conclusion, the combined application of Guizhi Longgu Muli Decoction, TCM foot bath, and five-tone therapy represents a scientific clinical mechanism that synergistically acts on the nervous, endocrine, and circulatory systems, as well as advanced brain functions, through pharmacological, physical, and psychoacoustic pathways. It comprehensively regulates the sleep-wake cycle through multiple targets and levels, ultimately rebuilding a natural

and healthy sleep pattern.

Disclosure statement

The author declares no conflict of interest.

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Determination of the Plasma Concentrations of Amygdalin and Paeoniflorin in Rat Serum Using Liquid Chromatography-tandem Mass Spectrometry

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Abstract: *Objective*: To establish a liquid chromatography tandem mass spectrometry (HPLC-MS/MS) method to determine amygdalin and paeoniflorin in rat blood serum. *Method*: After protein precipitation by acetonitrile, a gradient elution procedure was performed to separate the samples by using acetonitrile and ammonium acetate buffer as the mobile phase. The quantitative determination was based on an HPLC-MS/MS in negative electron spray ionization mode and in multiple reaction monitoring (MRM) mode. The precursor to product ion transitions for amygdalin and paeoniflorin were 456.2 to 323.1 and 479.2 to 121.0, respectively. *Results*: The linear ranges of amygdalin and paeoniflorin were 1–300 ng/mL (rAmy = 0.9994，rPae = 0.9993) with the lowest limits of quantification were 0.3 ng/ml. The extract recovery of amygdalin and paeoniflorin were 91.1%, 94.2%, 92.0% and 90.3%, 93.7%, 94.1% at concentrations of 3, 20, 100 ng/mL, respectively. All the intra and inter day precisions of analysis were less than 15%, and the RE were in the range of ± 15%. *Conclusion*: The method is specific, sensitive, accurate, and suitable for determination of amygdalin and paeoniflorin in rat blood serum.

Keywords: Fei Xin Decoction; Chinese medicinal preparation; Amygdalin; Paeoniflorin; Rat blood serum; HPLC-MS/MS

Online publication: Apr 21, 2026

1. Introduction

The material basis for the efficacy of traditional Chinese medicine (TCM) lies in the chemical constituents within the herbs or compound formulas, which are crucial for elucidating the mechanisms underlying their therapeutic effects. TCM and its compound formulas contain numerous components, but only those absorbed into the bloodstream can exert pharmacological effects *in vivo*. The TCM compound formula “Feixin Decoction”, primarily composed of over ten herbs including almonds, red peony root, astragalus, and safflower, is used for the prevention and treatment of pulmonary hypertension, with almonds and red peony root playing the most critical roles. Its main functions are promoting blood circulation and removing blood stasis. The primary active ingredients in

almonds and red peony root are amygdalin and paeoniflorin, respectively. Previous studies have reported the use of high-performance liquid chromatography-tandem mass spectrometry (LC-MS/MS) to detect paeoniflorin concentrations in serum or plasma samples [1–5]. However, no method has been reported for measuring amygdalin concentrations *in vivo*. Therefore, this study established a specific, sensitive, accurate, and rapid LC-MS/MS method to detect amygdalin and paeoniflorin in rat serum after intragastric administration of "Feixin Decoction". This lays the foundation for elucidating the in vivo metabolism and pharmacological mechanisms of the TCM compound formula "Feixin Decoction" and provides support for subsequent serum pharmacology experiments in this study.

2. Materials and methods

2.1. Instruments

A 4000 QTRAP LC-MS/MS system, including an electrospray ionization (ESI) source and data processing system (AB, USA); an Agilent 1200 high-performance liquid chromatograph equipped with an online degasser, quaternary pump, DAD UV detector, autosampler, and column oven (Agilent, USA); an M37610-33 vortex mixer (Thermo Scientific, USA); a Sigma 2-16K tabletop high-speed refrigerated centrifuge (Sigma, Germany); and a Mettler XP26 electronic balance (Mettler, Switzerland).

2.2. Drugs and reagents

Amygdalin reference standard (batch number: MUST-13011801, HPLC purity: ≥ 98%) and paeoniflorin reference standard (batch number: MUST-12113009, HPLC purity: ≥ 98%) were purchased from Chengdu Mansite Biotechnology Co., Ltd. Methanol and acetonitrile were of chromatographic grade (Merck, Germany). Ultrapure water was prepared using a Millipore ultrapure water system. All other reagents were of analytical grade.

2.3. Animals

Healthy adult male SPF-grade SD rats weighing approximately 300 g were provided by Changsha Tianqin Biotechnology Co., Ltd. (license number: SCXK (Xiang) 2009-0012).

2.4. Chromatographic and mass spectrometric conditions

(1) Pre-column

Phenomenex C18 guard column (4 mm × 2.0 mm, 5 μm); analytical column: XBridge BEH C18 column (2.1 × 50 mm, 2.5 μm); mobile phase: acetonitrile-20 mmol/L ammonium acetate + 0.1% ammonia water (gradient elution, specific program: 0–0.9 min 5% acetonitrile, 0.9–1.0 min 5–95% acetonitrile, 1.0–2.5 min 95% acetonitrile, 2.5–2.6 min 95–5% acetonitrile, 2.6–4.0 min 5% acetonitrile); flow rate: 0.4 mL/min; column temperature: 40 ℃; injection volume: 20 μL.

(2) Ion source

Electrospray ionization (ESI) source; ionization mode: negative mode; electrospray voltage: -4500 V; temperature: 550 ℃; in-source gas (GS1, N2) pressure: 40 psi; heating gas (GS2, N2) pressure: 60 psi; curtain gas (CUR, N2) pressure: 20 psi; collision gas (CAD, N2) pressure: medium; scanning mode: multiple reaction monitoring (MRM); ion reactions used for quantitative analysis were m/z 456.2 to 323.1 (amygdalin) and 479.2 to 121.0 (paeoniflorin); declustering potential (DP) values were -105 and -103 V, respectively; collision energy (CE) values were -18 and -32 V, respectively; detector voltage: 2200 V.

2.5. Preparation of reference standard stock solutions

Ten milligrams each of amygdalin and paeoniflorin reference standards were accurately weighed and placed in separate 10 mL volumetric flasks. Five milliliters of methanol were added to dissolve the standards, which were then diluted to 10 mL with methanol to obtain 1 mg/mL stock solutions of amygdalin and paeoniflorin. Subsequent reference solutions were prepared by diluting these stock solutions with 50% methanol-water to the desired concentrations.

2.6. Collection and processing of serum samples

(1) Animal grouping

Twelve healthy male SD rats were randomly divided into a TCM group (n = 6) and a saline group (n = 6).

(2) Dosage administration

The dosage for the TCM group was calculated using the formula proposed by Wang Liqian [6,7]: dosage = Commonly used clinical doses × animal equivalent area coefficient × serum dilution in culture medium. Using this formula, the equivalent dose for rats was theoretically 6.25 times the human dose per unit mass. Since the drug serum needed to be diluted to 20% (dilution factor of 5), the intragastric dosage per unit mass for rats was 31.25 times the human dose per unit mass, resulting in an approximate dosage of 25 mL/kg (containing 28 g/kg of "Feixin Decoction") per rat per administration. The saline group received the same feeding regimen as the TCM group but was administered an equivalent volume of saline.

(3) Preparation of TCM Decoction

Ten grams of peach kernels, 10 g of safflower, 20 g of red peony root, 30 g of *salvia miltiorrhiza*, 30 g of *lepidium* seeds, 10 g of white ginseng, 10 g of prepared aconite, 30 g of raw *astragalus*, 20 g of *plantago* seeds, 15 g of *poria*, and 12 g of *atractylodes* were added to 1500 mL of re-distilled water and boiled for 20 minutes. The filtrates from two boilings were combined and centrifuged at 14000 r/min for 15 minutes to obtain the supernatant.

(4) Collection of drug-containing serum

Rats were fasted for 12 hours before the first intragastric administration but had free access to water. A specific amount of the decoction was administered to the experimental group rats using a dedicated intragastric needle, while the saline group received an equivalent volume of saline. Administrations were performed twice daily at 8 AM and 8 PM. On the 10th day, serum samples were collected from the inferior vena cava under anesthesia 1 hour after administration. Serum samples from rats in the same group were pooled, inactivated in a 56 ℃ constant-temperature water bath for 30 minutes, filtered through a 22 μm membrane for sterilization, and stored in an ultra-low temperature freezer for subsequent in vitro culture of pulmonary artery smooth muscle cells.

(5) Processing of serum samples

A 0.4 mL aliquot of serum was transferred to a 2 mL centrifuge tube, followed by the addition of 0.8 mL of acetonitrile. The mixture was vortexed for 2 minutes and centrifuged at 12000 r/min for 10 minutes. The supernatant was directly injected into the LC-MS/MS system for analysis.

3. Results and discussion

3.1. Liquid chromatography and mass spectrometry investigation and optimization

The structures of amygdalin and paeoniflorin are shown in **Figure 1**. As polyhydroxy compounds, they exhibit

strong water solubility and lack acidic or basic functional groups, which is not conducive to electrospray ionization mass spectrometry response. In the experiments, positive ESI mode was initially selected for condition optimization. However, under various conditions, both amygdalin and paeoniflorin primarily responded as $[M + Na]^+$ ions, with weak $[M + H]^+$ ion responses. When selecting $[M + Na]^+$ ions for MS2 fragmentation experiments, stable secondary fragmentation ions could not be obtained, making MRM experiments difficult. Therefore, this method opted for further investigation and optimization under negative ESI mode, examining the response intensity of $[M–H]^-$ ions of amygdalin and paeoniflorin under acidic (0.1% formic acid), neutral (without any mobile phase modifier), and alkaline (20 mmol/L ammonium acetate + 0.1% ammonia water) mobile phase conditions. The experimental results indicated that stable $[M–H]^-$ ions could be generated for both amygdalin and paeoniflorin under all conditions. However, under alkaline conditions, the $[M–H]^-$ ion intensity of amygdalin was three times and two times that under neutral and acidic conditions, respectively, while that of paeoniflorin was 2.5 times and two times, respectively. Therefore, this method ultimately selected negative ESI mode and an alkaline mobile phase.

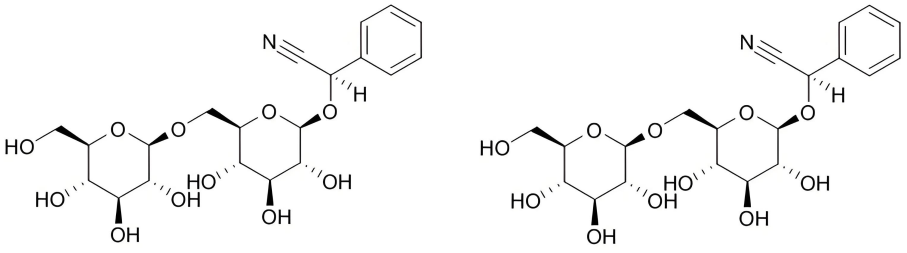


Figure 1. Chemical structural formulas of amygdalin and paeoniflorin.

To enhance method sensitivity, MRM monitoring mode was proposed for quantification. **Figure 2** shows the primary MS scan spectra and MS2 daughter ion scan spectra of $[M–H]^-$ ions for amygdalin and paeoniflorin under negative ESI mode. The $[M–H]^-$ ion of amygdalin was m/z 456.2, with the highest abundance of m/z 323.1 in its MS2 daughter ions; the $[M–H]^-$ ion of paeoniflorin was m/z 479.2, with the highest abundance of m/z 121.0 in its MS2 daughter ions. Therefore, the final selected MRM quantification channels were m/z 456.2 to 323.1 (amygdalin) and m/z 479.2 to 121.0 (paeoniflorin).

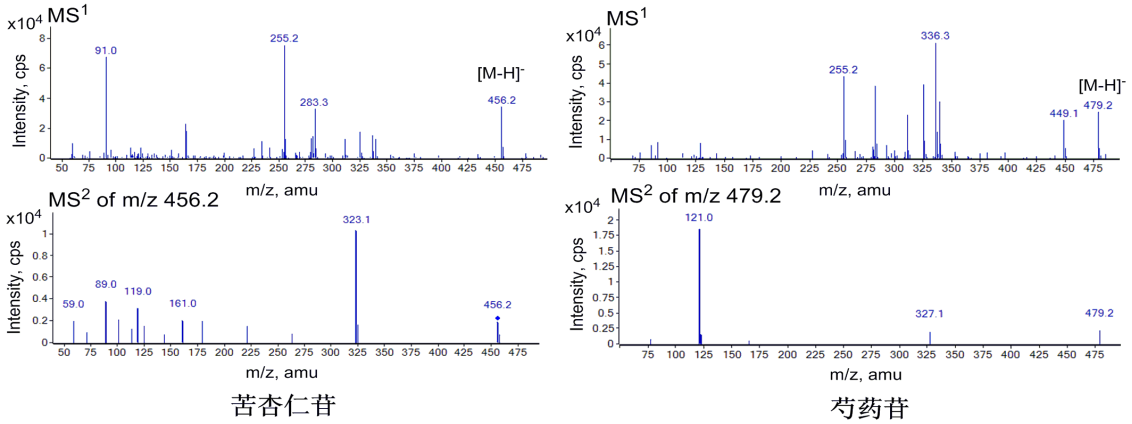


Figure 2. Primary MS scan spectra of amygdalin and paeoniflorin, along with their MS2 daughter ion scan spectra of $[M–H]^-$ ions.

Regarding the liquid chromatography elution method, isocratic elution was initially selected in the experiments. Although it could achieve separation of amygdalin and paeoniflorin, the peak shapes were poor, and there were concerns that some strongly retained components in the serum matrix might not be eluted under this condition. Therefore, this method ultimately adopted a large gradient elution method. Although amygdalin and paeoniflorin co-eluted under this method, subsequent specificity investigations proved that they did not interfere with each other's determination. This gradient method could obtain sharp peak shapes and ensure that components in the serum matrix could be eluted in a single injection without interfering with subsequent determinations.

3.2. Method specificity investigation

Blank serum, blank serum spiked with amygdalin and paeoniflorin (both at 10 ng/mL), blank serum spiked only with amygdalin (10 ng/mL), blank serum spiked only with paeoniflorin (10 ng/mL), and serum samples were processed and injected for determination according to Section 1.6. The results showed (see **Figure 3**) that the sample spiked with amygdalin and paeoniflorin in blank serum exhibited peaks at 2.01 min in the m/z 456.2 to 323.1 channel and at 2.02 min in the m/z 479.2 to 121.0 channel; the blank serum sample showed no significant peaks in either the m/z 456.2 to 323.1 or m/z 479.2 to 121.0 channels; the sample spiked only with amygdalin in blank serum showed no significant peak in the m/z 479.2 to 121.0 channel; and the sample spiked only with paeoniflorin in blank serum showed no significant peak in the m/z 456.2 to 323.1 channel. The specificity experiments proved that there were no endogenous matrix interferences in the plasma affecting the determination of amygdalin and paeoniflorin, and that amygdalin and paeoniflorin did not interfere with each other.

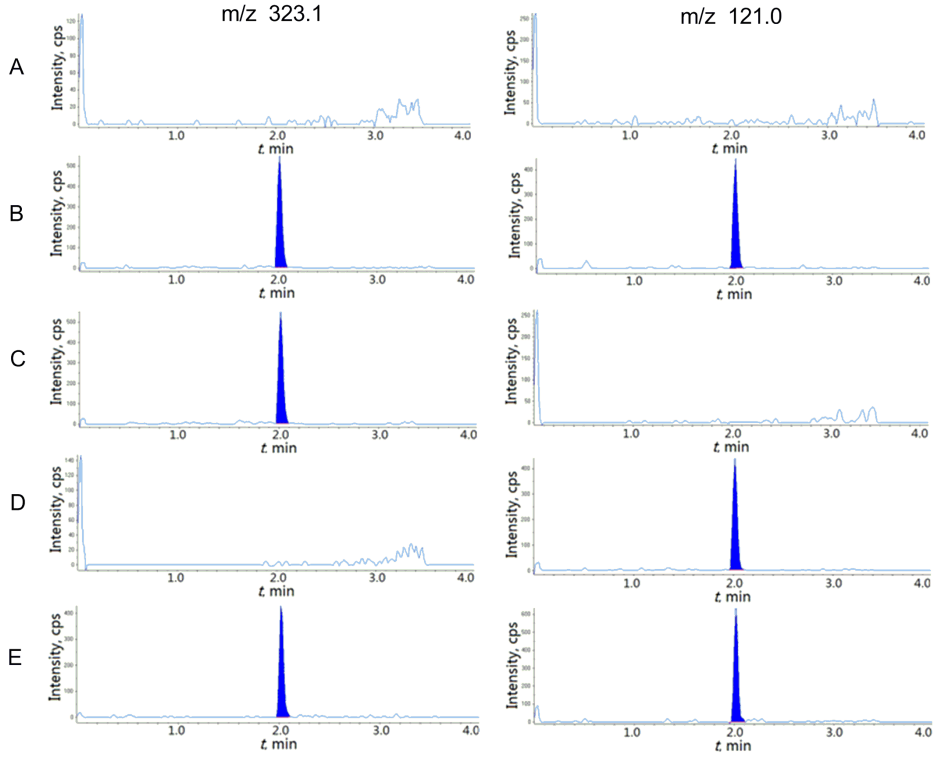


Figure 3. Liquid chromatography-tandem mass spectrometry (LC-MS/MS) chromatograms: A: Blank serum; B: Blank serum + Amygdalin + Paeoniflorin; C: Blank serum + Amygdalin; D: Blank serum + Paeoniflorin; E: Serum sample.

3.3. Matrix effect investigation

Multiple portions of blank serum were processed according to Section 1.6. Processed blank serum extracts were used to prepare high, medium, and low (amygdalin and paeoniflorin at 100, 20, and 3 ng/mL, respectively) concentration spiked blank samples, with three parallel preparations for each concentration. Simultaneously, neat solvents (water/acetonitrile = 1/2) were used to prepare spiked solutions with the same high, medium, and low concentrations, with three parallel preparations for each concentration. Injection analysis was performed according to the method in Section 1.4. The matrix effect was defined as the ratio of the peak areas of the target analytes in the processed spiked blank samples to those in the neat solvent spiked samples. The results showed that under this method, the matrix effects for amygdalin at high, medium, and low concentrations were 94.2% (RSD = 5.2%, n = 3), 95.7% (RSD = 2.2%, n = 3), and 99.1% (RSD = 3.4%, n = 3), respectively, while those for paeoniflorin were 97.2% (RSD = 3.7%, n = 3), 95.5% (RSD = 4.1%, n = 3), and 94.3% (RSD = 2.6%, n = 3), respectively. The results indicated that this method had no significant matrix effects.

3.4. Extraction recovery

Blank serum was taken, and pre-extraction spiking and post-extraction spiking were performed with consistent absolute amounts added. High, medium, and low concentrations (relative to pre-extraction serum, amygdalin and paeoniflorin at 100, 20, and 3 ng/mL, respectively) were also examined. The extraction method was according to Section 1.6, with three parallel preparations for each condition. The extraction recovery was defined as the ratio of the peak areas in the pre-extraction spiked blank samples to those in the post-extraction spiked blank samples. The results showed that under this method, the extraction recoveries for amygdalin at high, medium, and low concentrations were 91.1% (RSD = 7.0%, n = 3), 94.2% (RSD = 4.1%, n = 3), and 92.0% (RSD = 10.2%, n = 3), respectively, while those for paeoniflorin were 90.3% (RSD = 5.8%, n = 3), 93.7% (RSD = 8.2%, n = 3), and 94.1% (RSD = 12.5%, n = 3), respectively. The results indicated that this method had good extraction recovery with minimal losses during sample processing.

3.5. Linear range and lower limit of quantification investigation

Blank serum was taken and spiked to prepare blank serum spiked samples with amygdalin and paeoniflorin concentrations of 1, 2, 5, 10, 20, 50, 100, and 300 ng/ml. Three portions were prepared for each concentration, processed according to the method in Section 1.6, and injected for analysis according to the method in Section 1.4. Linear regression was performed with the mass concentrations (c) of amygdalin and paeoniflorin as the abscissa and their peak areas (Y) as the ordinate. The regression equations for amygdalin and paeoniflorin were Y = 455.0558c + 114.7196, r = 0.9994, and Y = 370.8633c + 38.5879, r = 0.9993, respectively. The linear ranges for both analytes were 1–300 ng/mL, and the lower limits of quantification for amygdalin and paeoniflorin were both 0.3 ng/mL (signal-to-noise ratio (S/N) > 10, relative standard deviations (RSDs) were 9.1% and 11%, respectively).

3.6. Precision and accuracy

Blank serum spiked samples with amygdalin and paeoniflorin concentrations of 3, 20, and 100 ng/mL were prepared, with six parallel preparations for each concentration. The preparations and determinations were performed continuously for 3 days. The measured concentrations of each sample were calculated based on the daily working curves, and the experimental results are shown in **Table 1**. The results showed that the intra-day and inter-day pre-

cision RSDs were both < 15%, and the relative errors (REs) were within ± 15%, indicating that this method had good precision and accuracy, meeting the determination requirements for biological samples.

Table 1. Results of precision and accuracy tests

Drug	Added Concentration (ng/mL)	Measured Concentration (ng/mL)	Precision RSD/%		Accuracy/%	RE/%
			Intra-day (n = 6)	Inter-day (n = 18)		
Amygdalin	3	3.231	3.4	5.2	107.7	7.7
	20	21.951	2.9	5.4	109.8	9.8
	100	97.999	5.7	6.9	98.0	-2.0
Paeoniflorin	3	3.355	3.9	4.5	111.8	11.8
	20	19.357	2.7	3.8	96.8	-3.2
	100	102.619	4.1	6.3	98.1	-1.9

3.7. Stability investigation

Blank serum was taken and spiked to prepare blank serum spiked samples with amygdalin and paeoniflorin mass concentrations of 3, 20, and 100 ng/mL. Three parallel preparations were made for each concentration. The drug concentrations were examined after placing at room temperature for 24 h, undergoing three freeze-thaw cycles at -40 ℃, and long-term freezing at -40 ℃ for 20 days. The results showed that the REs between all measured concentrations and theoretical concentrations were within ± 15%, indicating that amygdalin and paeoniflorin were stable during room temperature placement, repeated freeze-thaw cycles, and long-term freezing of serum samples, and that these storage conditions did not affect the accurate determination of the samples.

3.8. Sample determination

Serum samples were processed according to the method in Section 1.6, and the blood drug concentrations of amygdalin and paeoniflorin in various serum samples obtained from three dosages (high, medium, and low) were determined by recording the peak areas under the chromatographic-mass spectrometric conditions in Section 1.4. The results are shown in **Table 2**. The determination results indicated that amygdalin and paeoniflorin could be detected in the serum of rats after intragastric administration, and the higher the dosage, the greater the detected amount in the serum, proving the presence of traditional Chinese medicine ingredient groups represented by amygdalin and paeoniflorin in the drug-containing serum of rats after oral administration of “Feixin Decoction”.

Table 2. Test results of test samples

Dosage level	Sample name	Test Concentration (ng/mL)	
		Amygdalin	**Paeoniflorin**
Low	L_1	2.41	2.89
	L_2	2.12	4.85
	L_3	2.43	2.33
	L_4	2.74	3.53
	L_5	0.86	1.77
	L_6	1.38	2.41
	Mean	**1.99**	**2.96**
Medium	M_1	5.07	5.91
	M_2	2.99	9.23
	M_3	6.59	11.10
	M_4	3.08	6.58
	M_5	4.54	18.40
	M_6	2.48	6.85
	Mean	**4.12**	**9.67**
High	H_1	2.65	8.75
	H_2	8.25	22.85
	H_3	7.525	28.75
	H_4	6.625	10.05
	H_5	9.75	30.00
	H_6	8.20	18.22
	Mean	**7.17**	**19.77**

4. Conclusion

In this study, a high-performance liquid chromatography-tandem mass spectrometry (LC-MS/MS) method was established to determine the serum concentrations of amygdalin and paeoniflorin in serum samples. A specific, sensitive, accurate, and rapid LC-MS/MS method was developed for research in fields such as cytology and pharmacology related to traditional Chinese medicine compounds. This approach inherits and advances the research direction of traditional Chinese medicine, laying a foundation for elucidating the in vivo metabolism and pharmacodynamic mechanisms of the traditional Chinese medicine compound "Feixin Decoction", and providing support for subsequent serum pharmacological experiments in related research.

Disclosure statement

The author declares no conflict of interest.

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Research on the Application Effect of Digital Pathology-Assisted Technology in the Differential Diagnosis of Left and Right Hemicolon Cancer

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Abstract: *Objective*: To explore the application value of digital pathology-assisted technology in the differential diagnosis of left and right hemicolon cancer, compare the efficacy differences between conventional pathological diagnosis and digital pathology-assisted diagnosis, and provide a basis for clinical precise differential diagnosis. *Methods*: A total of 200 patients with colon cancer who underwent surgery in our hospital from October 2024 to October 2025 were selected as the study subjects. They were divided into a control group (100 cases) and an observation group (100 cases) according to the random number table method. The control group was diagnosed manually using conventional pathological sections, while the observation group was diagnosed with the assistance of digital pathological sections. Both groups clearly identified the lesion sites in the left and right hemicolon. The general data, diagnostic time consumption, diagnostic accuracy, and consistency in interpreting pathological features were compared between the two groups. *Results*: There were no statistically significant differences in general data such as gender, age, and disease duration between the two groups ($p > 0.05$). The average diagnostic time consumption in the observation group was significantly shorter than that in the control group, the diagnostic accuracy rate was significantly higher, and the misdiagnosis rates were significantly lower (all $p < 0.05$). There was no statistically significant difference in the missed diagnosis rate ($p = 0.088 > 0.05$). The consistency rates in interpreting the four indicators of tumor differentiation degree, infiltration depth, lymph node metastasis, and pathological morphology in the observation group were higher than those in the control group (all $p < 0.05$). Conclusion: The application of digital pathology-assisted technology in the differential diagnosis of left and right hemicolon cancer can significantly shorten the diagnostic time, improve the diagnostic accuracy rate, reduce the risks of misdiagnosis and missed diagnosis, and enhance the consistency in interpreting pathological features. It is suitable for promotion and application in clinical pathological diagnosis.

Keywords: Digital pathology; Colon cancer; Left and right hemicolon; Differential diagnosis; Controlled study

Online publication: Apr 21, 2026

1. Introduction

Colon cancer is a highly prevalent malignant tumor of the digestive tract in clinical settings, with notable differences in its incidence between the right and left halves of the colon. The right half of the colon encompasses the cecum, ascending colon, and proximal transverse colon, while the left half includes the distal transverse colon, descending colon, and sigmoid colon. Significant differences exist between the two in terms of clinical symptoms, pathological characteristics, treatment plans, and prognosis outcomes [1,2]. Clinical practice has demonstrated that accurately distinguishing between right- and left-sided colon cancer holds significant importance for developing individualized treatment plans, assessing prognosis, and selecting targeted drugs. Therefore, improving the accuracy of differential diagnosis for the location of colon cancer lesions has become a focal point of clinical research [3]. Conventional pathological diagnosis relies on pathologists visually examining tissue sections, which is influenced by factors such as the pathologist's experience, visual fatigue, and section quality. This approach is associated with issues such as prolonged diagnostic time, inadequate identification of subtle pathological features, and relatively high rates of misdiagnosis and missed diagnosis, particularly in cases of early lesions or those with ambiguous lesion boundaries, where differentiation is challenging. Digital pathology-assisted technology leverages whole-slide digital scanning technology to convert pathological sections into high-definition digital images. By employing techniques such as image optimization and feature extraction, it assists pathologists in diagnosis, overcoming the limitations of traditional visual observation and enhancing diagnostic accuracy and efficiency [4]. However, there is still a relative lack of comparative studies on its application in the differential diagnosis of right- and left-sided colon cancer, and large-sample research data are scarce. This study conducted a prospective controlled study involving 200 colon cancer patients to compare the application effects of conventional pathological diagnosis and digital pathology-assisted diagnosis, aiming to clarify the clinical value of digital pathology-assisted technology and provide empirical evidence for optimizing the pathological diagnosis process of colon cancer.

2. Materials and methods

2.1. General information

A total of 200 patients with colon cancer who underwent surgical resection in the General Surgery Department of our hospital from October 2024 to October 2025 were selected. Using a random number table method, these 200 patients were divided into a control group and an observation group, with 100 patients in each group.

2.1.1. Inclusion criteria

(1) Diagnosed with primary colon cancer based on postoperative pathology;
(2) Complete clinical data without any missing items;
(3) No neoadjuvant therapy such as radiotherapy, chemotherapy, or targeted therapy before surgery;
(4) Patients and their families provided informed consent and signed the research informed consent form;
(5) No severe dysfunction of vital organs such as the heart, liver, and kidneys, and able to tolerate surgery and pathological examination.

2.1.2. Exclusion criteria

(1) Metastatic or recurrent colon cancer;
(2) Concomitant with other malignant tumors of the digestive tract;

(3) Poor quality of pathological sections that cannot be digitally scanned;
(4) Presence of mental illness or cognitive impairment that prevents cooperation with the study;
(5) Incomplete clinical data or withdrawal from the study midway.

2.2. Methods

All surgical resection specimens from the patients were adequately fixed using a 4% neutral formaldehyde solution according to the clinical pathological specimen fixation standards, with a fixation time of 12–24 hours. The specimens were then routinely dehydrated, embedded in paraffin, and sectioned continuously into 4 μm-thick sections. These sections were stained with hematoxylin-eosin (HE) to prepare standard pathological sections.

2.2.1. Control group

Conventional pathological diagnosis was adopted. Two associate chief physicians or above with over 10 years of experience in gastrointestinal pathology diagnosis independently observed the sections using an optical microscope to determine the pathological type, degree of differentiation, depth of invasion, and lymph node metastasis status of the tumor, and accurately differentiate between right-sided and left-sided colon cancer. In cases of diagnostic disagreement, a third chief physician was consulted to determine the final result. The diagnostic process did not involve any digital assistive devices and relied solely on visual observation and clinical experience.

2.2.2. Observation group

Digital pathology-assisted diagnosis was adopted. First, the prepared HE-stained pathological sections were subjected to full-field digital scanning using an automatic digital pathology slide scanner to generate high-definition digital pathological images, which were then uploaded to a pathological diagnosis workstation. The same two senior pathologists observed the images through the digital pathology workstation and could perform operations such as zooming in, zooming out, adjusting contrast, and local focusing to assist in identifying pathological features. They completed the differentiation between right-sided and left-sided colon cancer and the assessment of pathological features according to the same diagnostic criteria. The method for handling disagreements was the same as that in the control group. The entire diagnostic process relied on digital pathological images, retaining the advantage of observing image details without additional reliance on intelligent analysis modules, focusing on the core value of digital image-assisted diagnosis.

2.3. Observation indicators

(1) Comparison of general information
Statistics on indicators such as gender, age, disease duration, tumor stage, and lesion location were collected for both groups to confirm inter-group balance.
(2) Diagnostic efficiency and effectiveness indicators
The average diagnostic time per patient in both groups was recorded, defined as the time from when the pathologist began observing the sections to when the final diagnostic report was issued. Using the localization of postoperative gross specimens and the results of multidisciplinary joint diagnosis as the gold standard, the diagnostic accuracy rate, misdiagnosis rate, and missed diagnosis rate of both groups were calculated. Accuracy rate = (number of confirmed cases / total number of cases) × 100.00%; Misdiagnosis rate = (number of misdiagnosed cases / total number of cases) × 100.00%; Missed diagnosis rate = (number

of missed cases / total number of cases) × 100.00%.

(3) Comparison of pathological features

The pathological types, degrees of differentiation, and lymph node metastasis status of patients in both groups were statistically analyzed to compare the differences in the distribution of pathological features among patients with different lesion locations.

2.4. Statistical methods

Data analysis was performed using SPSS 26.0 statistical software. Measurement data were expressed as (mean ± standard deviation), and independent sample t-tests were used for inter-group comparisons. Count data were expressed as [n (%)], and χ^2 tests were used for inter-group comparisons. A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of general information between the two groups

There were no statistically significant differences in general information such as gender, age, disease duration, and proportion of lesion locations between the two groups (all $p > 0.05$). See **Table 1** for details.

Table 1. Comparison of general information between the two groups

Group	Gender (M/F)	Average age (years, $\bar{x} \pm s$)	Average disease duration (months, $\bar{x} \pm s$)	Right colon [n (%)]	Left colon [n (%)]
Control group (n = 100)	57/43	58.64 ± 7.23	4.32 ± 1.56	46 (46.00)	54 (54.00)
Observation group (n = 100)	59/41	59.12 ± 6.89	4.45 ± 1.48	48 (48.00)	52 (52.00)
t/χ^2	0.082	0.490	0.606	0.080	
p	0.774	0.624	0.545	0.777	

3.2. Comparison of diagnostic time consumption and diagnostic efficacy

Between the two groups, the average diagnostic time consumption in the observation group was significantly shorter than that in the control group, with a significantly higher diagnostic accuracy rate and significantly lower misdiagnosis rates in the observation group (all $p < 0.05$). There was no statistically significant difference in the missed diagnosis rate ($p = 0.088 > 0.05$). See **Table 2** for details.

Table 2. Comparison of diagnostic time consumption and diagnostic efficacy between the two groups

Group	Average diagnosis time (min, $\bar{x} \pm s$)	Accuracy rate [n (%)]	Misdiagnosis rate [n (%)]	Missed diagnosis rate [n (%)]
Control group (n = 100)	35.78 ± 5.26	84 (84.00)	10 (10.00)	7 (7.00)
Observation group (n = 100)	18.62 ± 3.45	96 (96.00)	2 (2.00)	2 (2.00)
t/χ^2	27.250	8.000	5.674	2.909
p	< 0.001	0.005	0.017	0.088

3.3. Comparison of consistency rates in interpreting pathological indicators

Between the two groups, the consistency rates in interpreting the four indicators of tumor differentiation degree, infiltration depth, lymph node metastasis, and pathological morphology in the observation group were all higher than those in the control group (all $p < 0.05$). See **Table 3** for details.

Table 3. Comparison of consistency rates in interpreting pathological indicators between the two groups

Group	Degree of differentiation [n (%)]	Depth of invasion [n (%)]	Lymph node metastasis [n (%)]	Pathological morphology [n (%)]
Control group (n = 100)	82.00 (82/100)	83.00 (83/100)	80.00 (80/100)	84.00 (84/100)
Observation group (n = 100)	94.00 (94/100)	95.00 (95/100)	93.00 (93/100)	96.00 (96/100)
χ^2	6.819	7.354	7.236	8.000
p	0.009	0.007	0.007	0.005

4. Discussion

Although right-sided and left-sided colon cancers are both malignant tumors of the colon, due to differences in embryonic origin, intestinal anatomical structure, and intestinal microenvironment, they exhibit significant heterogeneity in clinical features, pathological morphology, and biological behavior, and have been clinically recognized as two distinct disease entities [5]. The right colon has a spacious lumen, and its contents are mostly liquid. Tumors there often grow in an exophytic manner, with clinical manifestations mainly including anemia, abdominal masses, and chronic abdominal pain. The pathological differentiation degree is relatively low, and the incidence of lymph node metastasis is comparatively low. In contrast, the left colon has a narrow lumen, and its contents are dry and hard. Tumors there often grow in an infiltrative manner, which is prone to causing intestinal obstruction, with prominent hematochezia symptoms. The pathological differentiation degree is relatively high, and the risk of lymph node metastasis is greater. Accurately differentiating between right-sided and left-sided colon cancers can guide the clinical selection of appropriate surgical methods, chemotherapy regimens, and targeted drugs, and improve patient prognosis. Therefore, enhancing the accuracy of pathological diagnosis is of crucial importance [6].

Conventional pathological diagnosis is a classic clinical diagnostic method that relies on visual observation of sections under an optical microscope, highly dependent on the professional competence and experience of pathologists [7]. Moreover, prolonged section reading can lead to visual fatigue. For cases with ambiguous lesion boundaries and subtle pathological features, misdiagnosis and missed diagnosis are prone to occur. Additionally, manual section reading is relatively slow, and the diagnostic process is time-consuming, making it difficult to meet the rapid diagnostic needs in clinical practice. The data from the control group in this study showed that the accuracy rate of conventional pathological diagnosis was only 84.00%, with a misdiagnosis rate of 10.00%, a missed diagnosis rate of 6.00%, and an average diagnostic time as long as 35.78 minutes. These results are consistent with the limitations in actual clinical application, especially for primary hospitals or pathologists with insufficient experience, where the risk of diagnostic errors is even higher.

Digital pathology-assisted technology converts pathological sections into high-definition digital images through automatic scanning, breaking through the field-of-view limitations of traditional optical microscopes. It allows for arbitrary magnification, local focusing, and contrast adjustment of images, enabling clear visualization of subtle pathological features such as cell morphology, tissue structure, and the extent of infiltration, and reducing

diagnostic errors caused by human factors [8]. Meanwhile, digital pathological images can be permanently stored and quickly retrieved, facilitating repeated observation by physicians and remote consultations, thereby significantly improving diagnostic efficiency. In this study, the observation group adopting digital pathology-assisted diagnosis had an average diagnostic time shortened to 18.62 minutes, with the diagnostic accuracy rate increased to 96.00%, and the misdiagnosis and missed diagnosis rates decreased to 2.00% and 2.00% respectively. All these indicators were significantly better than those of the control group, confirming that digital pathology-assisted technology can effectively optimize the diagnostic process and enhance the efficacy of differential diagnosis.

In terms of pathological indicators, there were significant statistical differences between patients with right-sided and left-sided colon cancers in aspects such as age, tumor diameter, degree of differentiation, and depth of invasion. Patients with right-sided colon cancer were generally older, had larger tumor diameters, and higher proportions of poorly differentiated and deeply infiltrating tumors. The digital pathology-assisted system can more precisely quantify these pathological differences through standardized image analysis, providing objective evidence for differential diagnosis and avoiding judgment biases caused by experience differences in conventional diagnosis [9]. Moreover, the digital pathology diagnostic process is more standardized, which can shorten the time for section retrieval and microscopic observation, improve the efficiency of pathological diagnosis, alleviate the work pressure of clinical pathologists, and is suitable for promotion and application in both primary hospitals and large tertiary hospitals [10].

This study has certain limitations. The research samples were sourced from a single center. Although the sample size of 200 cases met the requirements of a controlled study, multi-center and large-sample studies are still needed for further validation. The study only focused on HE-stained sections and did not incorporate immunohistochemical and molecular pathological indicators. Subsequent research can expand the scope and combine multiple types of pathological indicators to enhance diagnostic value. Additionally, long-term follow-up was not conducted, and the correlation between diagnostic results and patient prognosis was not analyzed. Subsequent longitudinal studies can be carried out to complete the evidence chain for clinical application.

5. Conclusion

In conclusion, the application of digital pathology-assisted technology in the differential diagnosis of right-sided and left-sided colon cancers can significantly shorten the pathological diagnostic time, greatly improve the diagnostic accuracy rate, and effectively reduce the misdiagnosis and missed diagnosis rates. It can accurately identify the pathological feature differences between right-sided and left-sided colon cancers, providing a reliable basis for clinical precise diagnosis and individualized treatment. This technology is easy to operate and highly practical, without excessive reliance on complex intelligent modules, and is suitable for promotion and application in pathology departments of hospitals at all levels. It can further optimize the pathological diagnostic process for colon cancer and improve the diagnosis and treatment level of digestive tract tumors.

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Disclosure statement

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A Study on the Management of Sedation and Analgesia in ICU Patients Based on Fault Tree Analysis and the eCASH Concept

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Abstract: *Objective*: To investigate the efficacy of combining fault tree analysis with the eCASH (early Comfort using Analgesia, Sedation, and delirium monitoring) concept in the management of sedation and analgesia for ICU patients. *Methods*: A total of 90 patients admitted to the ICU of a certain hospital between January and December 2025 who required sedation and analgesia were selected as subjects. Using a random number table, they were divided into a control group and an observation group, comprising 45 patients each. The control group received conventional sedation and analgesia nursing management, whilst the observation group was managed using fault tree theory combined with the eCASH concept. Indicators such as RASS scores for sedation levels, pain intensity (NRS and FPS-R scores), and PSQI scores for sleep quality were compared between the two groups before and after intervention. *Results*: Compared with pre-intervention levels, RASS, NRS, FPS-R and PSQI scores were significantly reduced in both groups; however, the observation group showed lower scores than the control group, with statistically significant differences ($p < 0.05$). *Conclusion*: The application of fault tree theory combined with the eCASH concept in the management of sedation and analgesia for ICU patients can effectively standardise the management process and improve the efficacy of sedation and analgesia, and is worthy of clinical promotion and application.

Keywords: Fault tree analysis; eCASH concept; ICU; Sedation and analgesia; Nursing management; Prognosis

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1. Introduction

Sedation and analgesia management is a critical component of intensive care unit (ICU) treatment, directly influencing patient comfort, safety, and clinical outcomes. Inadequate management may lead to delirium, prolonged mechanical ventilation, increased length of stay, and impaired recovery. The eCASH (early Comfort using Analgesia, Sedation, and delirium monitoring) concept emphasizes early, patient-centered comfort with minimal sedation, while fault tree analysis offers a systematic, logic-based approach to identifying and mitigating risks in complex

clinical processes. However, the combined application of these two strategies in ICU sedation and analgesia management remains underexplored. This study aims to evaluate the efficacy of integrating fault tree analysis with the eCASH concept in improving sedation and analgesia outcomes among ICU patients.

2. Materials and methods

2.1. General information

A total of 90 patients admitted to the ICU of a certain hospital between January and December 2025 were selected as subjects. Using a random number table, the 90 patients were divided into a control group and an observation group, comprising 45 patients each. In the control group, there were 25 males and 20 females; ages ranged from 22 to 78 years, with a mean age of (56.32 ± 10.25) years; disease types included 15 cases of severe trauma, 12 cases of severe pneumonia, 10 cases of postoperative monitoring, and 8 other cases. In the observation group, there were 24 males and 21 females; aged 23–79 years, with a mean age of (57.14 ± 10.31) years; disease types: severe trauma (14 cases), severe pneumonia (13 cases), postoperative care (9 cases), and other conditions (9 cases). Comparison of general characteristics, including gender, age and disease type, between the two groups revealed no statistically significant differences ($p > 0.05$), indicating comparability.

2.1.1. Inclusion criteria

(1) Length of stay in the ICU ≥ 72 hours, requiring sedation and analgesia;
(2) Age ≥ 18 years and ≤ 80 years;
(3) Alert and oriented, or able to cooperate with relevant assessments following sedation (non-verbal assessment tools were used for those unable to cooperate);
(4) Informed consent from the patient and their family, with voluntary participation in the study;
(5) No history of severe hepatic or renal insufficiency, coagulation disorders, psychiatric disorders, or allergy to sedative-analgesic drugs.

2.1.2. Exclusion criteria

(1) Length of stay in the ICU < 72 hours
(2) Age < 18 or > 80 years;
(3) Presence of severe cognitive impairment or psychiatric disorders rendering the patient unable to cooperate with assessments;
(4) History of allergy to sedative-analgesic drugs, severe hepatic or renal failure, or coagulation disorders;
(5) Transfer to another hospital, withdrawal from the study, or death during the study period.

2.2. Methods

Patients in both groups received standard ICU care, including basic treatments such as antimicrobial therapy, fluid resuscitation, nutritional support and organ function protection. Appropriate sedative-analgesic medications were selected according to the patient's clinical condition, with dosages dynamically adjusted based on the achieved level of sedation and analgesia.

2.2.1. Control group

Received routine nursing care and sedation and analgesia management. The designated nurse in charge provided health education and sedation and analgesia interventions during the patient's hospital stay and prior to discharge. Based on their clinical experience, the nurse assessed the effectiveness of sedation and analgesia using standard evaluation methods and adjusted drug doses as required; simultaneously, basic nursing care such as oral care, skin care, and turning and back-patting was carried out in accordance with standard ICU nursing procedures, with attention paid to the patient's sleep patterns and the provision of sleep-aid measures where necessary.

2.2.2. Observation group

Managed using a combination of fault tree analysis and the eCASH framework, with the specific implementation steps as follows:

(1) Formation of a dedicated management team

A dedicated management team was established comprising the Head of the ICU, the Head Nurse, Senior Nurses, Charge Nurses and Clinical Pharmacists. A one-week specialized training programmed was conducted, covering the fundamentals of fault tree analysis, the core principles of the eCASH framework, the use of sedation and analgesia assessment tools, relevant guidelines and standards, and management procedures.

(2) Investigation and analysis of existing issues

The dedicated management team conducted a comprehensive review of all patient sedation and analgesia assessment forms, nursing records, medical records and medical orders. Referencing relevant guidelines such as the 'Chinese Guidelines for Analgesia and Sedation in Adult ICUs (2021 Edition)' and the 'Expert Consensus on Pain Assessment and Analgesic Treatment for Critically Ill Patients', they drafted the 'Questionnaire on Sedation-Related Issues for ICU Nurses' and administered it to all charge nurses in the ICU [1]. The questionnaire covered four dimensions, self-assessment of sedation efficacy, medication monitoring capabilities, accuracy of sedation assessment, and standardization of sedation care—comprising a total of 25 items. A 5-point Likert scale (1–5, where 1 indicates 'completely non-proficient' and 5 indicates 'completely proficient') was employed to comprehensively identify issues in the management of sedation and analgesia within the ICU.

(3) Analysis of root causes based on fault tree theory

Taking 'adverse events in ICU sedation and analgesia management' as the top event (including inappropriate sedation, poor pain control, and the occurrence of delirium), and combining this with the results of the preliminary survey, this study identified the direct and indirect causes of the top event and constructed a fault tree for ICU sedation and analgesia management (**Figure 1**). Direct causes included: inaccurate nursing assessments, non-standardized sedation and analgesia management objectives and processes, and inadequate implementation of sedation and analgesia nursing measures; indirect causes included: lack of standardized assessment tools, incorrect assessment frequency, inaccurate assessment methods, inconsistent management objectives, non-standardized management processes, inadequate implementation of bundled care measures, and inadequate medication management.

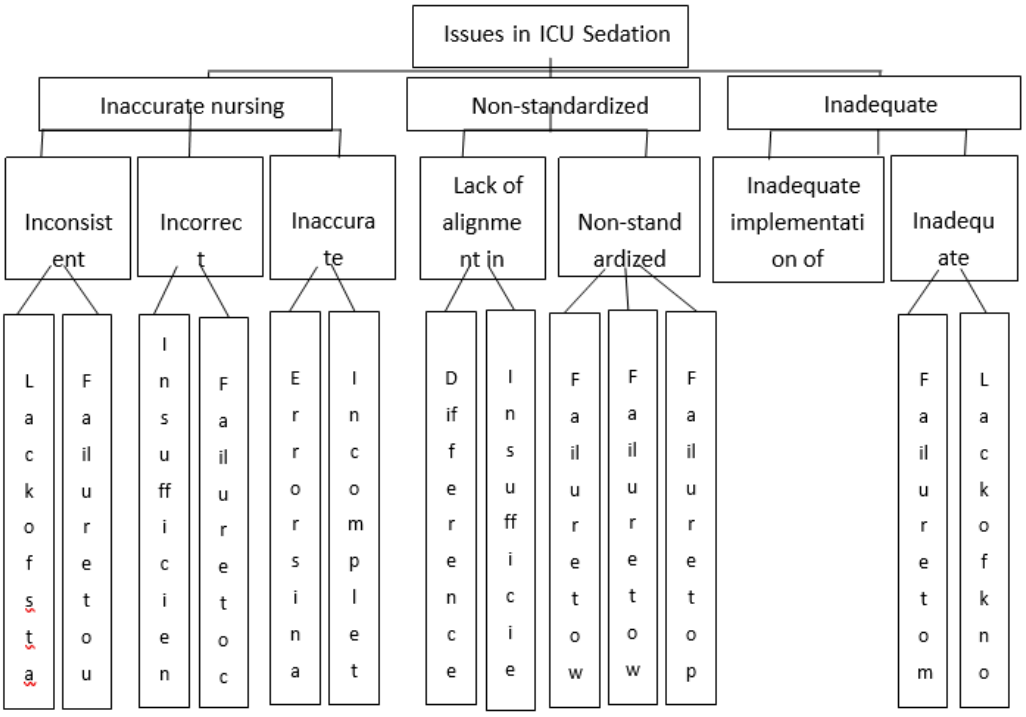


Figure 1. Fault tree for sedation and analgesia management in the ICU.

(4) Formulation and implementation of management strategies based on the eCASH concept

Through fault tree analysis, the logical relationships between events at various levels were clarified, and weaknesses in management were identified. Guided by these findings and in conjunction with the core requirements of the eCASH concept—'early comfort, individualized sedation and analgesia, enhanced delirium monitoring, and promotion of early patient mobilization'—targeted ICU sedation and analgesia management strategies were formulated and implemented, as detailed below: ① Standardized assessment tools and methods: All nursing staff shall use standardized assessment tools. Sedation levels shall be assessed using the Richmond Agitation-Sedation Scale (RASS); pain levels shall be assessed using the Numeric Rating Scale (NRS) and the Chinese Revised Adult Nonverbal Pain Scale (NVPS-R).Assessments are conducted at fixed intervals of once every 1–2 hours; for patients with unstable conditions or inadequate sedation and analgesia, the assessment interval is reduced to once every 30 minutes to 1 hour. ② Implementation of precise sedation and analgesia monitoring and intervention: Strictly adhering to the precise sedation targets of the eCASH concept, with 'optimal light sedation' (RASS score 0–2) as the core objective, and developing individualized sedation and analgesia plans based on the patient's specific condition. Clinical pharmacists guide nurses in the appropriate selection of sedative-analgesic drugs and initial dosages based on the patient's age, weight, disease severity, and hepatic and renal function; if the patient's NRS score is > 4, FPS-R score is > 3, or RASS score is >2 (insufficient sedation), promptly increase the dosage of sedative-analgesic drugs; If a patient's RASS score is < -3 (excessive sedation), promptly reduce the drug dose (by no more than 1–2 ml per hour per reduction) until the desired control target is achieved. For patients whose scores remain below the standard after multiple dose adjustments, conduct a comprehensive assessment to rule out irreversible factors such as severe infection or organ failure, and report to the doctor for investigation of the cause and targeted management. □ Strengthen

training and assessment on sedation and analgesia: In response to the issue of 'insufficient professional competence among nurses' identified by the fault tree analysis, develop a systematic training plan. Led by the clinical team and teaching supervisors, conduct regular training on theoretical knowledge and practical skills related to sedation and analgesia. Content should include: the pharmacological effects of sedative and analgesic drugs, methods of administration, management of adverse reactions, correct use of assessment tools, core concepts of the eCASH framework, and relevant guidelines and standards [2]. Following the training, assessments of theoretical knowledge and practical skills will be conducted. Only those who pass the assessment will be permitted to participate in sedation and analgesia nursing duties; those who fail will be suspended from work and required to undergo further intensive training, followed by a re-assessment, until they pass. ④ Optimizing sedation and analgesia nursing interventions: Comprehensive sedation and analgesia nursing interventions are implemented in accordance with the 'comfort-oriented care' requirements of the eCASH concept. Basic care: Perform warm sponge baths twice daily, oral care twice daily, and repositioning with back tapping (once every two hours) to keep the skin clean and dry, and prevent complications such as pressure ulcers and oral infections; Sleep care: Dim the lights in the ward and draw the curtains at set times to simulate a normal circadian rhythm, helping patients develop regular sleep patterns; Communication care: For patients unable to express themselves verbally, special identification cards are created to guide patients in communicating their wishes through gestures or the cards, ensuring their needs are met promptly. ⑤ Establish a quality tracking and continuous improvement mechanism: Drawing on the eCASH framework and the results of fault tree analysis, develop the 'Intensive Care Unit Precision Sedation Quality Tracking Form'. Analyze the causes of issues identified in the checklist, formulate improvement measures, specify deadlines and assign responsibility. Following the implementation of these measures, conduct follow-up inspections to establish a closed-loop management cycle of 'investigation–analysis–improvement–follow-up'.

2.3. Observation indicators

(1) Level of sedation

The RASS score was used to assess the level of sedation in both groups of patients prior to management and 7 days after management. The RASS score ranges from -5 to +4; a higher score indicates a shallower level of sedation. Specifically, -5 indicates unresponsiveness, -4 indicates deep sedation, -3 indicates moderate sedation, -2 to 0 indicates light sedation (optimal sedation state), and +1 to +4 indicates agitation.

(2) Pain intensity

The Numeric Rating Scale (NRS) and the revise

Facial Pain Scale-Revised (FPS-R) to assess pain levels in both groups of patients before treatment and 7 days after treatment. The NRS score ranges from 0 to 10, where 0 indicates no pain, 1–3 indicates mild pain, 4–6 indicates moderate pain, and 7–10 indicates severe pain; a higher score indicates more intense pain. The FPS-R score is assessed using six facial expression symbols, with a score range of 0–10; a higher score indicates more intense pain.

(3) Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) was used to assess sleep quality in both groups before management and 7 days after management. This scale comprises five dimensions: sleep quality, time to sleep, sleep duration, sleep efficiency, and sleep disturbances. Each dimension is scored on a scale of 0–3, with a

total score ranging from 0 to 15; a lower score indicates better sleep quality.

2.4. Statistical analysis

Data analysis was performed using SPSS 26.0 statistical software. Continuous variables are expressed as mean ± standard deviation ($\overline{x}$ ± s). Paired *t*-tests were used for comparisons within groups, and independent samples t-tests were used for comparisons between groups. Categorical variables are expressed as frequency (percentage) [n (%)], and chi-square (χ^2) tests were used for comparisons between groups. A *p*-value of < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of RASS scores between the two groups

Compared with pre-intervention levels, RASS scores in both groups decreased significantly, with the observation group scoring lower than the control group, and the difference was statistically significant ($p < 0.05$). See **Table 1**.

Table 1. Comparison of RASS scores between the two groups before and after intervention ($\overline{x}$ ± s, points)

Group	Before intervention	After intervention	t	p
Control group (n = 45)	2.54 ± 0.62	1.22 ± 0.48	11.293	< 0.001
Observation group (n = 45)	2.52 ± 0.59	0.71 ± 0.23	19.174	< 0.001
t	0.157	6.428		
p	0.876	< 0.001		

3.2. Comparison of sleep quality scores between the two groups

Following scientific nursing management, all sleep quality scores in the observation group were significantly lower than those in the control group, with the differences being statistically significant ($p < 0.05$), as shown in **Table 2**.

Table 2. Comparison of sleep quality scores between the two groups ($\overline{x}$ ± s, points)

Group	Sleep quality	Time to fall asleep	Sleep duration	Sleep efficiency	Sleep disorders
Control group (n = 45)	1.45 ± 0.49	1.24 ± 0.37	1.26 ± 0.35	1.34 ± 0.35	1.42 ± 0.53
Observation group (n = 45)	1.03 ± 0.37	0.82 ± 0.19	0.64 ± 0.22	1.03 ± 0.31	1.01 ± 0.35
t	4.589	6.774	10.061	4.448	4.330
p	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

3.3. Comparison of pain status between the two groups before and after management

Prior to management, there was no statistically significant difference in NRS and FPS-R scores between the two groups ($p > 0.05$); following systematic management, NRS and FPS-R scores decreased significantly in both groups, with the observation group showing lower scores than the control group, and the difference was statistically significant ($p < 0.05$), as shown in **Table 3**.

Table 3. Comparison of pain status between the two groups of patients ($\overline{x}$ ± s, points)

Group	NRS				FPS-R			
	Before management	Before management	t	p	Before management	After management	t	p
Control group (n = 45)	5.32 ± 1.39	4.11 ± 1.14	4.515	< 0.001	5.41 ± 1.37	3.42 ± 1.25	7.198	< 0.001
Observation group (n = 45)	5.28 ± 1.35	3.05 ± 1.04	8.778	< 0.001	5.39 ± 1.42	2.05 ± 1.03	12.772	< 0.001
t	1.139	1.609			0.068	5.674		
p	0.890	< 0.001			0.946	< 0.001		

4. Discussion

Many ICU patients require sedation and analgesia due to severe trauma, critical infections, or major surgery; however, current routine clinical management of sedation and analgesia largely relies on nurses' clinical experience. This approach suffers from issues such as inconsistent assessment criteria, non-standardized procedures, and inadequate interventions, resulting in suboptimal outcomes [3]. Therefore, exploring a scientific and efficient management model for sedation and analgesia in the ICU, optimizing management processes, and improving management quality holds significant clinical importance.

Fault tree analysis is a systematic safety analysis method. By establishing logical relationships between top-level events (adverse events) and causal events at various levels, it clearly identifies the root causes of adverse events and weaknesses in management, thereby providing a scientific basis for formulating targeted improvement measures. The eCASH concept is a novel approach to sedation and analgesia management for critically ill patients proposed in recent years. Its core principles are 'early comfort, individualized sedation and analgesia, enhanced delirium monitoring, and promotion of early patient mobilization'. It emphasizes a patient-centered approach, aiming to achieve optimized sedation and analgesia management through precise assessment, individualized intervention and continuous monitoring, thereby reducing the incidence of adverse events [4]. This study attempts to integrate fault tree analysis with the eCASH concept to achieve a closed-loop management system comprising "precise problem identification–systematic root cause analysis–scientific strategy formulation–continuous quality improvement". The aim is to address the shortcomings of conventional management models and enhance the scientific rigor and standardization of sedation and analgesia management in the ICU.

The results showed that following the implementation of the management strategy, the RASS, NRS, FPS-R and PSQI scores of patients in the observation group were significantly lower than those in the control group, with statistically significant differences ($p < 0.05$). This indicates that the combination of fault tree theory and the eCASH concept can effectively improve the efficacy of sedation and analgesia in ICU patients, alleviate pain and enhance sleep quality. The reasons for this are as follows:

(1) Problem analysis based on fault tree theory enables the precise identification of core issues in ICU sedation and analgesia management, such as 'inaccurate assessment, non-standardized procedures, and inadequate nursing measures', providing clear guidance for the formulation of management strategies and avoiding blind intervention;

(2) The standardization of sedation and analgesia assessment tools and methods effectively improves the accuracy and timeliness of assessment results, providing a reliable basis for the precise adjustment of sedation and analgesic drug doses [5];

(3) The development of individualized sedation and analgesia plans in accordance with the eCASH concept enables dynamic adjustment of drug dosages with the aim of achieving optimal light sedation, thereby preventing both oversedation and undersedation and significantly enhancing the safety and efficacy of sedation and analgesia treatment.

5. Conclusion

In summary, the management of sedation and analgesia in ICU patients based on a combination of fault tree theory and the eCASH concept has yielded favorable results. It effectively standardizes the management process, improves the accuracy of sedation and analgesia assessments and the compliance rate with procedural standards, optimizes the effects of sedation and analgesia, alleviates patient pain, improves sleep quality, and enhances patient prognosis. It is therefore worthy of widespread clinical application.

Disclosure statement

The authors declare no conflict of interest.

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Exploration on the Application of Airway Care Measures During the Coma Period in Pediatric Patients with Severe Craniocerebral Injury

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Abstract: *Objective*: This study aims to systematically evaluate the practical effects of an integrated airway care protocol in the clinical management of pediatric patients with severe craniocerebral injury in a coma, with the core objective of reducing airway-related complications and optimizing treatment outcomes. *Methods*: A prospective study was conducted involving 76 pediatric patients with severe craniocerebral injury in a coma who were admitted to the paediatrics of our hospital from January 2022 to December 2023 and met the inclusion criteria. These patients were randomly divided into an intervention group and a conventional group, with 38 cases in each group. The conventional group received standard neurosurgical airway care, while the intervention group implemented a systematic care strategy encompassing precise humidification, programmed suctioning, individualized positioning adjustments, and early respiratory function intervention. The incidence of ventilator-associated pneumonia and airway mucosal injury, duration of invasive ventilation, length of stay in the paediatrics, and improvements in arterial oxygen and carbon dioxide partial pressures before and after intervention were recorded and compared between the two groups. *Results*: The incidence of ventilator-associated pneumonia in the intervention group was 13.16%, significantly lower than the 34.21% in the conventional group. The incidence of airway mucosal injury in the intervention group was 10.53%, also lower than the 28.95% in the conventional group. In terms of time indicators, the intervention group had shorter average durations of mechanical ventilation and paediatrics stay compared to the conventional group. Blood gas analysis results showed that the intervention group had greater increases in arterial oxygen partial pressure and decreases in carbon dioxide partial pressure than the conventional group, with statistically significant differences between the groups. *Conclusion*: Comprehensive and proactive airway care interventions during the coma period in pediatric patients with severe craniocerebral injury can effectively safeguard airway function integrity, significantly reduce the risk of major complications, accelerate the critical care process, and thereby provide more stable support conditions for neurological recovery. This protocol holds clinical practical value.

Keywords: Children; Severe craniocerebral trauma; Consciousness disorder; Airway management; Ventilator-associated pneumonia

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1. Introduction

Pediatric severe craniocerebral trauma is a critical condition with high mortality and disability rates, and coma is a common and severe clinical state. During this stage, due to the inhibition of higher nervous activities, pediatric patients lose key airway defense mechanisms such as coughing and swallowing, making airway management a core challenge and a weak link in determining the success of treatment. Improper airway maintenance can directly induce or exacerbate pulmonary infections, atelectasis, physical airway injuries, and even respiratory failure. These secondary problems not only aggravate the primary brain injury but also pose significant mortality risks. Previous nursing practices have often been fragmented and reactive, lacking a proactive, evidence-based intervention system that spans the entire course of the disease and is difficult to cope with the complex and changing pathological conditions of pediatric patients. Therefore, exploring and establishing a scientific, standardized, and suitable airway maintenance strategy for the physiological structure of children to achieve proactive defense, reduce complications, and support the treatment of primary diseases has become an urgent need in the development of pediatric critical care nursing. This study focuses on this aspect, aiming to analyze the application efficacy of a comprehensive airway care protocol through clinical control and provide references for improving the nursing quality of such pediatric patients.

2. Materials and methods

2.1. General information

This research protocol has been approved by the institutional ethics committee. The study subjects comprised 76 children with severe traumatic brain injury and coma admitted to the paediatrics of our hospital from January 2022 to December 2023.

2.1.1. Inclusion criteria

Age between 1 and 12 years; confirmed diagnosis of severe traumatic brain injury with a Glasgow Coma Scale (GCS) score ranging from 3 to 8; anticipated duration of coma exceeding 72 hours; and established artificial airway for respiratory support.

2.1.2. Exclusion criteria

Pre-existing severe pneumonia, chronic respiratory diseases, or airway developmental abnormalities prior to admission; concurrent severe thoracoabdominal trauma directly affecting respiration; incomplete clinical data records; or withdrawal of active treatment by family members during the study.

2.1.3. Study design

Using a randomization method, the selected children were assigned to either the intervention group or the conventional group, with an equal number of 38 children in each group. Analysis of baseline information, including demographic characteristics, causes of injury, and neurological function scores at admission, revealed no statistically significant differences between the two groups, providing a comparable foundation.

2.2. Nursing methods

Children in the conventional group received standard airway care in the neurosurgical intensive care unit, which

included: regularly injecting humidified fluids into the airway as prescribed; performing superficial secretion aspiration based on clinical needs; regularly replacing the external ventilator circuit and humidification device; and performing basic oral hygiene care. Children in the intervention group received the above conventional care along with a structured comprehensive nursing intervention that integrated four key components: optimized humidification control, intelligent suctioning procedures, dynamic positioning adjustment, and early maintenance of respiratory muscle function. The implementation of this system emphasized proactivity, precision, and individualization.

2.3. Observation indicators

To comprehensively evaluate the intervention effects, the following observation indicators were set in this study. The primary endpoint indicator was the incidence rate of ventilator-associated pneumonia (VAP) during hospitalization, diagnosed strictly in accordance with the criteria issued by relevant domestic professional societies. Secondary endpoint indicators included: the incidence rate of visible airway mucosal injury; the total duration of invasive mechanical ventilation received; and the total number of days spent in the paediatrics. Additionally, laboratory physiological indicators, namely arterial partial pressure of oxygen (PaO_2) and partial pressure of carbon dioxide ($PaCO_2$), were measured before the initiation of the intervention measures and one week after continuous imple-mentation, and the changes in their values were calculated.

2.4. Statistical methods

All research data were statistically processed using the SPSS 26.0 software package. For measurement data conforming to a normal distribution, the mean ± standard deviation was used for representation. Comparisons of differences between groups were conducted using independent samples *t*-tests, while paired *t*-tests were used for comparisons within groups before and after the intervention. Categorical data were described in terms of case numbers and percentages, and comparisons of rates between groups were performed using the chi-square test or Fisher's exact probability method. A *p*-value less than 0.05 was used as the threshold for determining whether differences were statistically significant.

3. Implementation and evaluation of comprehensive airway nursing measures

3.1. Refined airway humidification and temperature management strategies

This section abandoned the traditional intermittent medication administration mode and instead adopted a dual-guarantee mode that combined continuous heating and humidification of the ventilator circuit with continuous infusion of humidified fluids via an external micro-pump. Specifically, the temperature of the ventilator humidifier was set and maintained within the physiological range of 34–37 ℃ to ensure that the absolute humidity of the delivered gas met the standard. Simultaneously, based on the graded assessment results of the children's sputum viscosity, a heated micro-pump was used to continuously infuse humidification media such as 0.45% sodium chloride solution at a rate of 0.5 to 2.0 milliliters per hour. The sputum properties were reassessed every four hours, and the pump rate was adjusted accordingly. This strategy aimed to create a stable and suitable intratracheal environment, ensure efficient ciliary movement, and prevent secretion crusting. The effects were evaluated by comparing the distribution proportions of sputum with different viscosities and the number of severe sputum plugs requiring bronchoscopy treatment between the two groups of children. See **Table 1**.

Table 1. Comparison of airway humidification management-related indicators between the two groups of children

Group	Number of cases	Proportion of grade I sputum viscosity (%)	Proportion of grade III sputum viscosity (%)	Number of cases requiring bronchoscopic sputum aspiration (%)
Intervention group	38	28 (73.68)	2 (5.26)	1 (2.63)
Conventional group	38	17 (44.74)	9 (23.68)	6 (15.79)
χ^2/t value		6.272	5.208	3.934
p value		0.012	0.022	0.047

3.2. Stepwise airway suctioning technique based on multimodal assessment

The core of this technique lies in integrating the principles of "necessary suctioning" and "safe suctioning". Firstly, a multi-indicator assessment system is established: the decision to perform suctioning is not solely based on abnormal ventilator parameters and decreased oxygen saturation but also takes into comprehensive consideration factors such as the pediatric patient's agitation, the presence of crackles during lung auscultation, and the effectiveness of physical airway clearance methods. Secondly, a step-by-step suctioning protocol is implemented: before the procedure, a few milliliters of humidification fluid are routinely instilled into the airway; during the procedure, a soft suction catheter with an appropriate diameter is selected, and a rotational withdrawal technique is employed, with strict control to ensure that each suctioning operation lasts no more than 15 seconds. The suction pressure is precisely set according to the patient's age. For thick secretions in the deep airway, a sequential approach of "instillation-dilution-suctioning" is adopted. This technique aims to efficiently clear secretions while minimizing the risk of airway injury and hypoxia. Quantitative assessment is conducted by statistically analyzing the average daily number of suctioning procedures, the number of instances of significant oxygen desaturation following suctioning, and cases of airway mucosal bleeding. See **Table 2**.

Table 2. Comparison of the incidence of adverse events related to suctioning procedures between the two groups of pediatric patients

Group	Number of cases	Mean daily suction frequency (times)	Number of Events with Post-Suction SpO_2 Decrease > 5% (%)	Number of cases with visible airway mucosal bleeding (%)
Intervention group	38	8.5 ± 2.1	42/532 (7.89)	3 (7.89)
Routine group	38	11.2 ± 3.4	89/510 (17.45)	9 (23.68)
t/χ^2 value		4.215	22.146	3.385
p value		< 0.001	< 0.001	0.066

3.3. Goal-oriented postural management and percussion vibration therapy

Based on the intracranial pressure level, circulatory stability status, and chest imaging findings of the pediatric patients, an individualized postural plan is formulated. When intracranial pressure permits, ensure that pediatric patients maintain a semi-reclined or lateral position with their head and chest elevated by 30–45 degrees for a cumulative total of no less than 6 hours per day, thereby utilizing gravity to promote diaphragmatic movement and the drainage of deep sputum. To prevent pressure injuries and pulmonary congestion, strictly adhere to a protocol of turning the patient along the axial line every two hours. Before and after turning, assist in the application of a high-frequency chest wall oscillation device to perform regular percussion on the bilateral hilar regions and the back, with the frequency set within the range of 15–25 Hz. Administer this treatment 3 to 4 times daily, with each

session lasting 10–15 minutes. This therapy facilitates the loosening of sputum adhering to the bronchial walls through external mechanical vibrations. The effectiveness of this section is evaluated by comparing the incidence of atelectasis cases and the time required for chest imaging improvement between the two groups. See **Table 3**.

Table 3. Comparison of imaging improvement in pulmonary complications between two groups of pediatric patients

Group	Number of cases	Incidence of atelectasis during hospitalization, n (%)	Median time to improvement on chest X-ray (days)	Number of cases requiring fiberoptic bronchoscopy alveolar lavage n (%)
Intervention group	38	4 (10.53)	5.0	2 (5.26)
Routine group	38	11 (28.95)	8.0	8 (21.05)
χ^2/Z/χ^2 value		4.110	-2.893*	4.145
p value		0.043	0.004	0.042

*Note: The Mann-Whitney U test was used.

3.4. Early respiratory muscle functional exercise and preparation for weaning from mechanical ventilation

Once the pediatric patient's vital signs are stable and intracranial pressure is well-controlled, even if they remain in a coma, passive respiratory muscle maintenance measures should be initiated. Specific methods include: using a respiratory trainer twice daily to perform manual lung volume retention exercises at the end of ventilator inspiration; implementing diaphragmatic electrical stimulation therapy by placing electrode patches on specific bilateral sites to induce regular diaphragmatic contractions with low-frequency electrical currents; performing several passive limb movements daily, with a focus on enhancing shoulder and thoracic cage stretching exercises to maintain chest wall elasticity. Twenty-four to forty-eight hours before planned weaning from mechanical ventilation, systematically conduct spontaneous breathing trial assessments and preparatory work, including gradually reducing ventilator support, evaluating signs of weak cough reflex, and performing thorough airway clearance. See **Table 4**.

Table 4. Comparison of outcome indicators related to ventilator weaning between two groups of pediatric patients

Group	Number of cases	Number of first SBT success (%)	Number of transitions to non-invasive ventilation (%)	Number of reintubations within 72 hours after weaning (%)
Intervention group	38	30 (78.95)	5 (13.16)	2 (5.26)
Routine group	38	22 (57.89)	10 (26.32)	7 (18.42)
χ^2 value		3.935	2.053	3.385
p value		0.047	0.152	0.066

4. Discussion

For pediatric patients in a coma due to severe traumatic brain injury, airway management represents a comprehensive and dynamic clinical endeavor that integrates respiratory physiology, neurocritical care, infection prevention and control, and early rehabilitation. The fundamental concept behind the integrated nursing protocol developed in this study is to achieve a transition from passive response to proactive planning, from isolated measures to

a coordinated system, and from experience-based to evidence-guided practices. The research findings clearly demonstrate that this protocol offers distinct advantages in reducing ventilator-associated pneumonia, minimizing airway injury, shortening support duration, and optimizing gas exchange, directly attributable to its holistic and forward-looking design.

Optimized humidification and temperature control management constitute the foundational elements for protecting the airway's physiological barrier [1]. Previous intermittent humidification methods often led to fluctuations in the airway's internal environment, potentially promoting the formation of hard crusts in secretions due to alternating dry and wet conditions. The continuous constant-temperature and constant-humidity combined with controlled-rate humidification employed in this study provides a consistently stable moist environment for the airway mucosa. The data in **Table 1** fully confirm that the physical and chemical properties of sputum in the intervention group significantly improved, with a notable increase in the proportion of thin sputum and a significant reduction in highly viscous sputum and sputum plug events requiring invasive bronchoscopy. This not only serves as a prerequisite for preventing mechanical obstruction but also lays a solid foundation for subsequent safe suctioning, reducing mucosal damage caused by difficulties in aspirating viscous sputum [2].

The programmed suctioning technique based on multi-parameter assessment represents a concrete application of precision nursing principles. The fragile airway tissues in children make arbitrary, high-frequency, and rough suctioning operations the primary cause of iatrogenic mucosal injury. This study expanded the suctioning trigger signals from device parameters to an integrated analysis of the pediatric patient's overall clinical signs, reducing unnecessary operations. The step-by-step, parameterized operational process, particularly the strict control of suction negative pressure and duration, significantly reduced shear damage to the airway's inner wall. The data in **Table 2** indicate that while effectively clearing the airway, the intervention group experienced a reduction in the average daily number of suctioning attempts, as well as a lower incidence of acute hypoxic events induced by suctioning and visible mucosal bleeding compared to the conventional group. This proves that the technique successfully reconciles the potential conflict between "effective clearance" and "tissue protection" [3].

Goal-oriented postural management and adjuvant physical therapy represent effective means of actively promoting airway clearance by utilizing physical principles. Such pediatric patients often require a supine position to facilitate intracranial pressure management, but prolonged supination is a key risk factor for the accumulation of secretions in the dorsal lung regions and the occurrence of ventilator-associated pneumonia [4]. Under close monitoring, this protocol safely implemented phased elevation of body position and regular turning, combined with high-frequency chest wall oscillation, simulating the clearing effects of physiological postural changes and coughing. The results in **Table 3** demonstrate that this combined strategy significantly reduced the incidence of atelectasis and accelerated the recovery of pulmonary imaging findings. This shows that even for comatose pediatric patients without autonomous ability, simulating physiological mechanisms through external means can effectively promote pulmonary ventilation and secretion drainage [5].

5. Conclusion

In conclusion, airway maintenance during the coma phase of pediatric severe traumatic brain injury necessitates the establishment of a management framework that provides full-course coverage, synergizes multiple techniques, and dynamically adapts to the disease progression. The comprehensive intervention implemented in this study constructed an interconnected nursing chain through the organic integration of four dimensions: humidification,

suctioning, postural management, and exercise. This chain achieves closed-loop management by preventing secretion accumulation beforehand, optimizing clearance methods during the process, promoting secretion drainage afterward, and maintaining respiratory function throughout.

Disclosure statement

The authors declare no conflict of interest.

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Research on the Construction and Application of a Homogeneous Training and Management Program for Nursing Interns in Primary-Level Hospitals

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Abstract: *Objective*: To construct a homogeneous training and management program for vocational nursing interns suitable for primary-level hospitals and explore its application effects in improving the quality of nursing intern training, providing practical evidence for the reform of nursing internship teaching in primary-level hospitals. *Methods*: Vocational nursing students who interned at Zhucheng People's Hospital from June 1, 2022, to May 30, 2024, were selected as the research subjects. They were divided into a control group and an experimental group using convenience sampling. The control group continued with the traditional one-on-one teaching model, while the experimental group implemented a homogeneous training and management program in addition to traditional teaching. The training effects of the two groups were compared using six indicators: theoretical assessment, skill operation, bedside comprehensive ability, nursing student satisfaction, teaching instructor satisfaction, and the occurrence of adverse events. Data were analyzed using SPSS 25.0. *Results*: The experimental group scored significantly higher than the control group in theoretical assessment, skill operation, and bedside comprehensive ability. Satisfaction among nursing students and teaching instructors in the experimental group was also significantly higher than that in the control group. Additionally, the incidence of adverse events in the experimental group was significantly lower than that in the control group, with all differences between the two groups being statistically significant ($p < 0.005$). *Conclusion*: Implementing a homogeneous training and management program for vocational nursing interns in primary-level hospitals can effectively improve nursing students' theoretical knowledge, operational skills, and clinical comprehensive abilities, enhance satisfaction among both students and instructors, and reduce the occurrence of nursing adverse events. It holds significant practical value for comprehensively improving the quality of nursing intern training and optimizing nursing internship teaching in primary-level hospitals.

Keywords: Homogeneous training; Primary-level hospitals; Nursing student management; Training and management program

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1. Introduction

Clinical nursing internships serve as a crucial link between theory and practice in the nursing education system and represent a core stage for nursing students (referred to as "nursing interns" in the text) to develop professional attitudes, enhance nursing skills, and adapt to occupational roles [1]. With the advancement of the "Healthy China 2030" strategy and the improvement of the primary-level medical service system, the demand for high-quality nursing personnel in primary-level hospitals has become increasingly urgent. However, several issues persist in the training of vocational nursing interns in primary-level hospitals: the traditional teaching model primarily relies on one-on-one experiential teaching, lacking unified teaching standards and management frameworks; teaching instructors are often clinical nurses who lack systematic nursing education concepts and teaching method training, resulting in significant differences in teaching quality across different departments and instructors; teaching evaluation methods are singular, mostly focusing on summative assessments while neglecting process management and bidirectional feedback [2]. These issues lead to uneven nursing levels among nursing interns, making it difficult to meet the homogeneous demands for nursing services in primary-level medical positions.

As an affiliated teaching hospital of Shandong Second Medical University and a regional medical center in Weifang, Zhucheng People's Hospital receives over 100 vocational nursing interns annually and has accumulated rich experience in nursing internship teaching. This study constructed a homogeneous training and management program based on the Delphi expert consultation method and verified its application effects through a controlled trial. It aims to address the pain points of "non-uniform standards, difficult quality control, and unbalanced effects" in nursing internship teaching in primary-level hospitals and provide a replicable and promotable practical model for nursing talent cultivation in primary-level hospitals.

2. Research subjects and methods

2.1. Research subjects

Higher vocational nursing students who completed internships at Zhucheng People's Hospital (a tertiary comprehensive hospital and regional medical center in Weifang City) from June 1, 2022, to May 30, 2024, were selected as the research subjects.

2.1.1. Inclusion criteria

(1) Full-time higher vocational nursing internship students;
(2) Internship duration ≥ 6 months;
(3) Voluntary participation in this study and signing of informed consent.

2.1.2. Exclusion criteria

(1) Those who terminated their internships for personal reasons during the internship period;
(2) Those with prior clinical nursing work experience;
(3) Those with cognitive impairments or communication deficits.

2.1.3. Study design

Based on preliminary experimental data and the sample size calculation formula $n1 = n2 = 2[(Z\alpha + Z\beta)/\delta]^2$ ($\alpha = 0.05$, $\beta = 0.2$, $\delta = 0.15$), it was determined that 82 participants were needed per group. Considering a 20% sample attri-

tion rate, the final sample size was set at 99 participants per group. Among them, the 2022 cohort of nursing students served as the control group (n = 99), aged 19–22 years, with an average age of (20.5 ± 1.2) years; the 2023 cohort of nursing students served as the experimental group (n = 99), aged 19–23 years, with an average age of (20.8 ± 1.1) years. There were no statistically significant differences in general information such as age, admission scores, and basic nursing course scores between the two groups of nursing students ($p > 0.05$), indicating comparability. This study complied with the ethical requirements of the Declaration of Helsinki and was approved by the Ethics Committee of Zhucheng People's Hospital (Ethics Approval Number: 2023-031).

2.2. Control group: Traditional teaching mode

The control group adopted the conventional nursing internship teaching mode used in primary hospitals, with the following specific content:

(1) Selection of teaching instructors

Nurses with at least 5 years of work experience in the department, holding the title of nurse practitioner or above, and possessing rich clinical experience were selected as teaching instructors, without specialized teaching ability training.

(2) Implementation of teaching plans

Teaching was conducted in stages according to the outline-based teaching plan formulated by the hospital's nursing department: Week 1, familiarization with the ward environment, departmental workflow, fire safety knowledge, and PDA usage; Weeks 2–4, mastery of nursing care for common diseases and pharmacological actions of commonly used drugs, with the learning of one specialized operation per week.

(3) Teaching methods

"One-on-one" paired teaching was adopted, with teaching conducted through oral explanations, operational demonstrations, and nursing students following along to learn, without standardized teaching materials or simulation training.

(4) Assessment and evaluation

At the end of the internship rotation, teaching instructors formulated their own examination questions, with the assessment content including department-related theoretical knowledge and one operational skill, without unified assessment standards or quality monitoring.

2.3. Experimental group: Homogenized training management program

On the basis of the control group, the experimental group implemented a homogenized training management program constructed using the Delphi expert consultation method, covering five dimensions: "organizational structure-teaching system-faculty management-teaching implementation-quality evaluation", with the following specific content:

2.3.1. Construction of a homogenized training management organizational structure

Relying on the hospital's teaching management committee, a four-level management system of "Science and Education Department-Nursing Teaching and Research Office-Teaching Team Leader-Teaching Instructor" was established:

(1) Decision-making level (science and education department)

Responsible for formulating overall training objectives, approving teaching funds, interfacing with uni-

versity teaching needs, and linking teaching quality control results with departmental comprehensive objective assessments.

(2) Coordination level (nursing teaching and research office)

Organizing experts to formulate homogenized training programs, compile unified teaching materials, and conduct faculty training and teaching supervision.

(3) Implementation level (teaching team leader)

Each clinical department appointed one teaching team leader (holding the title of associate senior or above) responsible for formulating specific departmental teaching plans, coordinating teaching tasks, and organizing departmental teaching seminars.

(4) Execution level (teaching instructors)

After selection and training, they were qualified to assume their positions and were responsible for daily teaching implementation, process evaluation, and feedback on nursing students.

2.3.2. Formulation of standardized teaching systems and content

Through two rounds of Delphi expert consultations (selecting 15 experts, including 3 nursing education experts, 4 nursing department directors from tertiary hospitals, 5 head nurses from primary hospitals, and 3 teachers from higher vocational nursing colleges, with an expert authority coefficient Cr = 0.89), the following core systems and content were determined:

(1) Teaching system specifications

Including the "Administrative Measures for Teaching Nursing Internship Students", "Detailed Rules for the Selection and Assessment of Nursing Teaching Instructors", and "Regulations on the Rotation Management of Nursing Internship Students", clarifying the responsibilities of personnel at all levels and teaching quality standards.

(2) Curriculum system setup

Based on the teaching syllabus for higher vocational nursing programs and combined with the clinical needs of primary hospitals, a curriculum system of "basic module + specialized module + humanities module" was constructed: the basic module (accounting for 40%) included nursing safety, communication skills, and commonly used operational norms; the specialized module (accounting for 50%) covered nursing care for common diseases in departments such as internal medicine, surgery, obstetrics and gynecology, and pediatrics; the humanities module (accounting for 10%) included occupational etiquette, doctor-patient communication, and primary health policies.

(3) Unified teaching resources

The Nursing Teaching and Research Office compiled the "Teaching Manual for Nursing Internship Students in the Hospital", produced standardized operational videos, and established a theoretical question bank containing 1,000 questions, categorized into easy, medium, and difficult levels, with a difficulty coefficient ranging from 0.3 to 0.8.

2.3.3. Implementation of professional faculty management

(1) Faculty selection

A four-dimensional selection standard of "education + title + clinical experience + teaching ability" was formulated, requiring teaching instructors to have a junior college degree or above, hold the title of charge

nurse or above, possess at least 5 years of clinical experience, and pass teaching trial lectures and communication ability assessments.

(2) Faculty training

A "online + offline" combined training mode was adopted, with online training relying on the "hospital's internal training platform" to offer courses such as nursing education theory, PBL teaching method, and the application of standardized patients (cumulative 24 class hours); offline, teaching seminars were organized quarterly, inviting university experts for on-site guidance, with assessments conducted after training, and those who failed were suspended from teaching duties.

(3) Faculty incentives

Teaching work was incorporated into the departmental performance and individual title promotion assessment systems, with "Outstanding Teaching Instructors" selected annually and awarded bonuses and honorary certificates.

2.3.4. Innovative teaching implementation methods

(1) Standardized patient (SP) teaching

Nurses from our hospital, after systematic training, acted as SPs to simulate various common clinical scenarios, focusing on assessing the practical abilities of nursing students in communication, emergency response, and humanistic care.

(2) Diversified teaching strategies

Based on the actual characteristics of primary hospitals, problem-based learning (PBL), action teaching methods, and integrated theoretical and practical teaching were widely adopted, gradually replacing the traditional teaching mode dominated by one-way cramming.

(3) Improved internship rotation mechanism

Personalized rotation plans were formulated based on the learning situation of each nursing student, with a general rotation period of 4 weeks in each department. Before rotation, induction training was arranged; during rotation, the teaching team leader organized a mini-lecture once a week; after rotation, an out-of-department assessment was conducted, forming a closed-loop management.

2.3.5. Improvement of the teaching quality evaluation system

(1) Process evaluation

The Science and Education Department conducted monthly teaching quality control, checking teaching records and the implementation of teaching plans; the departmental teaching team leader conducted weekly self-quality control, recording the learning progress and issues of nursing students.

(2) Bidirectional evaluation

After the internship, nursing students anonymously evaluated the teaching attitude, teaching methods, and teaching effects of teaching instructors; teaching instructors evaluated the learning attitude, operational ability, and professional qualities of nursing students.

(3) Functional department evaluation

The Nursing Department jointly conducted nursing safety inspections with the Quality Control Department every quarter, counting the number of adverse events involving nursing students; the Science and Education Department conducted comprehensive evaluations of teaching departments every six months,

with the results incorporated into departmental performance.

2.4. Evaluation indicators

2.4.1. Comprehensive ability indicators of nursing students

(1) Theoretical assessment scores

The Science and Education Department randomly selected questions from the question bank to form examination papers, with discipline and safety knowledge accounting for 20 points and professional knowledge accounting for 80 points, with assessments conducted once before and once after the internship.

(2) Skill operation scores

Based on the "Hospital Nursing Skill Assessment Standards", 10 core techniques were determined, and the average score of the assessment items was taken.

(3) Bedside comprehensive ability score

According to the hospital's N0-level nurse bedside comprehensive ability assessment standards, scores were given by teaching instructors from four dimensions, condition observation, nursing plan formulation, operation execution, and communication and coordination, at the end of the nursing students' rotation in each department, with the average score of all departments taken.

2.4.2. Satisfaction indicators

(1) Nursing student satisfaction

A self-designed "Nursing Internship Student Satisfaction Questionnaire" was used, including 7 items on internship teaching, 3 items on teaching management, and 2 items on teaching instructors, totaling 3 dimensions and 12 items, with a Likert 5-point scoring system (1 = very dissatisfied, 5 = very satisfied), with a total score ranging from 12 to 60, and a score ≥ 48 indicating satisfaction. The questionnaire had a Cronbach's α coefficient of 0.85 and a content validity index (CVI) of 0.89, indicating good reliability and validity.

(2) Teaching instructor evaluation

The "Teaching Instructor Evaluation Questionnaire" was used, including 6 aspects, namely nursing students' work ability, labor discipline, service attitude, occupational etiquette, teamwork, and medical safety, totaling 19 items, with a Likert 5-point scoring system, with a total score ranging from 19 to 95, and a score ≥ 76 indicating satisfaction. The questionnaire had a Cronbach's α coefficient of 0.87 and a CVI of 0.91, indicating good reliability and validity.

2.4.3. Adverse event indicators

The nursing adverse events involving nursing students during the internship period were counted and jointly confirmed by the hospital's Quality Control Department and Nursing Department to ensure data accuracy.

2.5. Statistical methods

SPSS 25.0 statistical software was used for data processing. Measurement data were expressed as ($\overline{x} \pm s$), with independent sample *t*-tests used for comparisons between groups and paired *t*-tests used for comparisons within groups before and after; enumeration data were expressed as [n (%)], with χ^2 tests used for comparisons. A *p*-value < 0.05 was considered statistically significant.

3. Research results

3.1. Comparison of comprehensive ability indicators between the two groups of nursing students before and after the internship

Before the internship, there were no statistically significant differences in the theoretical assessment scores, skill operation scores, and bedside comprehensive ability scores between the two groups of nursing students ($p > 0.05$). After the internship, all indicators in both groups showed significant improvements compared to those before the internship ($p < 0.05$), and the extent of improvement in the experimental group was significantly greater than that in the control group ($p < 0.05$). Specific data are shown in **Table 1**.

Table 1. Comparison of comprehensive ability indicators between the two groups of nursing students before and after the internship ($\overline{x} \pm s$, points)

Indicator	Group	Before internship	After internship	*t*-value (within group)	*p*-value (within group)
Theoretical assessment score	Control group (n = 99)	68.23 ± 5.67	81.56 ± 6.23	15.32	< 0.001
	Experimental group (n = 99)	67.89 ± 5.81	89.23 ± 5.12	25.64	< 0.001
Skill performance score	Control group (n = 99)	65.34 ± 6.12	82.34 ± 5.68	18.75	< 0.001
	Experimental group (n = 99)	64.98 ± 6.35	90.15 ± 4.87	28.91	< 0.001
Bedside comprehensive ability score	Control group (n = 99)	62.15 ± 6.89	80.21 ± 6.15	17.46	< 0.001
	Experimental group (n = 99)	61.87 ± 7.02	88.67 ± 5.34	26.78	< 0.001

3.2. Comparison of satisfaction levels between the two groups of nursing students and their teaching instructors

After the internship, the satisfaction levels of nursing students and teaching instructors in the experimental group were significantly higher than those in the control group, with statistically significant differences ($p < 0.05$). Specific data are shown in **Table 2**.

Table 2. Comparison of satisfaction levels between the two groups of nursing students and their teaching instructors [n (%)]

Indicator	Group	Satisfied	Dissatisfied	Overall satisfaction rate (%)	χ^2 value	*p* value
Nursing students' satisfaction	Control group (n = 99)	72	27	72.53	14.56	< 0.001
	Experimental group (n = 99)	89	10	89.36		
Clinical instructors' satisfaction	Control group (n = 99)	75	24	75.18	16.89	< 0.001
	Experimental group (n = 99)	91	8	91.24		

3.3. Comparison of the number of adverse events between the two groups of nursing students

During the internship, a total of 12 adverse events (12.12%) occurred in the control group, including 4 cases of infusion errors, 3 cases of specimen collection errors, 2 cases of patient falls, and 3 cases of other incidents. In the experimental group, a total of 3 adverse events (3.03%) occurred, including 1 case of infusion error, 1 case of specimen collection error, and 1 case of other incidents. The incidence of adverse events in the experimental group

was significantly lower than that in the control group ($\chi^2 = 6.78$, $p = 0.009$).

4. Discussion

4.1. The effect of the homogeneous training management program on enhancing the comprehensive abilities of nursing students

The results of this study showed that the experimental group scored significantly higher than the control group in theoretical assessments, skill operation scores, and bedside comprehensive ability scores after the internship, indicating that the homogeneous training management program can effectively enhance the clinical comprehensive abilities of vocational nursing interns. By constructing a "standardized-specialized-diversified" trinity teaching system and formulating unified curriculum and assessment standards through Delphi expert correspondence, the program has changed the situation of scattered content and inconsistent standards in traditional teaching, helping nursing students systematically master nursing knowledge and skills that meet the needs of primary healthcare [3]. In terms of faculty development, by strictly screening teaching instructors and organizing systematic training, the program has significantly enhanced teachers' teaching abilities and promoted the transformation of teaching methods from relying on experience to scientific standardization [4]. In terms of teaching methods, the introduction of SP simulation teaching and PBL teaching methods enables nursing students to exercise clinical thinking and operational skills in simulated scenarios, effectively overcoming the practical difficulties of a limited variety of common diseases and limited emergency opportunities in primary hospitals, thereby effectively improving their bedside comprehensive response abilities [5].

4.2. The effect of the homogeneous training management program on improving teaching satisfaction

The satisfaction of nursing students and teaching instructors in the experimental group was significantly higher than that in the control group, which was closely related to the program's emphasis on meeting "bidirectional needs". For nursing students, unified teaching resources, personalized rotation plans, and process feedback allowed them to clearly grasp learning objectives and progress, reducing the sense of confusion caused by inconsistent teaching standards. For teaching instructors, a comprehensive incentive mechanism and teaching support reduced the difficulty and pressure of teaching work, while the selection of "outstanding teaching instructors" enhanced their sense of professional achievement [6]. In addition, the establishment of a bidirectional evaluation mechanism allowed nursing students to participate in teaching quality feedback, making teaching improvements more aligned with nursing students' needs and forming a virtuous cycle of "teaching-feedback-optimization" [7].

4.3. The value of the homogeneous training management program in preventing and controlling adverse events

The significantly lower incidence of adverse events in the experimental group compared to the control group reflects the program's advantages in nursing safety management. On the one hand, the program incorporates nursing safety knowledge into the focus of theoretical assessments and strengthens nursing students' safety awareness through case analysis and scenario simulation. On the other hand, the construction of a four-level management system enables full-process monitoring of teaching quality, with regular quality control by the Science and Education Department and the Nursing Department to promptly identify and correct problems in nursing students'

operations, preventing adverse events [8]. At the same time, the professional training of teaching instructors has also improved their ability to guide and supervise nursing students' operations, reducing safety hazards caused by teaching negligence [9].

4.4. Research limitations and prospects

This study is a single-center study with samples all from Zhucheng People's Hospital, which may have geographical limitations. The research period was relatively long (2 years), during which it may have been affected by factors such as policy changes and faculty turnover. Future research can expand the sample size and conduct multi-center-controlled trials to further verify the program's universality. At the same time, artificial intelligence technology can be integrated to optimize teaching methods and enhance the intelligent level of homogeneous training [10]. In addition, the "hospital-university" collaborative education mechanism can be explored to align the homogeneous training program with the curriculum system of vocational nursing colleges, achieving full-process training from "pre-internship-internship-post-internship" and delivering higher-quality nursing talents to primary hospitals.

5. Conclusion

The homogeneous training management program for vocational nursing interns constructed in this study effectively enhances the clinical comprehensive abilities and teaching satisfaction of both parties in primary hospitals by establishing a standardized organizational structure, a professional faculty team, diversified teaching methods, and a full-process quality evaluation system, and reduces the incidence of nursing adverse events. The program fully considers the clinical characteristics and teaching needs of primary hospitals, has strong practical operability and promotion value, and can provide a reference for the reform of nursing internship teaching in primary hospitals, contributing to the construction of a primary nursing talent team under the "Healthy China" strategy.

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The Impact of Bidirectional Quality Feedback Nursing Model on the Quality of Life and Self-Management Ability of Patients with Chronic Obstructive Pulmonary Disease (COPD)

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Abstract: *Objective*: To explore the intervention effect of the bidirectional quality feedback nursing model on the quality of life and self-management ability of patients with chronic obstructive pulmonary disease (COPD). *Methods*: A total of 60 COPD cases in the stable phase of the disease admitted to our hospital from January to December 2024 were included. Using a random number table method, they were divided into a control group and an observation group, with 30 cases in each group. The control group received the standard nursing protocol, while the observation group underwent a three-month bidirectional quality feedback nursing intervention in addition to the standard protocol. The quality of life and self-management ability scores of the two groups were compared before and after the intervention. *Results*: After the intervention, compared with the control group, the observation group showed lower scores in all dimensions of the St. George's Respiratory Questionnaire (SGRQ) and higher scores in all domains and the total score of the Self-Care of Chronic Illness Inventory-Modified for COPD (SCMMS) ($p < 0.05$). *Conclusion*: The bidirectional quality feedback nursing intervention can significantly improve the self-care level and quality of life of patients with COPD, demonstrating clinical application value.

Keywords: Bidirectional quality feedback nursing; Chronic obstructive pulmonary disease; Quality of life; Self-management ability

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1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a prevalent chronic airway disease worldwide, characterized by persistent airflow limitation as its primary pathological feature. The condition is prone to recurrent exacerbations and is difficult to cure, leading to severe impairment of pulmonary ventilation function, a significant decline

in quality of life, and increased family caregiving burden and socioeconomic healthcare costs [1]. Clinical studies indicate that standardized nursing interventions are crucial for delaying the progression of COPD and improving patient clinical outcomes [2]. Traditional routine nursing often adopts a unidirectional approach to implementing measures without adequately considering patients' individualized needs, resulting in insufficient targeted nursing interventions and difficulty in fully mobilizing patients' initiative in treatment participation. In contrast, bidirectional quality feedback nursing emphasizes interactive communication between nurses and patients, enabling real-time collection of patients' subjective experiences and feedback of nursing assessment information to achieve individualized adjustment and optimization of care plans [3]. Based on this, this study selected 60 patients with stable COPD and employed a grouped control design to explore the impact of this nursing model on patients' quality of life and self-management abilities. The details are presented below.

2. Materials and methods

2.1. General information

Sixty patients with COPD were included (selected from January 2024 to December 2024) and randomly divided into a control group and an observation group using a random number table method, with 30 patients in each group.

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Clinically diagnosed with COPD and in a stable phase (no acute exacerbations in the past 4 weeks) [4];
(2) Aged between 45 and 75 years;
(3) Mentally competent and able to cooperate in completing questionnaire assessments and nursing procedures;
(4) Patients and their legal representatives provided informed consent and voluntarily signed consent documents.

2.2.2. Exclusion criteria

(1) Patients with severe impairment of vital organ functions such as heart, liver, or kidneys;
(2) Patients with other types of respiratory system diseases;
(3) Patients with cognitive deficits or psychiatric disorders that prevent cooperation in the study;
(4) Patients who have received similar nursing interventions recently.

2.3. Methods

2.3.1. Control group

Routine nursing and post-discharge follow-up were implemented, including hospital admission education, medication guidance, demonstration of respiratory function training, and telephone follow-up after discharge, with an intervention period of 3 months. Specific measures included:

(1) Conducting health education activities on the day of admission and before discharge to systematically explain COPD-related knowledge, covering pathological mechanisms, treatment strategies, triggering factors, and preventive measures;

(2) Guiding patients to master the correct use of medications such as bronchodilators and corticosteroids and demonstrating the specific operational norms of inhalation devices in person;
(3) Advising patients to quit smoking, limit alcohol intake, maintain a balanced diet, and keep warm to prevent respiratory infections;
(4) Instructing patients on pulmonary rehabilitation training techniques such as pursed-lip breathing and diaphragmatic breathing;
(5) After discharge, using telephone follow-up to monitor patients' condition changes and promptly respond to related concerns.

2.3.2. Observation group

On the basis of the control group, a bidirectional quality feedback nursing model was implemented, with an intervention period of 3 months. A "nurse-patient-nurse" bidirectional feedback mechanism was established, with the following specific measures:

(1) Establishing a specialized nursing team

Comprising one attending physician from the respiratory department, three senior nurses, and one rehabilitation therapist. Team members received unified training to master the bidirectional feedback process and communication skills. The attending physician was responsible for formulating individualized treatment plans, the responsible nurse for implementing nursing interventions and collecting feedback, and the rehabilitation therapist for guiding respiratory rehabilitation training. All team members received training related to the bidirectional quality feedback nursing model and were proficient in feedback processes, communication skills, and assessment methods. Based on the existing care model, individualized care plans were developed according to patients' specific conditions, including medication guidance, respiratory training, dietary management, and psychological counseling. Face-to-face interventions were conducted once a week for 30-40 minutes each time, and an online communication group was established to facilitate patient consultations at any time.

(2) Establishing a bidirectional feedback mechanism

① Patient feedback to healthcare providers (input): Patients provided daily feedback on medication reactions, completion of respiratory training, and encountered difficulties (such as difficulty in expectorating sputum or medication side effects) through a "nurse-patient communication book", WeChat follow-up group, or telephone. ② Healthcare provider feedback to patients (output): The responsible nurse assessed patients' adherence, symptom control, and pulmonary function weekly and provided feedback on the assessment results to patients during follow-up visits or telephone calls, affirming positive behaviors and correcting negative ones.

(3) Optimizing nursing plans

The team held monthly meetings to make individualized adjustments to nursing plans based on bidirectional feedback information. For example, for patients with poor adherence to respiratory training, the reasons were analyzed as excessive training intensity or poor mastery of methods, and the training frequency was adjusted or one-on-one video guidance was provided.

2.4. Observation indicators

(1) Quality of life

Assessed before and after the intervention using the St. George's Respiratory Questionnaire (SGRQ), which includes three dimensions: symptoms, activity ability, and disease impact [5]. Each dimension has a score range of 0 to 100, with higher scores indicating poorer health-related quality of life in patients.

(2) Self-management ability

Assessed before and after the intervention using the Self-Management Ability Scale for COPD (SCMMS), which includes five dimensions: disease cognition, medication management, symptom monitoring, respiratory training, and emotion regulation, with a total of 25 items scored on a 1–4 scale [6]. The total score ranges from 25 to 100, with higher scores indicating better self-care abilities.

2.5. Statistical methods

Data comparison was performed using SPSS 26.0 software. Count data were expressed as percentages (%), and the chi-square (χ^2) test was used. Measurement data, which conformed to a normal distribution, were expressed as mean ± standard deviation ($\overline{x} \pm s$), and the *t*-test was used. A *p*-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of general information

There was no significant difference in baseline data between the two groups ($p > 0.05$). See **Table 1**.

Table 1. Comparison of general information between the two groups [$\overline{x} \pm s$ / n (%)]

Group	Number of cases	Male/Female (cases)	Age (years)	Disease course (years)	Education level (Primary school and below/junior high school/high school and above)
Observation group	30	18/12	56.52 ± 5.56	3.43 ± 1.15	6/16/8
Control group	30	17/13	56.43 ± 5.44	3.35 ± 1.19	6/17/7
χ^2/t value	-	0.069	0.063	0.265	0.097
p value	-	0.793	0.950	0.792	0.953

3.2. Comparison of quality of life

After the intervention, compared with the control group, the observation group showed significantly lower scores in all dimensions of the St. George's Respiratory Questionnaire (SGRQ) ($p < 0.05$). See **Table 2**.

Table 2. Comparison of SGRQ scores between the two groups [$\overline{x} \pm s$, points]

Group	Number of cases (n)	Symptom dimension		Activity ability dimension		Disease impact dimension	
		Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Observation group	30	67.52 ± 4.43	32.45 ± 3.16	65.22 ± 4.27	33.42 ± 3.11	66.67 ± 4.22	30.89 ± 3.16
Control group	30	67.38 ± 4.32	50.66 ± 3.21	65.28 ± 4.22	48.49 ± 3.14	66.56 ± 4.29	47.65 ± 3.13
t value	-	0.124	22.143	0.055	18.677	0.100	20.639
p value	-	0.902	0.001	0.957	0.001	0.921	0.001

3.3. Comparison of self-management ability

After the intervention, compared with the control group, the observation group demonstrated significantly higher scores in all dimensions and the total score of the Self-Care of Chronic Illness Inventory-Modified for COPD (SCMMS) ($p < 0.05$). See **Table 3**.

Table 3. Comparison of SCMMS scores between the two groups [$\overline{x} \pm s$, points]

Group	Number of cases (n)	Disease knowledge		Medication management		Symptom monitoring		Breathing exercises		Emotional regulation		Total score	
		Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Observation group	30	10.45 ± 1.32	17.23 ± 1.17	10.21 ± 1.16	17.78 ± 1.32	10.88 ± 1.45	18.43 ± 1.10	11.76 ± 1.12	17.89 ± 1.21	9.23 ± 1.32	17.78 ± 1.23	50.78 ± 4.34	86.67± 4.34
Control group	30	10.37 ± 1.12	13.22 ± 1.13	10.11 ± 1.17	13.45 ± 1.33	10.67 ± 1.31	14.32 ± 1.12	11.56 ± 1.15	14.28 ± 1.24	9.45 ± 1.33	13.12 ± 1.36	50.56 ± 4.42	67.23 ± 3.23
t value	-	0.253	13.503	0.332	12.657	0.589	14.340	0.682	11.413	0.643	13.919	0.195	19.681
p value	-	0.801	0.001	0.741	0.001	0.558	0.001	0.498	0.001	0.523	0.001	0.846	0.001

4. Discussion

The key objectives of long-term management of Chronic Obstructive Pulmonary Disease (COPD) encompass not only alleviating patients' symptoms and slowing down the rate of lung function decline but also employing evidence-based nursing methods to foster patients' proactive awareness of self-monitoring their disease, thereby enhancing their long-term quality of life. In clinical practice, it can be observed that conventional care models often fail to track patients' subjective experiences in real-time, leading to discrepancies between intervention measures and patients' actual needs. This makes it challenging to transition from "passive nursing" to "proactive health management". In contrast, the core advantage of the bidirectional quality feedback nursing model lies in its ability to establish a closed-loop interactive mechanism that integrates patients' subjective experiences with nursing assessment results bidirectionally, paving the way for more innovative approaches to the long-term management of COPD [7].

The results of this study indicate a significant reduction in SGRQ scores in the observation group following the intervention. Analyzing the mechanism, traditional unilateral nursing models often overlook patients' subjective experiences, resulting in "nurse-patient information asymmetry". The bidirectional quality feedback model introduces the concept of closed-loop management, enabling precise delivery of nursing measures through real-time collection of patient feedback. For instance, when patients report worsening dyspnea, nurses can promptly intervene to assess and eliminate triggers or adjust rehabilitation plans, effectively alleviating symptoms and reducing disease-related restrictions on daily activities. This significantly enhances patients' subjective quality of life and minimizes disease interference in daily life [8]. Research by Wang Fang et al. also confirms that bidirectional feedback interventions contribute to improving lung function and quality of life in COPD patients, further supporting the application significance of this care model in enhancing patients' living standards [9]. Additionally, self-management ability is crucial for COPD patients to achieve long-term disease control. In this study, the significant improvement in SCMMS scores in the observation group aligns with Bandura's self-efficacy theory. The bidirectional feedback mechanism enhances patients' self-efficacy through a process of "behavioral feedback-positive reinforcement". Nurses regularly assess and provide feedback on patients' self-management behaviors, correcting erroneous health behaviors (such as improper oxygen inhalation and unplanned cessation of medication) and inspiring patients' intrinsic motivation through timely affirmation and encouragement. This transforms patients from

passive “compliance with medical advice” to proactive “self-managers” [10].

5. Conclusion

This study confirms that integrating bidirectional quality feedback mechanisms into COPD chronic disease management can effectively overcome the temporal and spatial limitations of traditional nursing. As clinical nursing managers, further studies should prioritize establishing normalized bidirectional communication channels (such as utilizing information platforms) and cultivating nurses’ critical thinking and communication skills to achieve a transition from “disease nursing” to “health management”.

Disclosure statement

The authors declare no conflict of interest.

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Evaluation of the Effectiveness of Oral Care Intervention Programs for Adult Mechanically Ventilated Patients in the ICU

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Abstract: *Objective*: To evaluate the application effect of an individualized comprehensive oral care intervention program in adult mechanically ventilated patients in the ICU an evidence-based basis for clinical oral care. *Methods*: A total of 80 adult mechanically ventilated patients in the ICU of a tertiary hospital from January to December selected and randomly divided into a control group and an observation group, with 40 cases in each group. The control group received routine oral care, while the observation group received incomprehensive oral care. The intervention continued until the patients were extubated or transferred out of the ICU. SPSS 26.0 software was used for analysis. Measure was expressed as ($\overline{x} \pm s$) and analyzed using *t*-tests; count data were expressed as [n(%)] and analyzed using χ^2 tests. $p < 0.05$ was statistically significant. *Results*: After the intervention, the oral hygiene score (2.15 ± 0.62), VAP incidence rate (7.50%, 3/40), and total incidence rate of oral complications (5.00%, 2/40) in the observation group were significantly lower than those in the control group (4.82 ± 0.95, 25.00%, 10/40, and 22.50%, 9/40, respectively) (all $p < 0.05$). The duration of mechanical ventilation (6.82 ± 2.15 days) and ICU length of stays (10.35 ± 3.26 days) in the observation group were significantly shorter than those in the control group ($p < 0.001$). *Conclusion*: Individualized comprehensive oral care improves oral hygiene in adult mechanically ventilated patients in the ICU, reduce the incidence of VAP and oral complications, and shorten the duration of mechanical ventilation and ICU length of stay, demonstrating clinical value.

Keywords: ICU; Adult; Mechanical ventilation; Oral care; Intervention effect; Ventilator-associated pneumonia

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1. Introduction

Mechanical ventilation is a crucial life support measure for critically ill patients in the ICU, maintaining respiratory function and buying time for the treatment of the underling disease. However, prolonged mechanical ventilation disrupts the oral physiological environment, causes mucosal dryness and microbial imbalance, and combined with impaired consciousness and swallowing function, prevents patients from cleaning independently, making

them prone to oral complications and ventilator-associated pneumonia (VAP). VAP is the most common hospital-acquired infection in mechanically ventilated ICU patient incidence of 8–28% and a mortality rate of 24–50%; it prolongs hospital stays, increases medical costs, and affects patient clinical oral care often involves wiping with cotton balls or simple rinsing, which are monotonous procedures that do not account for individual differences, resulting in poor efficacy and an y to inhibit oral microbial proliferation or the occurrence of VAP. Although the individualized comprehensive oral care model has garnered clinical attention, its effectiveness requires further validation with more clinical data. This study evaluated the effects of this protocol on patients' oral hygiene, complications, and prognosis through a controlled trial, providing a reference for optimizing oral care.

2. Research methods

2.1. Study subjects

A total of 80 adult patients undergoing mechanical ventilation admitted to the ICU of a tertiary from January 2024 to December 2024 were selected as study subjects.

2.1.1. Inclusion criteria

Age ≥ 18 years, duration of mechanical ventilation ≥ 48 hours, impaired consciousness (Glasgow Coma Scale ≤ 12), inability to perform oral hygiene independently, no history of oral surgery, oral malignancy, or severe oral deformity, no coagulation disorders, severe hepatic or renal insufficiency, and signed informed consent by family members.

2.1.2. Exclusion criteria

Duration of mechanical ventilation < 48 hours, transfer out of the ICU, withdrawal of treatment or death, concurrent severe oral infection, systemic infectious diseases, or allergy to drugs or materials used in oral care [1].

2.1.3. Study design

The subjects divided into a control group and an observation group using a random number table, with 40 cases in each group. There were no statistically significant differences in general data such as gender, age, cause of mechanical ventilation, and underlying diseases between the two groups ($p > 0.05$), indicating comparability. See **Table 1** for details.

Table 1. Comparison of general characteristics between the two groups of patients

Group	Number of cases (n)	Sex (Male/Female) [n (%)]	Age ($\overline{x} \pm s$, years)	Reason for mechanical ventilation [n (%)]	Comorbidities [n (%)]
Control group	40	23/17 (57.50/42.50)	62.35 ± 10.28	Respiratory failure 18 (45.00), cerebral infarction 10 (25.00), severe pneumonia 8 (20.00), others 4 (10.00)	Hypertension 22 (55.00), Diabetes mellitus 15 (37.50), coronary heart disease 11 (27.50), Chronic obstructive pulmonary disease 9 (22.50)
Observation group	40	25/15 (62.50/37.50)	63.12 ± 9.85	Respiratory failure 19 (47.50), cerebral infarction 9 (22.50), severe pneumonia 7 (17.50), others 5 (12.50)	Hypertension 23 (57.50), diabetes mellitus 14 (35.00), coronary heart disease 12 (30.00), chronic obstructive pulmonary disease 8 (20.00)
χ^2/t value	-	0.289	0.347	0.352	0.216
p value	-	0.591	0.729	0.950	0.974

2.2. Nursing intervention protocol

2.2.1. Control group

Routine oral care protocol, performed once in the morning and once in the evening. Nursing wore sterile gloves and sequentially wiped the patient's lips, teeth, gums, tongue surface, and buccal mucosa using sterile cotton balls moistened with normal saline, wiping each area 2–3 times. After wiping, a suction catheter was used to aspirate residual fluid from the oral cavity to prevent aspiration. If the patient's oral mucosa was dry, a small amount of sterile paraffin oil could be applied for moisturizing. Vital signs were closely monitored during the procedure; if choking, dyspnea, or other adverse conditions occurred, the procedure was immediately stopped and appropriate measures taken.

2.2.2. Observation group

An individualized comprehensive oral care intervention plan was adopted. Based on routine care, targeted nursing measures were formulated according to individual patient's condition, specifically as follows:

(1) Individualized assessment

Within 24 hours of admission, the assigned nurse conducted an oral assessment on the nt. The Beck Oral Assessment Scale (BOAS) was used to evaluate oral hygiene status, and records were made of the patient's level of consciousness, oral mucosa condition, dental status, sputum characteristics, and oral infection status. Combined with the patient's underlying diseases (diabetes, hypertension) and duration of mechanical ventilation, an individualized nursing plan was formulated.

(2) Graded oral cleaning

Nursing care was graded based on the oral assessment results. For mild contamination (BOAS score ≤ 5), a child's soft-bristle toothbrush was used with 0.12% chlorhexidine mouthwash for brushing three times daily (morning, noon, and evening), each session lasting es, focusing on cleaning interdental spaces, gingival sulci, and the tongue surface. After brushing, the mouth was rinsed with sterile normal saline to suction out residual. For moderate contamination (BOAS score 6–10), the frequency of oral rinsing was increased to four times daily based on brushing, and the oral mucosa was rinse with an oral care solution (selected based on microbiological test results; sodium bicarbonate solution was used for fungal infections) after each rinse. For severe contamination (BOASe > 10), oral cleaning was performed 4–5 times daily combined with negative pressure suction-assisted oral rinsing to remove oral secretions, food residues, and bacteria; topical anti-microbial ointment was applied locally if necessary, according to medical orders.

(3) Mucosal hydration and care

Select moisturizers based on the degree of oral mucosal dryness. For mild dryness, apply stile paraffin oil; for moderate to severe dryness, apply oral moisturizing gel. Apply three times daily to the lips, buccal mucosa, and tongue surface to prevent from cracking. When oral mucosal congestion or erosion occurs, apply medication to promote mucosal repair (Kangfuxin Liquid) twice daily as prescribed by the physician.

(4) Positioning care and suctioning coordination

Elevate the patient's head of the bed to 30–45° and place the patient in recumbent position during oral care to prevent aspiration of oral secretions. Administer suctioning 10 minutes prior to care to clear sputum from the aisle monitor the patient's respiration and heart rate during care; if sputum increases, immediately stop the procedure and suction to avoid aspiration-induced pulmonary infection.

(5) Nursing staff training: All nurses involved in care have received specialized training covering individualized oral care protocols, oral assessment methods, cleaning techniques, aspiration prevention, and management of complications. They are only d to perform care operations after passing the assessment. Regular case discussions are conducted to timely improve care plans [2].

Both groups of patients received intervention until the end of mechanical ventilation or transfer out of the ICU, with a mean intervention duration of (7.82 ± 2.35) days.

2.3. Observation indicators

(1) Oral hygiene status

Evaluated using the BOAS scale before and at the end of the intervention. The BOAS scale includes six dimensions: lips, mucosa, gums, teeth, tongue surface, and saliva. Each dimension is scored from 0 to 3, with a total ranging from 0 to 18; a higher score indicates poorer oral hygiene.

(2) Incidence of VAP

The occurrence of VAP during the intervention period was shown in both groups. The diagnostic criteria for VAP referred to the "Guidelines for the Diagnosis and Treatment of Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia in Chinese Adults (2021 Edition)", which includes fever with a temperature ≥ 38.5 ℃, cough, purulent sputum, positive culture, and new pulmonary inflammatory infiltrates on chest imaging after mechanical ventilation for 48 hours.

(3) Incidence of oral complications

The occurrence of complications such as oral mucosal injury, oral ulcers, and halitosis during the intervention period was observed and recorded in both groups, and the total incidence rate was calculated.

(4) Prognostic indicators

The duration of mechanical ventilation and ICU length of stay were recorded for both groups.

2.4. Statistical methods

Data were analyzed using SPSS 26.0 software. Measurement data are expressed as ($\overline{x} \pm s$); paired *t*-test were used for comparisons before and after intervention within groups, and independent sample *t*-tests were used for comparisons between groups. Count data are expressed as [n (%)], and comparisons between groups were presented using the χ^2 test. Rank data were analyzed using the rank-sum test. A value of $p < 0.05$ was considered statistically significant.

3. Research results

3.1. Comparison of oral hygiene scores between the two groups before and after intervention

Before the intervention, there was no statistically significant difference in BOAS scores between the two groups ($p > 0.05$). After the intervention, BOAS scores in both groups decreased significantly, with the observation group showing significantly lower than the control group, and the difference was statistically significant ($p < 0.001$), as shown in **Table 2**.

Table 2. Comparison of oral hygiene scores between the two groups before and after intervention

Group	Number of cases (n)	Before intervention ($\overline{x}$ ± s, points)	After intervention ($\overline{x}$ ± s, points)	*t*-value	*p*-value
Control group	40	8.76 ± 1.32	4.82 ± 0.95	15.682	< 0.001
Observation group	40	8.85 ± 1.28	2.15 ± 0.62	28.753	< 0.001
Between-group *t*-value	-	0.302	14.367	-	-
Between-group *p*-value	-	0.763	< 0.001	-	-

3.2. Comparison of VAP incidence between the two groups

During the intervention period, the VAP incidence in the observation group was 7.50% (3/40), and in the control group, it was 25.00% (10/40). The incidence in the observation group was significant than that in the control group, and the difference was statistically significant ($\chi^2 = 4.507$, $p = 0.034$). See **Table 3**.

Table 3. Comparison of VAP incidence between the two groups

Group	Number of cases (n)	Number of VAP cases [n(%)]	Number of cases without VAP [n (%)]	χ^2-value	*p*-value
Control group	40	10 (25.00)	30 (75.00)	4.507	0.034
Observation group	40	3 (7.50)	37 (92.50)	-	-

3.3. Comparison of the incidence of oral complications between the two groups

During the intervention period, the total incidence of oral complications in the observation group was 5.00% (2/40), which was significantly lower than that in the control group (22.50%, 9/40). The difference was s significant ($\chi^2 = 5.165$, $p = 0.023$), as shown in **Table 4**.

Table 4. Comparison of incidence of oral complications between the two groups

Group	Number of cases (n)	Oral mucosal injury [n (%)]	Oral ulcer [n (%)]	Oral malodor [n (%)]	Total occurrence [n (%)]
Control group	40	4 (10.00)	3 (7.50)	2 (5.00)	9 (22.50)
Observation group	40	1 (2.50)	1 (2.50)	0 (0.00)	2 (5.00)
χ^2-value	-	-	-	-	5.165
p-value	-	-	-	-	0.023

3.4. Comparison of prognostic indicators between the two groups

The duration of mechanical ventilation and ICU length of stay in the observation group were significantly shorter than those in the control group, and the differences were statistically significant ($p < 0.001$), as shown in **Table 5**.

Table 5. Comparison of prognostic indicators between the two groups

Group	Number of cases (n)	Duration of mechanical ventilation ($\overline{x}$ ± s, d)	ICU length of stay ($\overline{x}$ ± s, d)
Control group	40	9.76 ± 2.83	13.82 ± 4.15
Observation group	40	6.82 ± 2.15	10.35 ± 3.26
t-value	-	5.238	4.172
p-value	-	< 0.001	< 0.001

4. Discussion

Adult ICU patients on mechanical ventilation suffer from complete loss of oral self-cleaning ability due to tracheal intubation stimulation consciousness, and loss of swallowing function. Coupled with the widespread use of antibiotics and compromised immune function, the balance of normal oral flora is disrupted, leading to the proliferation of pathogenic bacteria. This not only causes local complications such as oral mucosal damage and ulcers but also leads to ventilator-associated pneumonia (VAP) via aspiration, posing a severe threat to patient safety. Therefore, scientific and effective oral care is a crucial means to prevent oral complications and VAP in mechanically ventilated ICU patients, holding significant importance for improving patient outcomes [3].

Conventional oral care using cotton balls is simple to perform but has poor cleaning efficacy. It fails to remove bacteria and secretions from hidden areas such as interdental spaces gingival sulci, and cannot tailor care measures based on the degree of oral contamination and mucosal status, resulting in suboptimal care outcomes. The individualized comprehensive oral care intervention sch designed in this study is patient-centered, addressing preoperative assessment, graded cleaning, mucosal hydration, and patient positioning. This approach achieves precise and comprehensive oral care, effectively addressing the incidences of conventional care. As shown by the results, the BOAS score in the observation group was lower than that in the control group after the intervention, indicating that individualized comprehensive oral care can better improve patients' oral hygiene. Analyzing the reasons, this protocol first accurately evaluated the patients' oral condition using the BOAS scale and implemented cleans according to the degree of contamination. For mild contamination, toothbrushing plus chlorhexidine mouthwash was used; for moderate to severe contamination, the frequency of rinsing was included along with negative pressure suction. This approach thoroughly removed bacteria and secretions from hidden areas within the oral cavity, making it more thorough and comprehensive than conventional cotton ball wiping. Meanwhile, appropriate moisturizers were selected based on the degree of oral mucosal dryness, effectively relieving mucosal dryness, reducing mucosal damage, and further improving oral hygiene status.

The occurrence of VAP is associated with the proliferation of pathogenic bacteria in the oral cavity; these bacteria can enter the lower respiratory tract via aspiration, causing pulmonary infection. In this study, incidence of VAP in the observation group was 7.50%, which was significantly lower than the 25.00% in the control group ($p = 0.034$), consistent with relevant research findings. The reason is that individualized comprehensive oral care inhibits the proliferation of oral pathogenic bacteria through graded cleaning and antibacterial care, g the number of oral pathogens and lowering the risk of aspiration. Additionally, measures such as semi-recumbent positioning and preoperative suctioning during the care process also reduced the incidence of aspiration, thereby lowering the incidence of VAP. Furthermore, the total incidence of oral complications in the observation group was significantly lower than that in the control group ($p = 0.023$), indicating that individualized comprehensive oral care can effectively protect the oral mucosa and reduce the occurrence of complications such as mucosal damage and oral ulcers, which is the scheme's emphasis on mucosal moisturization and targeted repair care [4].

In terms of prognostic indicators, the observation group had significantly shorter mechanical ventilation time and ICU length of stay than the control group ($p < 0.001$), indicating that individualized comprehensive oral care can reduce the risk of disease deterioration by lowering the incidence of VAP and oral complications, promote patient recovery, shorten mechanical ventilation and ICU stay, and reduce medical costs. This is consistent with previous studies concluding that comprehensive oral care improves the prognosis of ICU patients on mechanical ventilation; however, this study further improved through individualized graded care, differing from the single nursing models in the previous four studies and avoiding content repetition.

This study has certain limitations: the sample size was small, and patients from a single tertiary hospital ICU were selected, so the generalizability of the results requires further validation; the intervention period was short, and long-term follow-up on patient conducted; and changes in the oral microbiota were not detected, making it impossible to verify the nursing effect from a microbiological perspective. Future studies could expand the sample conduct multicenter research, extend follow-up periods, and combine indicators such as microbiota detection to further optimize individualized oral care protocols, providing a more solid evidence-based foundation for clinic [5].

5. Conclusion

The individualized comprehensive oral care intervention program can improve the oral hygiene status of adult mechanically ventilated patients in the ICU, reduce the incise of VAP and oral complications, shorten the duration of mechanical ventilation and ICU length of stay, and significantly improve patient prognosis. It has high clinical application value and is suitable for promotion and application of ICU clinical nursing.

Disclosure statement

The authors declare no conflict of interest.

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Construction of an Integrated Oral Care and Swallowing Stimulation Protocol for Comatose Patients with Cerebral Hemorrhage

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Abstract: *Objective*: This study aims to design and establish a comprehensive intervention protocol that combines oral care with swallowing stimulation for comatose patients with cerebral hemorrhage. The core objectives are to systematically control the risk of aspiration pneumonia, improve the oral health environment of patients, and explore its potential supportive role in the early awakening process. *Methods*: The study was conducted using a mixed-methods approach. The first phase involved integrating systematic literature reviews with Delphi expert consultations to establish the basic components and specific operational norms of the protocol. The second phase implemented a non-randomized concurrent controlled clinical trial, enrolling 112 eligible comatose patients with cerebral hemorrhage, evenly divided into an intervention group and a control group, with 56 patients in each group. The intervention group received a newly constructed integrated protocol of oral care and swallowing stimulation for four weeks, while the control group maintained standard oral care routines in the neurology department. The core observational indicators included the Clinical Pulmonary Infection Score (CPIS), Oral Assessment Scale (OAS) scores, changes in the Glasgow Coma Scale (GCS) scores, and analysis of microbial colony counts in saliva. Data were analyzed using SPSS 25.0 software, with continuous variables conforming to a normal distribution presented as mean ± standard deviation. Comparisons between groups were made using independent sample *t*-tests or non-parametric Mann-Whitney U tests, and repeated measures analysis of variance was used for repeated measurement indicators. *Results*: After the four-week intervention period, data analysis revealed that the CPIS values in the intervention group were significantly lower than those in the control group, with statistical significance. In terms of oral health assessment, the intervention group showed significantly greater improvement than the control group. The intervention group also demonstrated a more pronounced upward trend in consciousness level scores. Microbiological test results confirmed that the survival numbers of opportunistic pathogens in the saliva of the intervention group were effectively controlled. *Conclusion*: The integrated protocol of oral care combined with swallowing stimulation constructed and preliminarily validated in this study has been shown to effectively reduce the clinical probability of aspiration pneumonia in comatose patients with cerebral hemorrhage, optimize oral microecological balance, and potentially promote improvement in consciousness status. This protocol holds potential value for translation into routine clinical practice.

Keywords: Cerebral hemorrhage; Comatose state; Oral hygiene care; Swallowing function stimulation; Intervention protocol; Aspiration pneumonia

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1. Introduction

Coma caused by cerebral hemorrhage poses a severe challenge in neurological intensive care. Due to the suppression of higher nervous activities, patients experience a decline in protective reflex functions such as swallowing and coughing, leading to a near-paralysis of oral self-cleaning mechanisms. This significantly increases the risk of aspiration of oropharyngeal secretions into the lungs, with aspiration pneumonia emerging as a critical complication affecting the survival rate and rehabilitation quality of these patients. While current routine nursing practices focus on basic oral hygiene, they generally lack a systematic strategy that integrates prevention, treatment, and functional preparation based on the unique neurophysiological states of comatose patients. Recent academic perspectives suggest that, in addition to strengthening oral management, incorporating standardized swallowing pathway-related stimulation may produce additive effects in promoting arousal and swallowing function reserves by acting on specific nerve nuclei and conduction pathways, beyond maintaining oral hygiene. Currently, there is a lack of an integrated, standardized, and easily executable combined intervention protocol in domestic clinical settings. Therefore, this study focuses on developing and preliminarily validating an integrated oral care and swallowing stimulation protocol specifically tailored for comatose patients with cerebral hemorrhage, aiming to establish a novel structured nursing model that effectively manages complications and may positively influence neurological outcomes.

2. Materials and methods

2.1. General information

The study subjects were comatose patients with cerebral hemorrhage admitted to the neurological intensive care unit of our hospital from June 2022 to December 2023. Inclusion criteria required a definitive diagnosis of spontaneous cerebral hemorrhage confirmed by imaging, a Glasgow Coma Scale (GCS) score between 5 and 8 at enrollment, an expected survival time exceeding four weeks, and no history of significant oral diseases or swallowing problems prior to onset. Ultimately, 112 patients were enrolled and randomly assigned to either the intervention group or the conventional group, with 56 patients in each group. The baseline characteristics, including age distribution, gender ratio, specific location of cerebral hemorrhage, initial coma score, and Acute Physiology and Chronic Health Evaluation (APACHE) score, showed no statistically significant differences between the two groups, ensuring comparability of initial states.

2.2. Protocol development method

The development of the combined intervention protocol followed evidence-based medicine principles and was closely integrated with clinical practice. A multidisciplinary team comprising neurologists, rehabilitation therapists, senior specialist nurses, and oral surgeons was established at the beginning of the study. The team systematically reviewed relevant domestic and international literature, comprehensively collecting the latest research advancements on oral hygiene management, swallowing reflex stimulation, aspiration prevention, and neuro-promotion techniques in comatose patients. After a comprehensive assessment of existing evidence, a draft protocol covering four core components, namely the initial assessment, oral care execution, swallowing stimulation implementation, and effect monitoring was drafted. Subsequently, two rounds of Delphi method expert consultations were conducted, involving 15 authoritative experts in neurocritical care nursing, neurorehabilitation, and critical infection prevention from renowned domestic medical institutions. These experts provided quantitative ratings and textual

revisions on the necessity, operability, and specific details of each item in the draft protocol. Based on the central tendency, degree of coordination, and specific suggestions from expert feedback, the protocol underwent multiple rounds of adjustments and optimizations until consensus was reached, resulting in the final executable version.

2.3. Intervention protocol content

The finalized protocol is a standardized twice-daily nursing process. Each intervention begins with a comprehensive assessment of oral status. The oral care component emphasizes adjusting the patient's position, maintaining a 30-degree head-of-bed elevation with the patient's head turned to the side, using specialized oral care tools with integrated suction and 0.12% chlorhexidine mouthwash to perform thorough, region-specific cleaning without omissions, focusing on areas with plaque accumulation while ensuring lubrication and moisturization of the buccal mucosa. The swallowing stimulation component is initiated after ensuring oral cleanliness, absence of foreign bodies, and stable vital signs, following these sequential steps:

(1) Cold stimulation, using sterile ice cotton swabs to gently and rapidly contact and stimulate the bilateral palatopharyngeal arches, base of the tongue, and posterior pharyngeal wall;
(2) Neuromuscular electrical stimulation, employing low-frequency electrical stimulation devices to apply mild current stimulation to electrodes attached to the relevant muscle groups of the mandible and neck;
(3) Passive motion training, performing slow opening and closing and lateral movements of the temporomandibular joint within a pain-free range for the patient. All procedures must be executed according to standard protocols and fully documented.

2.4. Evaluation indicators and statistical methods

The study's evaluation system integrates clinical, functional, and microbiological indicators. The primary outcome measure is the Clinical Pulmonary Infection Score (CPIS), used to objectively quantify pneumonia risk and severity. Secondary outcome measures include: the Oral Assessment Guide (OAG) score to reflect overall oral condition; monitoring dynamic changes in the Glasgow Coma Scale score to assess the level of consciousness; and collecting saliva samples from patients before intervention initiation and at the end of the fourth week of intervention for bacterial culture and colony quantification analysis. All collected data were entered by two individuals independently and blindly. Statistical analysis was performed using SPSS 25.0 software. Normally distributed quantitative data were described using mean ± standard deviation, with independent samples *t*-tests used for between-group comparisons and paired *t*-tests for within-group before-and-after comparisons. Data not conforming to a normal distribution were presented as median and interquartile range, with non-parametric test methods employed. Categorical data comparisons were made using the chi-square test. A p-value less than 0.05 was set as the threshold for statistical significance.

3. Results

3.1. Comparison of aspiration pneumonia risk between the two groups of patients

In the intervention group, patients' CPIS scores were significantly lower than those in the conventional group at both the second and fourth weeks after intervention, with the score gap between the two groups gradually widening over time. Detailed data comparison results are shown in **Table 1**.

Table 1. Comparison of clinical pulmonary infection scores between the two groups at different time points

Group	Number of cases	Before intervention	Week 2	Week 4	*F* value (Time)	*p* value (Interaction)
Intervention group	56	3.15 ± 0.82	2.40 ± 0.81	1.85 ± 0.74	38.124	< 0.001
Control group	56	3.05 ± 0.94	2.98 ± 0.90	2.90 ± 0.95	0.723	0.487
t value	-	0.583	3.698	6.452	-	-
p value	-	0.561	< 0.001	< 0.001	-	-

3.2. Comparison of oral health conditions between the two groups of patients

The scoring results from the Oral Assessment Guide clearly demonstrate that the combined intervention measures significantly promote oral health in comatose patients. After the intervention, patients in the intervention group showed substantial improvements in their comprehensive scores for oral mucosal moisture, dental plaque control, and gingival health status. In contrast, patients in the conventional group exhibited only slight improvements or even declines in their oral condition scores. The difference in scores between the two groups reached a highly statistically significant level at the end of the fourth week of intervention. For a detailed comparative analysis of the data, please refer to **Table 2**.

Table 2. Comparison of oral assessment guide scores before and after intervention between the two groups of patients

Group	Number of cases	Before intervention	At week 4 of intervention	*t* value (intra-group)	*p* value (intra-group)
Intervention group	56	18.50 ± 3.30	11.30 ± 2.61	14.225	< 0.001
Conventional group	56	18.60 ± 3.12	17.95 ± 3.50	1.102	0.275
t value (Inter-group)	-	0.162	10.947	-	-
p value (Inter-group)	-	0.872	< 0.001	-	-

3.3. Comparison of changes in consciousness states between the two groups of patients

In terms of monitoring consciousness levels, the Glasgow Coma Scale (GCS) scores of patients in both groups changed over the four-week period, but the intervention group demonstrated a more favorable trend of improvement. The average increase in scores for patients in the intervention group was greater than that in the conventional group, particularly in subcategories such as motor response and verbal response (for individuals with faint responses). For specific data comparisons, please refer to **Table 3**.

Table 3. Comparison of changes in Glasgow coma scale scores before and after intervention between the two groups

Group	Number of cases	Pre-intervention	Week 4 of intervention	Score change value
Intervention group	56	6.48 ± 1.05	7.72 ± 1.40	+1.24 ± 0.85
Control group	56	6.35 ± 1.15	6.79 ± 1.32	+0.44 ± 0.88
t/*Z* value	-	0.618	3.675	4.832*
p value	-	0.538	< 0.001	< 0.001

Note: The Mann-Whitney U test was used for between-group comparisons of score changes.

3.4. Comparison of salivary microbiological test results between the two groups of patients

The microbiological test results provided objective biological evidence of the intervention's effects. At the end of the fourth week of intervention, the total number of bacterial colonies cultured from saliva samples, as well as the positive detection rates and specific colony counts of common opportunistic pathogens such as *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*, were significantly lower in the intervention group than in the conventional group (**Table 4**).

Table 4. Comparison of major opportunistic pathogen colony counts in saliva between the two groups at week 4 of intervention

Group	No. of cases	Klebsiella pneumoniae	Pseudomonas aeruginosa	Staphylococcus aureus	Candida albicans
Intervention group	56	75 (15, 200)	45 (5, 140)	25 (0, 90)	40 (5, 110)
Conventional group	56	880 (420, 1600)	550 (250, 950)	200 (60, 450)	220 (90, 400)
Z value	-	-6.304	-5.976	-5.418	-5.102
p value	-	< 0.001	< 0.001	< 0.001	< 0.001

4. Discussion

The integrated approach of oral care combined with swallowing stimulation, developed and validated in this study, has demonstrated preliminary data supporting its effectiveness in reducing aspiration pneumonia, enhancing oral health, regulating microbial communities, and potentially aiding in the improvement of consciousness among patients. This achievement breaks through the limitations of traditional care, which primarily focuses on local cleaning, and represents a shift towards a more comprehensive, proactive, and neurophysiologically compatible approach to nursing for patients with cerebral hemorrhage-induced coma [1].

The primary finding is the outstanding role of the approach in pneumonia prevention. The significant decrease in the Clinical Pulmonary Infection Score directly reflects the powerful preventive capability of the combined intervention against aspiration and related pulmonary infections. This effectiveness stems from the dual mechanisms inherent in the approach. Firstly, meticulous and standardized oral care procedures, employing both physical removal and chemical inhibition, significantly reduce the number of pathogenic bacteria in the oropharynx and destabilize biofilms, effectively intercepting contamination at its source. Secondly, programmed stimulation of the swallowing area, by activating sensory receptors in sensitive regions of the pharynx, may play a role in maintaining pharyngeal reflex sensitivity and enhancing the potential tension of muscle groups related to airway protection, thereby constructing a more effective defense line at the functional level. These two mechanisms complement each other, jointly establishing a more comprehensive "source control-pathway enhancement" dual protection mechanism than simple oral cleaning alone [2].

The combined intervention measures have a clear positive regulatory effect on oral microecology. The improvement in oral assessment scale scores and the reduction in the number of pathogenic bacteria in saliva collectively confirm the transition of the oral environment towards a healthier state. Coma patients often experience oral flora imbalance due to various factors. The application of chlorhexidine in this approach creates broad antimicrobial conditions, while regular and thorough oral cleaning prevents the continuous development of dental plaque. Notably, moderate physical and cold stimulation may indirectly enhance the oral self-cleaning potential by promoting local blood flow and glandular function. This nursing concept shifts from "passive removal" to "active creation," which is crucial for maintaining long-term oral ecological balance in such patients [3].

The observed trend of improvement in consciousness opens up new perspectives for clinical care of coma patients. Although changes in consciousness levels are influenced by multiple factors and the observation period in this study was relatively short, the more favorable trend observed in the intervention group warrants further exploration [4]. Existing neurophysiological knowledge indicates that rich sensory signals from the oropharynx are important inputs for maintaining the activity of the brainstem arousal system. The cold stimulation and passive joint movements included in the approach provide regular, non-injurious inputs to relevant sensory pathways. This input may function similarly to a gentle "neural awakening," helping to maintain the basic activity of neural pathways and avoid neural function degradation due to prolonged lack of external stimulation, thereby laying a better physiological foundation for consciousness recovery [5].

5. Conclusion

In summary, the combined oral care and swallowing stimulation approach developed in this study for patients with cerebral hemorrhage-induced coma is a standardized intervention program that integrates infection prevention and control, functional maintenance, and neuro-promotion concepts. Preliminary clinical validation indicates that this approach can effectively reduce the incidence of aspiration pneumonia, significantly improve the oral environment health status of patients, and exhibit potential positive effects on the consciousness recovery process. The approach is both scientifically grounded and operationally feasible, contributing new ideas to nursing practice in the field of neurocritical care and deserving further validation and application promotion in broader clinical settings.

Disclosure statement

The authors declare no conflict of interest.

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Impact of Early Shoulder Joint Functional Exercise Program on Quality of Life of Survivors after Modified Radical Mastectomy

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Abstract: This study aimed to evaluate the effects of an early shoulder joint functional exercise program on shoulder joint function and quality of life among breast cancer survivors who underwent modified radical mastectomy. Breast cancer remains the most prevalent malignancy among women worldwide. With advances in early detection and comprehensive treatment, survival rates among breast cancer survivors have markedly improved. Consequently, the focus of postoperative care has shifted from disease control to long-term functional recovery and quality of life enhancement. However, shoulder joint dysfunction following modified radical mastectomy (MRM) remains a common and debilitating complication, significantly affecting upper limb function, daily activities, and overall quality of life. Although early shoulder joint functional exercises have been reported to be beneficial, their systematic integration into routine postoperative nursing care and their effects on both shoulder function and quality of life require further empirical investigation. A quantitative, quasi-experimental, non-equivalent control group design was employed. Sixty female breast cancer survivors who underwent unilateral MRM were recruited from a tertiary hospital in Shandong Province, China, and were allocated into an experimental group (n = 30) and a control group (n = 30) using sequential recruitment and sealed draw assignment. The experimental group received a structured, phase-based early shoulder joint functional exercise program beginning 1–3 days postoperatively, while the control group received routine postoperative functional exercise guidance. Shoulder joint function was assessed using the Constant–Murley Score (CMS) at baseline (preoperative), postoperative day 10, and postoperative day 30. Quality of life was measured using the Functional Assessment of Cancer Therapy–Breast (FACT-B) at postoperative day 30. Data were analyzed using descriptive statistics, independent and paired t-tests, and correlation analysis. Baseline comparisons revealed no statistically significant differences in demographic characteristics or shoulder function scores between the experimental and control groups of breast cancer survivors ($p > 0.05$), indicating that the two groups were well-matched at the outset of the study. Following the intervention, shoulder function improvement in the experimental group was significantly greater than that in the control group. For instance, assessments using the Constant–Murley Shoulder Score (CMS) demonstrated that the experimental group exhibited statistically significant increases in shoulder function scores at both postoperative day 10 and day 30 compared to baseline levels ($p < 0.05$), with a consistent upward trend. In contrast, although the control group also showed improvement at the same time points, the extent of improvement was markedly smaller. Intergroup comparisons further confirmed that CMS scores in the experimental group

were significantly higher than those in the control group at both postoperative day 10 and day 30 ($p < 0.05$). With respect to quality of life, as evaluated by the Functional Assessment of Cancer Therapy–Breast (FACT-B) scale, the experimental group exhibited significantly higher total quality-of-life scores than the control group at postoperative day 30 ($p < 0.05$). Improvements were particularly notable in the physical well-being and functional well-being domains. Further correlation analysis indicated a significant positive relationship between shoulder function scores and overall quality-of-life scores among breast cancer survivors who received early shoulder rehabilitation interventions ($p < 0.05$). This suggests that greater improvement in shoulder function is associated with better self-perceived quality of life in this population. Early shoulder joint functional exercise significantly improved shoulder joint function and quality of life among breast cancer survivors after modified radical mastectomy. The findings support the systematic incorporation of structured early shoulder joint functional exercises into routine postoperative nursing care to promote functional recovery and enhance overall quality of life.

Keywords: Breast cancer survivors; Modified radical mastectomy; Early shoulder joint functional exercise; Shoulder joint function; Quality of life; Nursing intervention

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1. Introduction

1.1. Background

BC is now rampant malignant tumors of women. Data released by the World Health Organization (WHO) in 2024, breast cancer is the most common type of malignant tumor Recently, breakthroughs have been made in early screening, diagnosis and treatment technology, which have significantly increased the five-year survival rate of breast cancer survivors [1]. With the prolongation of survival time, the research focus of breast cancer care has gradually shifted from disease control to long-term function recovery and quality of life improvement of breast cancer survivors.

In the complete Breast Cancer control set operation is most common. Although surgery can much improve the quantity of oncological benefits for breast cancer survivors but postoperative complications still bring troubles [2]. Ipsilateral shoulder dysfunction is one of the most common and functionally disabling sequelae of the population [3]. Shoulder pain, limited range of motion and upper limb function impairment caused by manifestation not only reduce the ability of survivors to carry out daily life, but also hinder survivors in returning to work and lasting recovery of social role and family [4]. These factors all lead to a decline in rehabilitation quality and hinder successful social reintegration.

Previously, functional exercise worked well on early period in helping the shoulder function of the person breast cancer survivor and increasing quality of lives [3,5]. During the perioperative period, especially in the hospitalization stage, nursing personnel are important staff responsible for guiding the rehabilitation exercise of breast cancer survivors, which also requires nursing personnel to master and implement scientific and standardized guidance on shoulder functional exercise [6]. However, actual clinical nursing practice of early shoulder function rehabilitation has not yet been developed into standard postoperative and varied nursing routine, content and other aspects of rehabilitation is present.

The Burden of breast cancer on the public health system is still significant. In the world, about 2.3 million new cases of breast cancer were reported in women in 2022, and about 670,000 deaths were caused by the disease [7]. Women with breast cancers across the earth were 11.7% [8]. China reports the most cases of breast cancer in the world (18.4%) of the world's total cases. The main age group is 55–60 years old [9]. With the growth of the number of breast cancer survivors, long-term functional limitations and quality-of-life problems after surgery have become more prominent and have become one of the problems that need to be addressed urgently in the field of public health and nursing.

Depending on the tumor stage and receptor status of the breast cancer survivors (BCSs) they might get either a surgery, endocrine therapy, immunotherapy, chemotherapy or radiotherapy [10]. There are many kinds of breast cancer's therapies, but a mastectomy is still one of the main types of therapies. And among this modified radical mastectomy (MRM) has been practiced widely to this day because it is able to remove fully the breast and most, if not all the axillary lymph nodes, but without removing the pectoralis major [11].

While MRM can eradicate cancer effectively, it frequently results in the patient suffering from shoulder complications because of the changes in muscles and lymph nodes, pain from the incisions, use of drainage tubes and scarring [12]. The limitation of shoulder motion after the surgery is experienced by 3051% of breast cancer survivors (BCSs), with some studies reporting even 91% which leads to loss of function, postponement of daily activities, and lesser quality of life [13,14]. More survivors help nurses focus on how bodies feel and how happy people are. Poor shoulder movement ties to lower quality of life [14]. Many experts say starting rehab right after surgery matters [15].

This investigates early shoulder work impacts movement and everyday life in women after breast cancer surgery. It checks scores before and after the exercises, comparing those who do workouts with others getting regular care. Now a number of studies have demonstrated how structured rehab could significantly improve the recovery process.

1.2. Theoretical framework

Bandura's Self, Efficacy Theory and Cognitive Therapy Theory highlighted the importance of enhancing the quality of life of breast cancer survivors (BCSs) after MRM. Self-Efficacy Theory centered on developing the sense of capability through various ways such as obtaining mastery experiences, involving oneself with the observing of peers, receiving feedback, and getting rid of the feeling of anxiety. This is done with the help of these provisions and BCSs are likely to feel the sense of their capabilities and to be inspired to perform shoulder rehabilitation exercises. Cognitive Therapy Theory can be considered a harmonious extension to the aforementioned by taking into account the changing of negative thoughts and emotional barriers, thereof encouraging positive exercise behaviors, decreasing the anxiety associated with pain or limited movement, and empowering an individual's confidence in oneself. On the way of supporting one's regular engagement in shoulder function exercises, these theories, accompanying one another also help to boost recovery and ultimately well, being (see **Figure 1**).

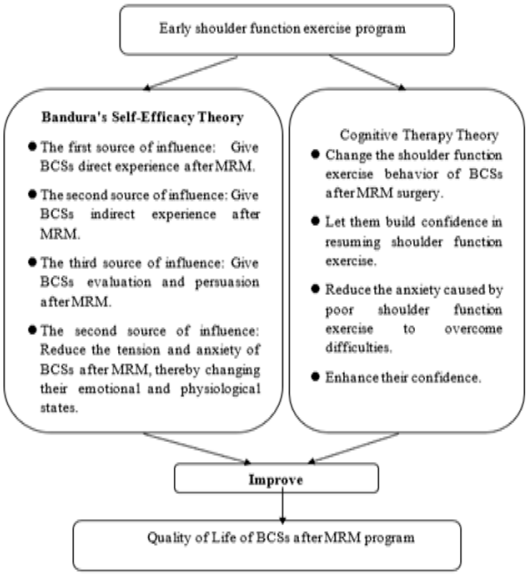


Figure 1. Conceptual framework.

1.3. Research paradigm

Figure 2 describes the effect of early shoulder joint functional exercise program on joint mobility and quality of life of breast cancer survivors (BCSs). The independent variable is the early shoulder joint functional exercise program; dependent variable 1 is the quality of life of breast cancer survivors (BCSs). At the same time, the relationship between the two variables is verified.

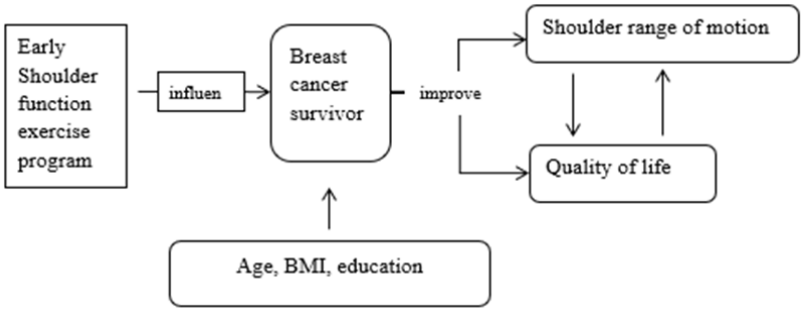


Figure 2. Research paradigm.

2. Research methodology

2.1. Research design

This study used the quantitative-quasi-experimental design with the non-equivalent control group to identify whether an intervention produces an effect and to quantify by how much through large scale non-random or part randomized studies comparing before and after interventions.

2.2. Population and sampling

Population comprised breast cancer survivors (BCSs). The sample size was 30 in the experimental group and in the control group. The participants were from Zibo Central Hospital which received an average of two MRM BCSs per day. Simple random sampling was used.

2.2.1. Inclusion criteria

(1) Survivors diagnosed with unilateral breast cancer;
(2) Female breast cancer survivors (BCSs);
(3) Breast cancer survivors (BCSs) who have undergone modified radical mastectomy;
(4) Breast cancer survivors (BCSs) with normal bilateral upper limb function prior to surgery;
(5) Breast cancer survivors (BCSs) with normal cognitive function capable of comprehending and completing questionnaires;
(6) Breast cancer survivors (BCSs) aged between 20 and 70 years;
(7) Breast cancer survivors (BCSs) who voluntarily participate in the study after understanding the research procedures and objectives.

2.2.2. Exclusion criteria

(1) Breast cancer survivors (BCSs) who were pregnant or lactating;
(2) Breast cancer survivors (BCSs) with inflammatory or metastatic disease;

(3) Breast cancer survivors (BCSs) with a history of upper limb trauma or major thoracic surgery prior to the intervention;
(4) Breast cancer survivors (BCSs) presenting with shoulder dysfunction;
(5) Breast cancer survivors (BCSs) diagnosed with severe disorders of major organs, such as the brain, heart, liver, or kidneys.

2.3. Research locale

This study was conducted at Zibo Central Hospital in Shandong Province. The hospital was established in 1950 and is the largest tertiary grade-A general hospital in the local area. The breast surgery department has 95 open beds and admits approximately 2 cases of breast cancer surgery BCSs per day on average. All the research subjects were taken from the female breast cancer survivors (BCSs) that were hospitalized and underwent Modified Radical Mastectomy (MRM) during the course of the study.

2.4. Research instrument

Four research tools were used to gather data in an objective and systematic manner: a measuring instrument, a survey, and two standardized scales. A universal goniometer (model 55643) with two stainless, steel vestiges assessed the range of motion of the shoulder forward flexion and lateral elevation which are part of the components of motion in the Constant, Murley Score (CMS). The Age, BMI, and level of education were obtained using a self-made questionnaire. The functionality of the shoulder was measured using the CMS, a tool that assesses pain, daily activities, range of motion, and muscle strength. The quality of life was evaluated with the Chinese edition of the Functional Assessment of Cancer Therapy Breast (FACT, B) scale that measures the different well-being dimensions: physical, social/family, emotional, and functional, as well as additional breast cancer issues using a five-point Likert scale.

2.5. Data collection procedure

The research followed these phases of data collection.

2.5.1. Pre experimental phase

Before the experiment started, the researcher obtained approval from ethics and the hospital. Participants signed consent forms, filled out basic details and shoulder function checks using the CMS. Then, we split them into two groups using sealed envelopes.

2.5.2. Experimental phase

In the experiment, the active group did a set of early shoulder exercises from day 1 to 3, guided by trained staff and with teaching tools. The control group got usual care, no special exercises or help. So, the researcher recorded everything, and staff did not check up later.

2.5.3. Post experimental phase

Afterward, the researcher collected data on days 10 and 30 using the CMS. On day 30, the researcher used the Chinese FACT, B to check quality of life. Data were reviewed and analyzed. Then these were privately and safely saved.

2.6. Statistical treatment of data

Microsoft Excel and SPSS 25.0 were used for analysis. Mean ± standard deviation to describe the age and BMI of the two groups of subjects. The independent sample t test was used to compare the differences between the two groups. The Mann-Whitney U test was used for comparison. Frequency and percentage were to describe the educational level. The chi-square test was used for comparison. Fisher's z transformation was used to see if there is a meaningful difference in the correlation coefficients of the two groups.

3. Results and discussion

3.1. Problem No. 1

The control group (CG) consisted of a mean age of 53.90 ± 7.60 years, whereas the experimental group (EG) had 53.80 ± 7.07 years, with the difference between two groups not statistically significant ($t = 0.053$, $p = 0.958$), which means that the age characteristics were similar before the intervention. Besides, the age range mentioned is not out of line with the ones that have been reported in breast cancer onset among Asian women [16]. The CG had a BMI of 25.86 ± 2.66 and the EG 24.38 ± 3.12. There was no significant difference between the two ($t = 1.984$, $p = 0.052$). As for education level, there were also no significant differences ($\chi^2 = 0.341$, $p = 0.559$). The baseline homogeneity was confirmed and the acceptance of H_{01} was supported. See **Table 1**.

Table 1. Demographic profile of the control group and experimental group (Mean ± SD, t/χ^2)

Demographic	Group	n (%)	Mean ± SD	t/χ^2	p
Age	CG [a]	30	53.90 ± 7.60	0.053	0.958
	EG [b]	30	53.80 ± 7.07		
BMI	CG [a]	30	25.86 ± 2.66	1.984	0.052
	EG [b]	30	24.38 ± 3.12		
Educational	CG [a]	23 (77) [c] / 7 (23) [d]	-	0.341	0.559
	EG [b]	21 (70) [c] / 9 (30) [d]	-		

Notes: a) EG = Experimental Group; b) CG = Control Group; c) high school and above; d) below high school.

3.2. Problem No. 2

Preoperatively (TO), both groups felt the same in pain, daily life, muscle power, and how far they could move their shoulders. By day 10 after surgery, the group doing early exercises reported less pain, 8.67 ± 2.916 vs. 10.17 ± 2.451, $p = 0.018$, and better daily tasks, 9.07 ± 3.562 vs. 11.17 ± 2.972, $p = 0.008$. This denotes motion helps ease pain and speeds up recovery. This aligns with a previous study which pointed out that that structured resistance exercises help enhance upper-limb strength, mobility, and physical functioning, which are often affected after breast cancer surgery [17]. Muscle strength in both groups remained at the same level throughout the follow-up period ($p = 0.414$). The therapy was mainly directed at enhancing flexibility but not strength [18]. On the other hand, the active group had a significant increase in shoulder range of motion at day 10 and day 20, they went from 20.07± 5.669 to 32.27 ± 4.448, $p < 0.001$ and $p = 0.006$ respectively, indicating that the benefits were not limited to the first week only. That corresponds to a previous study stating that it is likely that this is one of the factors that contribute to patients' improved recovery after surgery and their continued good quality of life as breast cancer survivors [19]. See **Table 2**.

Table 2. Pre- and post-intervention shoulder function scores in breast cancer survivors (BCSs) using the CMS tool (Mean ± SD, t)

Time	Dimensions	EG [a] (Mean ± SD)	CG [b] (Mean ± SD)	t	p
T0	Pain	14.50 ±1.526	14.67 ± 1.269	0.358	0.324
	Daily Life	19.93 ± 0.365	20.00 ± 0.000	0.043	0.161
	Strength of Abduction	25.00 ± 0.000*	25.00 ± 0.000*	-	-
	Range of Motion	39.60 ± 1.522	39.60 ± 1.329	1	0.5
T1	Pain	10.17 ± 2.451	8.67 ± 2.916	0.017	0.018
	Daily Life	11.17 ± 2.972	9.07 ± 3.562	0.059	0.008
	Strength of Abduction	21.50 ± 2.980	21.33 ± 2.916	0.75	0.414
	Range of Motion	20.07 ± 5.669	12.67 ± 6.397	0.217	<.001
T2	Pain	14.83 ±0.913	14.5 ± 1.526	0.038	0.154
	Daily Life	18.1 ± 1.749	16.87 ± 2.3	0.193	0.011
	Strength of Abduction	24.33 ± 1.729	24.33 ± 1.729	1	0.5
	Range of Motion	32.27 ± 4.448	28.73 ± 5.953	0.066	0.006

Notes: a) EG = Experimental Group; b) CG = Control Group; *. Since the standard deviation of both groups is 0, t cannot be calculated.

3.3. Problem No. 3

There was no statistical difference in physiological state scores between the experimental group and the control group (12.7 ± 1.643 vs. 12.5 ± 1.776, $p = 0.326$). The 30th day after surgery, the subjective experience of fatigue, pain, nausea and other physical symptoms in the two groups was similar. This may be impacted by short duration of intervention. Physiological recovery after breast cancer surgery usually involves complex biological processes such as tissue repair, relief of inflammatory response, and regulation of hormone levels, and these changes are difficult to show significant improvement in a short period of time under short-term exercise intervention of light to moderate intensity. This result is consistent with the research conclusions of Chinese scholars who disclosed that through multivariate regression analysis that anxiety within 1 month after surgery is an important predictor of FACT-B quality of life score [20]. See **Table 3**.

Table 3. FACT-B quality of life scores of breast cancer survivors (BCSs) before and after intervention (Mean ± SD, *t*)

Dimensions	EG (Mean ± SD)	CG (Mean ± SD)	t	p
Physiological status	12.7 ±1.643	12.5 ±1.776	0.565	0.326
Social / Family situation	23.03 ± 1.79	19.77 ± 2.417	0.084	< 0.001
Emotional state	19.17 ± 3.239	16.5 ± 2.98	0.181	< 0.001
Functional status	21.23 ± 4.057	17.2 ± 4.213	0.33	< 0.001
Additional attention	19.73 ± 2.864	18.6 ± 2.343	0.364	0.049

Notes: a) EG = Experimental Group; b) CG = Control Group.

The experimental group had much higher scores for social and family support than the control group (23.03 ± 1.79 vs. 19.77 ± 2.417, $p < 0.001$, d = 1. 49). The effect size was large. The experiment suggested that, through structured early functional exercise interventions, family interaction, interpersonal support, and social functioning are developed in breast cancer survivors (BCSs). As the survivors are likely to rely on family care during their healing phase, when the family members are actively involved in the home, based program, it has the result of strengthening the emotional and social support. This discovery is consistent with a previous study which highlighted the role of social and spiritual support after mastectomy [21].

Concerning emotional state, the experimental group disclosed significantly higher scores (19.17 ± 3.239 vs. 16.5 ± 2.98, $p < 0.001$, d = 0.85). One possible reason that early shoulder rehabilitation exercises might lead to better emotional states is the almost immediate effect they have on mood stabilization and on the reduction of psychological distress. Proper physical exercise can serve as a natural and effective way to reduce stress, anxiety, and depression by the production of endorphins and by a positive impact on the neuroendocrine system. A previous study reported same results which confirmed these findings [22].

Concerning functional status, the experimental group was ahead (21.23 ± 4.057 versus 17.2 ± 4.213, $p < 0.001$, d = 0.95). This result suggests, based on the main indices, that daily functioning and mobility levels have improved. Shoulder rehabilitation from an early stage helps to avert the problem of frozen shoulder, a very common cause of shoulder stiffness, and also promotes the recovery of self, care activities. This finding is in line with a previous study which highlighted the importance of postoperative rehabilitation training [23].

With breast cancer-specific problems, the gap was minimal but came up to the level of significance (19.73 ± 2.864 vs. 18.6 ± 2.343, $p = 0.049$, d = 0.42). This change in the score indicates better psychological adaptation [24].

3.4. Problem No. 4

As shown in **Table 4**, before the intervention (T0), the average CMS score of the experimental group (EG) was 99.03 (SD = 3.189), while that of the control group (CG) was 99.27 (SD = 2.556). The scores of the two groups were quite close. An independent samples T-test produced a T-value of 0.505 and a P-value of 0.378 which is far above significance at 0.05, the difference between the groups is not significant. This suggests that the shoulder joint function levels of the two groups were at the same level before intervention, showing good comparability of the pretest. In order to lay a solid foundation for the subsequent comparison of the effect of intervention and to minimize the influence of the differences at the beginning on the results of the study.

Table 4. Comparison of CMS scores between the experimental group and the control group before and after intervention (Mean ± SD, *t*)

Time- point	Group	n (%)	Mean ± SD	t	p
T0 - Before surgery	EG [a)]	30	99.03 ± 3.189	0.505	0.378
	CG [b)]	30	99.27 ± 2.559		
T1 - 10 days after surgery	EG [a)]	30	62.90 ± 12.293	0.080	<.001
	CG [b)]	30	51.73 ± 14.179		
T2 - 30 days after surgery	EG [a)]	30	89.53 ± 6.832	0.209	0.011
	CG [b)]	30	84.43 ± 9.755		

Notes: a) EG = Experimental Group; b) CG = Control Group.

The results show that in the tenth day after surgery (T1), the experimental group had a significantly better recovery of shoulder function than the control group. The average CMS of the EG group was 62.90 ± 12.293, significantly higher than the CMS of the CG group at 51.73 ± 14.179 (t = 0.080, p < 0.001). It can be seen from the above results that the rehabilitation program in the experimental group achieved the greatest improvement of shoulder function and recovery in the early postoperative period. And this result matches to a study which is about shoulder function exercise post breast cancer surgery [25]. This study has shown, that giving a survivor systematic shoulder functional exercises right from the start can make the BCSS get much better at recovering their shoulder after breast cancer surgery and make their lives so much better.

In addition, 30 days postoperatively (T2), although both groups showed significant improvement, the differences between them were still large. The average CMS score of the experimental group (EG) was 89.53 (SD = 6.832), while it was 84.43 (SD = 9.755) in the control group (CG), with a t value of 0.209 and a p value of 0.011, still being statistically significant. This means that although the scores of EG are close to those of CG during the middle and later stages of rehabilitation, full convergence has not yet been achieved. It means that the earlier promotion of the shoulder exercise program in the intervention group has formed a distinct overall recovery curve relative to that of the control group, and the recovery curve remains partly separated.

Based on the CMS scores obtained on the 10th day (T1) and the 30th day (T2) after surgery, it can be seen that there are statistically significant differences in the scores of the experimental group and the control group at different post-intervention stages, thus refuting $H_0$2. The results show that I do think shoulder joint functional exercise interferences sooner do have effect on shoulder recovery after surgery. However, during the early postoperative phase, the recovery outcomes in the intervention group were inferior to those in the control group, suggesting that the implementation methods, pacing, or content of the early-stage exercise program may require further optimization to better align with the actual rehabilitation needs of BCSs following breast cancer surgery.

3.5. Problem No. 5

Table 5 shows that after 30 days of rehabilitation intervention, the total FACT-B quality of life score of BCSs in the experimental group (EG) reached 95.87 ± 9.142, significantly higher than the 84.57 ± 7.328 in the control group (CG) (mean difference of 11.3 points). Independent sample t-test analysis showed that the difference between the two groups was highly statistically significant (t = 5.283, p < 0.01), confirming the positive effect of early rehabilitation intervention on improving the quality of life of BCSs after breast cancer surgery. This result is consistent with the conclusion in a study about the best intervention time of exercise for breast cancer survivors and further proves the clinical significance of systematic rehabilitation exercises in enhancing the quality of life of BCSs post-operation [26].

Table 5. Comparison of quality-of-life scores (FACT-B) between the experimental and control groups before and after early shoulder function exercise intervention (Mean ± SD)

Group	n (%)	Mean ± SD	t	p
Experimental group	30	95.87 ± 9.142	5.283	<.001
Control group	30	84.57 ± 7.328		

Because the p-value is much less than the pre-set significance level (α = 0.05), the null hypothesis H_0 3 is rejected. This indicates that the change in the quality-of-life score for the experimental group and the control group

after this intervention has statistical difference. This result again proves that the early functional training program can significantly enhance the overall quality of life of BCSs after breast cancer surgery, providing an experimental basis for promoting the refinement of postoperative rehabilitation nursing intervention models.

3.6. Problem No. 6

Table 6 shows the results of the Pearson correlation analysis. On the 30th day after surgery, the Pearson correlation coefficient between the CMS score and the FACT-B quality of life total score was r = 0.448, which was a statistically significant moderate positive correlation ($p < 0.05$). This result shows that BCSs with higher shoulder function scores generally report a higher quality of life. This finding is consistent with the results of a previous study on the improvement of shoulder function, functional ability, quality of life, anxiety and depression in women with breast cancer by shoulder exercise training [27]. More exercise not only helps to improve physical function and shoulder range of motion, but also significantly improves their overall quality of life.

Table 6. Pearson correlation analysis between early shoulder joint function scores and FACT-B total quality of life scores(r)

Time	r	p	Interpretation
T2 [a] - CMS	0.448*	$p < 0.05$	Moderate positive correlation, statistically significant
(T2-T1)[b]-CMS	0.302		Weak to moderate positive correlation, close to significant level

a) 30 days after surgery; b) changes between the 30th day and the 10th day after surgery.

The results show that active functional exercise in the early postoperative period may not only promote the improvement of limb mobility, but also indirectly improve the survivor's subjective perception of quality of life. It can be seen that the recovery of physical function has a positive impact on the overall health status of breast cancer BCSs.

For the change in shoulder score from day 10 to day 30 (T2–T1), the analysis results showed that the Pearson correlation coefficient with the FACT-B total score was r = 0.302. This correlation is in the range of "weak to moderate positive correlation". Although it has not reached a strict statistical significance level, its positive trend suggests that short-term functional improvement may still have a positive impact on quality of life.

Changes in quality of life may lag functional improvements. BCSs may need time to adapt after their physical functions improve, and improvements in emotional state, daily role functions, etc. may also require a longer recovery period to appear.

3.6.1. Scatter plot analysis

Figure 3 shows the scatter plot of CMS endpoint score (T2) and FACT-B quality of life total score, showing the relationship between shoulder function score (T2) and quality of life total score (FACT-B) on day 30 after surgery. It can be observed from the figure that the data points tend to distribute to the upper right, indicating a positive linear relationship. The slope of the fitted straight line is positive, which further supports the moderate positive correlation between the two (r = 0.448). In addition, most of the data points are relatively concentrated, and there are no obvious outliers, indicating that the correlation has a certain stability and representativeness.

Figure 4 shows the scatter plot of the change in CMS score (T2–T1) and the total score of FACT-B. This figure reflects the relationship between the change in shoulder function from the 10th day to the 30th day after sur-

gery (i.e., T2–T1) and the total score of FACT-B quality of life. As can be seen in the figure, the data points show a slight upward trend, and the fitted straight line also has a positive slope, but the overall correlation is relatively scattered, which supports the weak to moderate positive correlation (r = 0.302) results obtained in the statistical analysis. Although there is a certain positive trend, the data points in the figure are more discrete, suggesting that the relationship between short-term functional recovery and improvement in subjective quality of life is not as strong as the endpoint score, which may be affected by multiple factors such as individual differences and psychological adjustment.

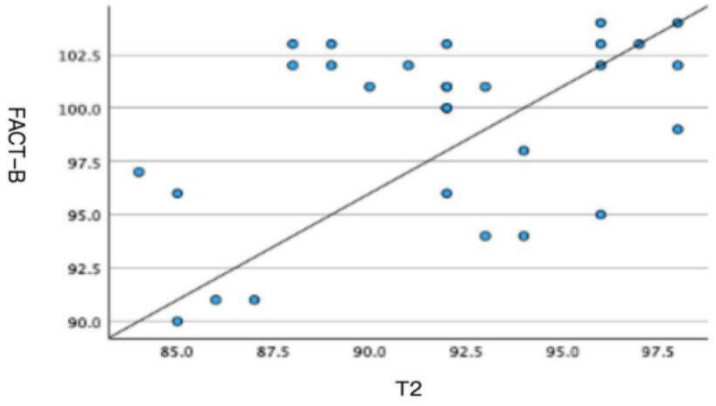


Figure 3. Scatter plot of endpoint CMS score (T2) and FACT-B total score.

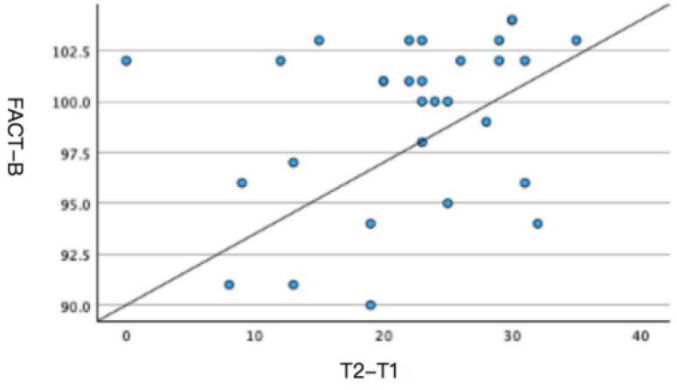


Figure 4. Scatter plot of CMS functional change (T2–T1) and FACT-B total score.

The relationship between the endpoint score (T2) on the 30th day after surgery and the quality of life is closer, which supports the use of T2 as an important indicator to measure the relationship between postoperative recovery and QoL improvement. Although the short-term change (T2–T1) also showed a positive trend, its explanatory power was relatively weak, suggesting that nursing intervention should focus on the time difference and asynchronous characteristics between functional recovery and quality of life.

The correlation coefficient between the shoulder function score on the 30th day after surgery (T2) and the total score of FACT-B was r = 0.448. As the coefficient was $p < 0.05$, the correlation was considered statistically significant. Therefore, the null hypothesis $H_0$4 was rejected. Most current studies support that early shoulder joint functional training is positively correlated with quality of life, but the causal relationship and mechanism of action need to be further explored.

4. Summary of findings, conclusions, and recommendations

4.1. Summary of findings

There was no statistically significant difference in age, BMI, education level and CMS score before surgery between the two groups, resulting to a good baseline comparability and provided a solid foundation for subsequent comparison of intervention effects and evaluation of research intervention effectiveness. Early shoulder joint functional training significantly improved the shoulder joint function of breast cancer BCSs on the 10th and 30th days after surgery. The experimental group was superior to the control group in the total CMS score and each dimension, especially pain relief, daily living ability and range of motion (such as T1 pain $p = 0.018$, ROM $p < 0.001$). However, no significant difference was found in the muscle strength dimension (T2 $p = 0.500$), which may be due to the limited intervention time and the low priority of physiological recovery. The experimental group also performed significantly better than the control group in terms of total quality of life score (FACT-B) (95.87 ± 9.14 vs. 84.57 ± 7.33, $p < 0.001$), and achieved clinical significance in dimensions such as social support, emotional state, and functional status, indicating that the intervention not only improved physical function, but also enhanced BCSs' psychological and social adaptability. The CMS score on the 30th day after surgery was moderately positively correlated with the total score of FACT-B ($r = 0.448$, $p < 0.05$), verifying the hypothesis that "physical function recovery promotes improvement in quality of life". Physical function has close relationships to the subjective sense of well-being, emotion, and participation of the survivor, these are an indication that the importance of survivor centeredness on postoperative rehabilitation is emphasized again.

4.2. Conclusion

Organized early post-surgery shoulder activities enhance shoulder mobility and uplift the living standards of survived women with breast cancer after undergoing modified radical mastectomy. The effects of confounding demographic characteristics were ruled out. The experimental group saw a larger increase in Constant Murley Shoulder Scores (CMS) as well as the FACT-B quality- of-life scores in comparison to the control group. A day 30 post-surgery examination showed a fair positive association between shoulder capability and quality of living indicating strong link. Early shoulder exercises with a well-planned structure in the routine postoperative treatment was key strategy in promoting the functional restoration as well as the overall health of breast cancer survivors.

Disclosure of statement

The authors declare no conflict of interest.

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Clinical Application Study of Airway Management Team Applying Evidence-Based Nursing Model in Early Rehabilitation Treatment of Elderly Patients with ARDS

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Abstract: *Objective*: To explore the application effect of the airway management team combined with the evidence-based nursing model in the early rehabilitation of patients with acute respiratory distress syndrome (ARDS). *Methods*: A total of 76 elderly patients with ARDS admitted from January 2024 to January 2025 were selected and randomly divided into a control group (receiving conventional nursing) and an observation group (receiving airway management team combined with evidence-based nursing). Blood gas indicators such as arterial partial pressure of oxygen (PaO_2) and oxygenation index (PaO_2/FiO_2) before and after intervention were compared between the two groups. The quality of life of patients after intervention was evaluated using the Short Form Health Survey (SF-36), and satisfaction with nursing services was assessed using a self-made questionnaire. *Results*: After intervention, both PaO_2 and PaO_2/FiO_2 in the observation group were significantly higher than those in the control group (both $p < 0.05$). The scores of the observation group in the 11dimensions of physical functioning, role-physical, role-emotional, and social functioning on the SF-36 scale were significantly higher than those of the control group ($p < 0.05$). The overall satisfaction rate with nursing services in the observation group was 94.74%, significantly higher than the 76.32% in the control group ($p < 0.05$). *Conclusion*: The intervention model of the airway management team combined with evidence-based nursing can effectively improve the oxygenation status and quality of life of elderly patients with ARDS and enhance their satisfaction with nursing services. It is an optimized critical care nursing plan worthy of clinical promotion.

Keywords: Airway management team; Evidence-based nursing; ARDS; Early rehabilitation; Quality of life; Nursing satisfaction

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1. Introduction

Acute Respiratory Distress Syndrome (ARDS) is an acute diffuse inflammatory lung disease caused by various intra-pulmonary or extra-pulmonary factors, clinically characterized by refractory hypoxemia, respiratory distress, and respiratory failure [1]. Despite continuous advancements in respiratory support technology in recent years, the incidence and mortality rates of ARDS in the intensive care unit (ICU) remain high, imposing a heavy burden on patients' families and the healthcare system [2]. ARDS is characterized by refractory hypoxemia, progressive dyspnea, and decreased lung compliance [3]. The pathophysiological process of this disease is complex, and despite continuous innovations in respiratory support technology, its mortality rate remains high. Traditional nursing models focus on basic life support and symptom management. Studies have shown that the incidence of ARDS in Chinese ICUs is 3.57%, with moderate to severe cases accounting for 90.3% and a mortality rate as high as 17.5%, posing a significant burden on China's healthcare system [4]. Epidemiological surveys of elderly patients with ARDS indicate that the incidence of ARDS in China is as high as 8.1%, with a mortality rate of 32.7% among ICU patients, 60% among hospitalized patients, and 20–40% among elderly ARDS patients at home [5]. Moreover, the epidemiological incidence of ARDS among the elderly in China is characterized by high incidence rates, heavy disease burdens, and high rates of adverse outcomes such as death. Although traditional nursing models can partially alleviate symptoms, they lack standardized and individualized intervention plans, making it difficult to continuously improve patient prognosis [6]. In recent years, the introduction of airway management teams has integrated multidisciplinary nursing resources. Studies have shown that after implementing nursing interventions by airway management teams, patient prognosis has been effectively improved [7]. Evidence-based nursing (EBN) refers to providing a basis for formulating scientific, systematic, and individualized nursing strategies by integrating the best scientific research evidence, clinical expertise, and patient values. This study aims to explore the application effect of the airway management team combined with evidence-based nursing in the early rehabilitation of patients with ARDS, with a view to providing clinical references.

2. Materials and methods

2.1. General information

Seventy-six patients with ARDS admitted to the ICU of Liangzhou District Integrated Traditional Chinese and Western Medicine Hospital from January 2024 to June 2025 were selected.

2.1.1. Inclusion criteria

(1) All patients met the diagnostic criteria outlined in the "Chinese Guidelines for the Diagnosis and Non-Mechanical Ventilation Treatment of Adult Acute Respiratory Distress Syndrome (ARDS) (2023)" and the indications for mechanical ventilation therapy [2];
(2) Age ≥ 60 years;
(3) Expected ICU stay > 72 hours;
(4) Both patients and their families provided informed consent for the study.

2.1.2. Exclusion criteria

(1) Complicated with severe cranial injury, thoracic trauma, or active bleeding;
(2) History of mental illness or severe cognitive impairment;
(3) Accompanied by advanced malignant tumors or other irreversible end-stage diseases;

(4) Incomplete clinical data.

2.1.3. Study design

A total of 76 patients were included and randomly divided into a control group and an observation group using a random number table method, with 38 patients in each group. There were no statistically significant differences in baseline data such as age, gender, and Acute Physiology and Chronic Health Evaluation II (APACHE II) scores between the two groups ($p > 0.05$), as shown in **Table 1**.

Table 1. Comparison of general information between the two groups of patients (n = 38)

Item	Control group	Intervention group	t/χ^2 value	p value
Age (years)	71.05 ± 4.74	70.92 ± 4.61	0.124	0.902
Gender (Male/Female)	20/18	21/17	0.053	0.818
APACHE II score	22.47 ± 3.63	21.82 ± 3.95	0.721	0.473

2.2. Methods

2.2.1. Intervention methods for the control group

The control group received routine ICU care, which included continuous monitoring of vital signs and ventilator parameters; airway humidification and closed suctioning as needed; standardized implementation of prone positioning ventilation procedures with enhanced skin care; sedation and analgesia management as prescribed by the physician; and routine weaning assessment and attempts under medical guidance.

2.2.2. Intervention methods for the observation group

On the basis of routine care, the airway management team implemented evidence-based nursing interventions.

(1) Establishment of a multidisciplinary airway management skills team

An airway management team was established with joint guidance and assistance from medical experts and specialist nurses from the Department of Critical Care Medicine at the First Hospital of Lanzhou University. The core members included respiratory therapists, dietitians, critical care nurses, psychiatric specialist nurses, and respiratory nurses. The team developed personalized nursing plans based on patient assessment results. After patient enrollment, all team members participated in patient assessments and organized patient case study meetings twice a week to develop and adjust personalized nursing plans. During each meeting, the effectiveness of the previous stage's nursing plan was evaluated to further refine the subsequent personalized nursing approach.

(2) Implementation of systematic evidence-based nursing interventions

① Evidence-based respiratory rehabilitation training management: Daily checks of the patient's respiratory and conscious states were conducted, strictly adhering to the standards and procedures of the spontaneous breathing trial (SBT). Bedside ultrasound was used to monitor diaphragm thickness and mobility, providing reliable clinical evidence for respiratory muscle rehabilitation guidance and weaning timing assessment. Through the SBT process, combined with bedside ultrasound monitoring of diaphragm function, weaning rehabilitation training was gradually implemented. Before and after weaning, patients were instructed to perform abdominal breathing exercises and use respiratory trainers for muscle strength training, gradually increasing inspiratory pressure to enhance respiratory function and achieve improved early rehabilitation outcomes in

elderly ARDS patients. ② Evidence-based physical rehabilitation management: Rehabilitation exercises were initiated within 24 to 48 hours of patient admission, conducted through multidisciplinary collaboration involving rehabilitation experts, critical care physicians, and medical staff. A personalized rehabilitation plan was developed based on the patient's respiratory function and muscle strength, in addition to early rehabilitation activities. During the acute phase, our nursing team performed passive rehabilitation training in conjunction with patient positioning management, typically changing the patient's position every 2 hours. If the patient was undergoing prone positioning ventilation, rehabilitation therapists assisted with ankle, knee, hip, and elbow flexion and abduction, usually performing each movement gently about 10 times, twice a day [8]. Once the patient's condition stabilized and consciousness cleared, we encouraged them to attempt active limb exercises, such as clenching fists or lifting legs, gradually increasing the intensity based on their tolerance. Additionally, we recommended using resistance bands for upper and lower limb muscle strength training, approximately 10 times a day [9]. ③ Evidence-based nutritional management: Nutritional risk screening was conducted on the day of patient admission, followed by dynamic assessments twice a week. Based on measurements of energy expenditure, assessment data, and indicators such as liver and kidney function, dietitians formulated an enteral nutrition support plan, which was continuously adjusted throughout the process, with a focus on adequate protein supplementation to maintain a positive nitrogen balance. ④ Evidence-based airway management and infection control: Closed suctioning combined with subglottic suctioning was applied, with attention to sputum characteristics every 4 to 6 hours. The volume and temperature of airway humidification fluids were no longer rigid standards but were individually adjusted according to evidence-based guidelines [10]. Strict hand hygiene and aseptic techniques were implemented throughout the process, and the team reviewed daily for risk factors associated with ventilator-associated pneumonia. ⑥ Evidence-based psychological support: Psychological nursing staff assessed the patient's mental state on the day of admission, employing supportive psychological intervention methods and encouraging family members to communicate more with the patient. Once hemodynamic stability was achieved, a phased activity plan was established, gradually transitioning from passive bed activities to sitting and standing. ⑦ Evidence-based health education: We used specialized graphic materials and videos to educate patients and their families about the basics of ARDS, treatment goals, the significance of rehabilitation exercises, and post-discharge precautions. After the explanation, the "teach-back" method was used to have them repeat the information to ensure comprehension.

2.3. Observation indicators

2.3.1. Quality of life

Assessed using the SF-36 scale, which covers eight dimensions including physical functioning, role-physical, role-emotional, and social functioning. Higher scores indicate better quality of life.

2.3.2. Arterial blood gas analysis and oxygenation index

Arterial blood gas analysis was performed using a blood gas analyzer to detect arterial blood samples, obtaining data on arterial oxygen partial pressure (PaO_2) and carbon dioxide partial pressure ($PaCO_2$). The oxygenation index was calculated based on these values, and the indicators were compared between the two groups.

2.3.3 Nursing satisfaction

Evaluated using a self-designed questionnaire, with results categorized into three levels: very satisfied, basically

satisfied, and dissatisfied. The overall satisfaction rate was then calculated accordingly.

2.4. Statistical methods

Continuous data obtained in this study were expressed as ($\overline{x} \pm s$), and subjected to t-tests; categorical data were expressed as (n, %), and subjected to χ^2 tests. The data were analyzed using SPSS 28.0 software. During data analysis with SPSS 28.0, differences between data were assessed using *p*-values. A *p*-value < 0.05 indicated a statistically significant difference.

3. Results

3.1. Comparison of blood gas indicators between the two groups of patients

Before the intervention, there were no statistically significant differences in PaO_2 and PaO_2/FiO_2 between the two groups ($p > 0.05$).

After the intervention, both groups showed significant improvements in these indicators compared to before the intervention ($p < 0.05$). Moreover, the PaO_2 and PaO_2/FiO_2 levels in the observation group were significantly higher than those in the control group, with statistically significant differences ($p < 0.05$). See **Table 2** for details.

Table 2. Comparison of blood gas indicators before and after intervention between the two groups of patients ($\overline{x} \pm s$)

Indicator	Time point	Control group (n = 38)	Observation group (n = 38)	Inter-group comparison *t*-value (Post-intervention)	*p* value
PaO_2 (mmHg)	Pre-intervention	62.52 ± 8.37	63.12 ± 7.95	-	0.739
	Post-intervention	78.61 ± 9.43*	85.26 ± 8.72*	3.213	0.002
PaO_2/FiO_2 (mmHg)	Pre-intervention	152.44 ± 21.64	154.8 ± 20.38	-	0.618
	Post-intervention	215.76 ± 25.82*	248.3 ± 28.54*	5.346	< 0.001

Note: * indicates $p < 0.05$ compared with the same group before intervention.

3.2. Comparison of quality of life between the two groups of patients

After the intervention, the scores of all dimensions of the SF-36 in the intervention group were significantly higher than those in the control group ($p < 0.05$), as shown in **Table 3**.

Table 3. Comparison of SF-36 scores between the two groups after intervention ($\overline{x} \pm s$, points)

Dimension	Control group (n = 38)	Intervention group (n = 38)	*t* value	*p* value
Physical functioning	58.24 ± 6.36	72.46 ± 7.13	9.324	< 0.001
Role-physical	55.65 ± 5.84	70.82 ± 6.57	10.521	< 0.001
Bodily pain	61.53 ± 6.07	73.23 ± 6.85	7.982	< 0.001
General health	59.82 ± 5.79	71.94 ± 6.49	8.765	< 0.001
Vitality	57.31 ± 6.14	69.57 ± 7.06	8.241	< 0.001
Social functioning	59.49 ± 6.21	73.66 ± 7.03	9.843	< 0.001
Role-emotional	60.12 ± 5.92	75.39 ± 6.82	10.876	< 0.001
Mental health	58.96 ± 6.05	72.14 ± 6.96	9.012	< 0.001

3.3. Comparison of nursing satisfaction between the two groups of patients

The overall satisfaction rate with the intervention nursing was 94.74% (36/38), significantly higher than the 76.32% (29/38) in the control group, with a statistically significant difference ($p < 0.05$). See **Table 4**.

Table 4. Comparison of satisfaction between the two groups after intervention

Group	Number of cases	Very satisfied	Satisfied	Dissatisfied	Overall satisfaction rate
Control group	38	15 (39.47)	14 (36.84)	9 (23.68)	29 (76.32)
Intervention group	38	23 (60.53)	13 (34.21)	2 (5.26)	36 (94.74)

4. Discussion

The results of this study indicate that the application of an evidence-based management protocol by the airway management team has a notably significant effect on elderly patients with ARDS. Patients' oxygenation status indeed improved, with marked increases in indicators such as PaO_2 and PaO_2/FiO_2. Additionally, their quality of life upon discharge from the ICU was better than before, and nursing satisfaction levels were considerably higher. This provides practical validation for comprehensive rehabilitation treatment for critically ill patients in the early stages.

4.1. The multidisciplinary collaborative nursing model demonstrates positive effects in improving patients' oxygenation status

Oxygenation dysfunction is the primary pathophysiological change in acute respiratory distress syndrome. The ratio of arterial oxygen partial pressure to inspired oxygen concentration (PaO_2/FiO_2) serves as a critical indicator for assessing disease severity and prognosis. In this study, the improvement in PaO_2 and PaO_2/FiO_2 in the observation group after intervention was significantly better than that in the control group. This result may be attributed to the synergistic effects of multiple intervention measures under the collaborative nursing model. Firstly, precise respiratory management led by respiratory therapists, such as dynamically adjusting positive end-expiratory pressure (PEEP) based on blood gas analysis and waveform monitoring, directly promoted the improvement of the ventilation-perfusion ratio. Secondly, the implementation of evidence-based airway management measures, including appropriate humidification and closed suctioning, helped maintain airway patency and reduced the risk of atelectasis and decreased oxygenation caused by secretion retention. Additionally, early mobilization interventions facilitated respiratory system expansion and improved circulatory efficiency, while adequate nutritional support provided the necessary energy foundation for maintaining respiratory muscle function. The synergistic effects of these measures through multiple pathways collectively promoted lung function improvement and enhanced oxygen uptake efficiency.

4.2. The characteristic of the airway management team nursing model lies in multidisciplinary team collaboration

The airway management team established in this study exemplifies this point, breaking away from the relatively independent work mode of various specialties in traditional nursing. Within the team, respiratory therapists are responsible for precise respiratory rehabilitation, dietitians provide personalized nutritional support, psychological nurses undertake emotional regulation tasks, and specialist nurses organize early mobilization activities, all parties collaborate to form a closely interconnected intervention system. This collaborative approach ensures the continuity and integrity of nursing from the acute phase of the disease to the rehabilitation phase, while also making nurs-

ing measures more systematic and comprehensive. This concept aligns with the idea emphasized in the diverse nursing models for chronic heart failure patients that "comprehensive nursing is more conducive to addressing complex conditions" [11].

4.3. Evidence-based practice is crucial for ensuring the scientific validity and effectiveness of nursing measures

All intervention measures adopted in this study are based on the best available evidence currently. For example, the use of ultrasound technology to assess diaphragm function provides critical data support for ventilator weaning decisions; the integration of ventilator-associated pneumonia (VAP) prevention strategies based on relevant guidelines helps reduce the risk of infection. Structured psychological support and early mobilization plans represent extensions and applications of the Enhanced Recovery After Surgery (ERAS) concept in the intensive care unit. This evidence-centered approach significantly reduces subjectivity and reliance on personal experience in nursing operations, while enhancing the precision and safety of intervention measures. Numerous studies have confirmed that evidence-based nursing has distinct advantages in the management of respiratory diseases, such as effectively improving lung function in patients with Mycoplasma pneumoniae infection complicated by asthma. In this study, the improvement in blood gas analysis indicators is also closely related to these mechanisms.

4.4. Meeting patients' multifaceted needs are key to achieving comprehensive rehabilitation

This intervention protocol not only focuses on improving patients' physiological function and oxygenation status but also actively responds to their emotional and social support needs through psychological counseling, health education, and encouraging family involvement. From the results, the simultaneous improvement in dimensions such as physiological and emotional functioning in the quality-of-life scores, as well as the significant increase in nursing satisfaction, indicate that a "patient-centered" comprehensive nursing model is of great significance for improving patients' subjective rehabilitation experiences. Improvements in physiological indicators lay the foundation for enhancing quality of life, while psychosocial support further strengthens patients' rehabilitation confidence and compliance, creating a virtuous cycle where the two mutually reinforce each other.

4.5. Study limitations and prospects

This study employed a single-center design with a relatively limited sample size and primarily focused on short-term intervention effects. Due to the multifaceted nature of the intervention measures, it is challenging to quantify the independent contributions of each component to the final outcomes. Subsequent studies could consider conducting multi-center, large-sample randomized controlled trials with appropriately extended follow-up periods to further clarify the impact of this model on patients' long-term prognosis, such as readmission rates and changes in long-term quality of life. Additionally, future research could delve deeper into exploring multidisciplinary team collaboration processes based on information platforms and incorporate health economic analyses to provide more comprehensive evidence-based support for clinical practice.

5. Conclusion

The airway management team model, formed by integrating multidisciplinary team collaboration with evidence-based nursing, can effectively improve the oxygenation status of elderly patients with ARDS, promote their early physical and mental rehabilitation, and significantly enhance their quality of life and healthcare experience in

the short term. This approach not only aligns with the development trends of modern critical care nursing but also possesses strong clinical practical value, warranting broader promotion and application.

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Effect Evaluation under the Control of Connotation Construction of Antimicrobial Use Density after Multiple Strategic Interventions

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Abstract: *Objective*: To evaluate the effect of connotation construction control on antimicrobial use density (AUD) after the application of multiple strategic interventions. *Methods*: The experimental subjects were discharge data from Dehong Prefectural People's Hospital, with the scope of this study spanning from January 2024 to December 2025. Comprehensive data from 2024 were included in the pre-intervention group, while comprehensive data from 2025 were included in the post-intervention group. A set of antimicrobial management systems was constructed, characterized by precision, standardization, and systematization, and multiple measures were implemented (including organizational system restructuring, information-based precise control, personalized indicator management, dynamic authorization and training of prescription rights, and multidisciplinary collaboration (MDT), etc.). The following indicators before and after the intervention were statistically analyzed and compared: AUD, antimicrobial use rate, etiological examination submission rate, and irrational prescription rate. *Results*: The post-intervention AUD was significantly lower than that before the intervention [(39.46 ± 2.08) DDDs/(100 person-days) vs (36.79 ± 0.22) DDDs/(100 person-days)], and the post-intervention antimicrobial use rate, proportion of special-grade antimicrobials used, and irrational prescription rate showed a lower trend compared to those before the intervention ($p < 0.05$); the etiological examination submission rate for therapeutic medications showed a higher trend compared to that before the intervention ($p < 0.05$). *Conclusion*: By focusing on connotation construction and implementing multiple strategic interventions, a shift from simple indicator control to precise diagnosis and treatment and rational medication use was achieved, significantly reducing the antimicrobial use density and improving the rationality of medication use.

Keywords: Connotation construction; Antimicrobial use density; Comprehensive intervention; Clinical pharmacy; Effect evaluation

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1. Introduction

The "Antimicrobial Use Density (AUD)" of inpatients is one of the crucial criteria for evaluating the rational use of clinical antimicrobials and has consistently been a key indicator for antimicrobial management in medical institutions [1]. It also serves as a core indicator for rational drug use in the performance assessment of public hospitals. In recent years, although China has achieved initial success in controlling AUD through administrative measures, some medical institutions tend to "meet targets for the sake of meeting targets"; many clinicians are only familiar with the term but do not understand its true meaning, failing to truly grasp the essence of rational drug use. Consequently, it is challenging to establish a long-term mechanism for controlling the intensity of use indicators, which may even impact the quality of medical care [2]. Against this backdrop, mere administrative orders are insufficient, and a shift towards refined management centered on "content construction" is necessary. Content construction emphasizes quality control throughout the entire process of antimicrobial use, from "source, process, to outcome", with the core aim of promoting standardized and precise clinical diagnosis and treatment behaviors, making the reduction of AUD a natural outcome of improved medical quality [3,4]. This study aims to systematically elaborate on a series of comprehensive intervention strategies implemented by our hospital based on the concept of content construction and scientifically evaluate their control effects on AUD and other indicators of rational drug use.

2. Materials and methods

2.1. General information

This study is a single-center retrospective study. The study subjects are the antimicrobial use data of all discharged patients in our hospital from January 1, 2024, to December 31, 2024. The data for the entire year of 2024 were set as the pre-intervention control group, and the data for the entire year of 2025 were set as the post-intervention observation group. Through the Hospital Information System (HIS) and PASS Clinical Pharmacy Management System, data were collected on the total number of inpatients, the number of patient-days admitted during the same period, antimicrobial consumption, antimicrobial use rate, pathogen testing status, approval status of special-use antimicrobials, and irrational drug use issues identified in prescription reviews for both groups. There were no significant differences between the two groups in terms of age, gender composition, and distribution of major diseases ($p > 0.05$), making them comparable.

2.2. Methods

Starting from January 1, 2024, our hospital built a management system centered on content construction based on the existing management framework and implemented a series of comprehensive intervention strategies integrating administration, technical guidance from clinical pharmacists, and training, specifically including:

2.2.1. Organizational system and institutional construction: Shifting from formal construction to authoritative implementation

The hospital established a specialized, substantive AMS management team: led by hospital-level leaders, it formed a cross-departmental (medical affairs, pharmacy, hospital infection, laboratory) collaborative management approach, achieving a top-down linkage model; the hospital and each department signed responsibility letters for the rational use of antimicrobials, with AUD and use rate set as core indicators directly linked to performance assessments. Failure to meet these indicators resulted in a veto, to consolidate management responsibilities at all levels from the root.

2.2.2. Informatization empowerment: Shifting from post-hoc statistics to real-time intervention

Informatization empowerment is of positive significance for management efficiency. In the hospital's existing electronic medical record system, new antimicrobial use rules were added, focusing on the timing of perioperative prophylactic medication, medication duration, and precautions. Real-time reminders were implemented when prescribing, or non-compliant prescriptions were intercepted to reduce irrational drug use from the source. Simultaneously, a dynamic monitoring platform for antimicrobial use density was established: all AUD indicators were visually displayed and comprehensively analyzed in conjunction with data such as the number of discharged patients and the number of surgeries, making indicator monitoring and analysis more scientific and effective.

2.2.3. Antimicrobial use density: Shifting from a hospital-wide unified model to department-specific differential management

Based on the specific conditions of each department (disease structure, surgical types, etc.), benchmark values and management targets for antimicrobial use density were formulated according to the department's actual situation. For high-risk departments, such as the ICU and Infectious Diseases Department, where patients have complex conditions and high infection risks, higher target benchmark values were set, but with a clear requirement for an annual decreasing trend to ensure management effectiveness. Based on this, the assessment of antimicrobial use for treatment and prophylactic antimicrobial use intensity was separated to help clinicians recognize the importance of rationality in therapeutic drug use, with drug selection and duration as key aspects of management.

2.2.4. Professional capacity building: Shifting from general training to precise individualized empowerment

There is a direct link between physicians' professional capabilities and the quality of antimicrobial use. A dynamic adjustment and hierarchical management system for antimicrobial prescription rights was implemented: prescription rights were not only linked to physicians' titles but also comprehensively evaluated based on their assessment scores and actual prescription quality, with a comprehensive review conducted annually. Measures such as demotion or suspension of prescription rights were taken to address those who did not meet the standards. Simultaneously, the training model was further upgraded to align with clinical practice, with regular organization of physicians for learning and discussion on irrational medical records, CMI, etc.

2.2.5. Diagnosis and treatment model: Shifting from empirical medication to precise antimicrobials

The shift in the diagnosis and treatment model lies in providing evidence for medication. The pathogen testing rate before therapeutic medication was used as a core evaluation indicator, closely linked to rapid detection technologies. Therefore, vigorous promotion of PCT, G/GM tests, etc., was undertaken to minimize blind medication in clinical practice. For complex patients, such as those with multidrug-resistant bacterial infections, multidisciplinary consultations were conducted as required and regulations to optimize treatment plans and help patients recover as soon as possible.

2.2.6. Education and training: Shifting from hospital-wide popularization to precise departmental alignment

To enhance the professional skills and comprehensive qualities of physicians and pharmacists hospital-wide, quarterly specialized training on the latest clinical guidelines, industry policies, and the current status of bacterial resistance was required. The Pharmacy Department compiled key departmental indicators and provided feedback

to department heads in a report format, with special guidance provided for abnormal data.

2.3. Evaluation indicators

The primary indicator was Antimicrobial Use Density (AUD), calculated as (antimicrobial consumption [cumulative DDDs]/total bed-days occupied by discharged patients during the same period) × 100.

The secondary indicators included the following four: antimicrobial use rate, pathogen testing rate for therapeutic medication, proportion of special-use antimicrobials, and irrational prescription review rate.

2.4. Statistical methods

Data analysis was performed using SPSS 22.0 software. Measurement data were expressed as mean ± standard deviation ($\overline{x} \pm s$), and comparisons between groups were made using the *t*-test; count data were expressed as rates (%), and comparisons between groups were made using the χ^2 test. A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Changes in antimicrobial use density (AUD) and use rate

After the intervention, the hospital-wide AUD significantly decreased from (39.46 ± 2.08) DDDs/(100 person-days) before the intervention to (36.79 ± 0.22) DDDs/(100 person-days), with a statistically significant difference (*t*-value, $p < 0.05$). See **Table 1** for details.

Table 1. Comparison of AUD and use rate before and after intervention ($\overline{x} \pm s$)

Group	Number of discharged patients	AUD (DDDs/100 person-days)
Pre-intervention group	79,948	39.46 ± 2.08
Post-intervention group	74,746	36.79 ± 0.22
t value		349.126
p value		< 0.001

3.2. Comparison of AUD in the entire hospital and key departments before and after the intervention

After the intervention, the AUD in both the entire hospital and key departments significantly decreased, with statistically significant differences ($p < 0.05$). See **Table 2**.

Table 2. Comparison of AUD in the entire hospital and key departments before and after the intervention ($\overline{x} \pm s$)

Department	Pre-intervention (2024)	Post-intervention (2025)	*t* value	*p* value
Whole hospital	39.46 ± 2.08	36.79 ± 0.22	349.126	< 0.001
Intensive care unit	130.54 ± 0.45	123.67 ± 3.26	589.878	< 0.001
Respiratory department	96.30 ± 0.43	86.38 ± 9.51	294.619	< 0.001
First orthopedics department	49.42 ± 0.50	41.52 ± 0.53	3016.631	< 0.001
Infectious diseases department	95.66 ± 2.77	89.41 ± 10.36	164.409	< 0.001
Obstetrics ward	25.81 ± 3.31	23.00 ± 1.61	210.029	< 0.001

3.3. Changes in other indicators of rational drug use

After the intervention, the usage rate of antimicrobial agents, the proportion of special-grade antimicrobial use, and the rate of irrational prescriptions all significantly decreased ($p < 0.05$); in contrast, the etiological examination submission rate for therapeutic medications significantly increased ($p < 0.01$). See **Table 3**.

Table 3. Comparison of other indicators of rational drug use before and after the intervention (n/%)

Indicator	Pre-intervention (2024)	Post-intervention (2025)	χ^2 value	*p* value
Antibiotic usage rate	35,841 (44.83%)	30,252 (40.47%)	299.719	< 0.01
Pathogen testing rate for therapeutic antibiotic use	69,355 (86.75%)	65,303 (87.37%)	13.019	< 0.01
Proportion of special-grade antibiotic use	2,287 (2.86%)	2,008 (2.69%)	4.342	0.037
Irrational prescription rate	74,560 (93.26%)	67,388 (90.16%)	492.475	< 0.01

4. Discussion

By conducting this experiment and implementing measures centered on connotation construction, our hospital has witnessed a significant reduction in AUD and a notable enhancement in the efficiency of antimicrobial management. The success can be attributed to the alignment of the measures with actual clinical needs, ensuring high feasibility and operability.

4.1. Connotation construction promotes the transformation of management from supervision to optimization guidance

Traditional management models primarily focus on restraint and supervision, resulting in low enthusiasm and initiative among clinical healthcare professionals. This paper introduces a departure from the conventional approach by implementing a series of connotation construction strategies, including setting individualized departmental goals, providing real-time information support, and offering multidisciplinary team technical guidance. These strategies shift the management focus from “supervision and control” to “professional guidance”, addressing practical clinical challenges and further enhancing healthcare professionals’ enthusiasm for participating in rational drug use initiatives [5].

4.2. Precision control as the core element in reducing AUD

The implementation of intelligent information review has effectively curbed some irrational drug use behaviors. Simultaneously, implementing sub-item assessments for AUD in therapeutic and prophylactic medication guides clinical efforts toward optimizing drug use, particularly by shortening excessive antibiotic courses during surgical perioperative periods, thereby contributing to the overall reduction in AUD across the hospital [6,7].

4.3. Capacity building and incentive mechanisms support sustainable management

The dynamic prescription authority combined with case-based training has significantly enhanced physicians’ prescribing capabilities. Linking assessment results directly to performance has established effective positive incentives and negative constraints, facilitating the long-term implementation and execution of various intervention measures [8,9].

4.4. Challenges in sustainable management

Firstly, it is essential to remain vigilant against the potential manipulation of drug use data due to assessment pressures. A reduction in AUD will continue to impact the hospital's resistance rates and patient outcomes, necessitating ongoing monitoring [10]. Secondly, with the significant advancements in medical technology in recent years, there has been an increase in immunocompromised patients due to tumor chemotherapy and organ transplantation. These patients present complex infection scenarios, requiring more scientific and effective antimicrobial management. Going forward, our hospital's antimicrobial management will transition from simple indicator control to individualized and refined management, such as enhancing dose adjustments based on therapeutic drug monitoring (TDM) and further promoting faster molecular diagnostic techniques.

5. Conclusion

In summary, after implementing multiple strategic interventions, significant progress has been achieved in controlling the connotation construction of antimicrobial use intensity. This approach not only effectively controls the intensity of antimicrobial use but also fundamentally promotes more standardized and precise clinical practices, leading to a qualitative leap in antimicrobial management. This management model can be applied to other medical institutions and lays a solid foundation for implementing China's future action plan to curb bacterial resistance.

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Disclosure statement

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Application Progress of 3D Printing in Orthopedic Clinical Practice

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Abstract: In recent years, 3D printing technology has been widely applied in the field of orthopedics, covering preoperative planning, surgical simulation, personalized implants, and surgical guides, all demonstrating broad application prospects. This article systematically elaborates on the basic principles, methods, and materials of 3D printing technology, as well as its current application status, technological progress, and clinical effects in orthopedics. It also briefly outlines future directions such as artificial intelligence-assisted design and bio-printing. In the future, the combination of 3D printing and artificial intelligence will further reduce printing costs and simplify clinical operation procedures, enabling more patients to benefit from personalized and precise treatments. This will become an important direction for the next stage of orthopedic research.

Keywords: 3D printing; Model; Personalized implant; Surgical guide; Orthosis

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1. Introduction

Orthopedic diseases encompass various types such as trauma, degeneration, tumors, and congenital deformities. Traditional orthopedic surgeries mainly rely on standardized implants, intraoperative fluoroscopy, and the surgeon's experience. When dealing with complex anatomical structures, severe deformities, and large-scale bone defects, these surgeries often encounter problems such as poor matching of implants, inaccurate mechanical axis reconstruction, prolonged operative time, and significant radiation exposure. 3D printing technology, with its advantages of personalized design, has become an important innovative force in the field of orthopedics. From anatomical models, surgical guides to customized implants and orthoses, 3D printing is changing the paradigm of orthopedic diagnosis and treatment. This article reviews the current progress of 3D printing technology in clinical orthopedic treatment as follows.

2. Methods and materials

2.1. Definition and basic principles of 3D printing

3D printing, also known as Additive Manufacturing (AM), is an advanced manufacturing technology that creates physical parts by layering materials on top of each other based on three-dimensional computer-aided design (CAD) data. Its core workflow involves creating a three-dimensional digital model of an object using computer-aided design software or medical imaging data (such as DICOM files from CT or MRI scans), which can include complex internal structures and detailed external shapes. Then, using slicing software, the three-dimensional model will be divided into a series of extremely thin two-dimensional slices (typically ranging from several tens to several hundred micrometers), with each slice representing the cross-sectional contour at that height. The slicing software simultaneously generates detailed printing paths and device instructions. Finally, the 3D printer will build the solid model by stacking materials layer by layer based on these two-dimensional data.

2.2. Methods of 3D printing

Table 1. Methods, advantages and limitations of 3D printing technologies [1]

3D printing technology	Methods	Advantages	Limitations
Stereolithography apparatus (SLA) & Digital light processing (DLP)	Both technologies use liquid photopolymer resin as the raw material. SLA cures the resin by scanning point by point with an ultraviolet laser beam in a layer-by-layer manner. DLP, a derivative technology of SLA, projects an entire layer image onto the resin surface at once using a digital light projector.	Extremely high resolution, smooth surface	Limited mechanical strength, relatively long printing time
Fused deposition modeling (FDM)	This technology uses a heated nozzle to melt and extrude thermoplastic filaments, which are then deposited layer by layer along a predefined path and solidified upon deposition.	Low equipment cost, easy to operate, a wide variety of available materials	Relatively low forming accuracy, visible layer lines on the surface, require post-processing
Selective laser sintering / Selective laser melting (SLS/SLM) & Electron beam melting (EBM)	SLS uses a laser to selectively sinter polymer or ceramic powders. SLM and EBM fully melt metal powders using a high-energy laser beam or electron beam.	No need for support structures, recyclability of unused powder, a wide range of applicable materials	High equipment cost, relatively long printing time, rough surface
Direct ink writing (DIW)	DIW extrudes viscoelastic inks—such as hydrogels, ceramic slurries, and biomacromolecules—through a micron-scale nozzle using pneumatic pressure or mechanical force, and builds up layer by layer to form a structure.	Avoid heat-induced damage to bioactive materials by printing at room temperature, possess excellent biocompatibility and biodegradability	Relatively poor mechanical strength, require post-processing to maintain structural integrity, require stringent printing conditions to preserve cell viability
Three-dimensional printing (3DP) & material jetting	3DP selectively ejects a binder through a nozzle to fuse powder materials into a shape. Material Jetting, directly jets droplets of photopolymer resin, and they are instantly cured by ultraviolet light.	Require no support structures, fast printing speed	The accuracy and surface quality will be influenced by factors such as powder particle size, relatively low mechanical strength

2.3. Materials for 3D printing

Table 2. Advantages, limitations and orthopedic applications of different 3D printing materials [1]

Material	Advantages	Limitations	Orthopedic applications
Metal	High strength, high hardness, wear resistance, corrosion resistance, good biocompatibility	Require post-processing, excessively high elastic modulus led to stress shielding	Load-bearing implants, porous structures can reduce the elastic modulus and promote osseointegration
Polymer	Good plasticity and processability, elastic modulus close to that of bone, radiolucency, easy to print, low cost, high accuracy	Low strength, non-osteogenic	Models, catheters, implants, bone repair scaffolds, drug delivery
Ceramic	Excellent bioactivity and osteoconductive, wear resistance, promote bone growth	High brittleness, require high-temperature processing, require polishing	Bone defect treatment, bone grafting, coatings, joint surface
Bioink	Excellent biocompatibility, biodegradability	Low mechanical strength, regulatory hurdles	Cartilage and bone tissue construction, enhancement of osteogenesis, regenerative scaffolds, active repair, anti-infection functionality

3. Clinical applications of 3D printing

3D printing technology can be used for preoperative planning, surgical simulation, and the design of personalized implants and surgical guides. In the treatment of complex fractures, 3D-printed models can be used for preoperative planning and simulation, assisting surgeons in intuitively understanding the morphology of complex fractures, simulating osteotomy and reduction, and significantly shortening operative time while reducing blood loss. In addition, 3D-printed implants can be used to repair bone defects in patients, while the application of 3D-printed guides can improve the accuracy of implant placement and reduce the frequency of intraoperative fluoroscopy. In summary, 3D printing technology has demonstrated significant advantages in fields such as spinal surgery, complex fracture management, and joint arthroplasty [2].

3.1. Spinal surgery

In the field of spinal surgery, the use of 3D printing has grown significantly, and its potential benefits have attracted widespread attention. It offers advantages such as improved surgical accuracy, better treatment outcomes, shortened operative time, and reduced blood loss and ionizing radiation exposure [3]. Compared with traditional methods, it lowers the risk of surgical complications such as nerve injury, ultimately improving patients' overall quality of life. 3D-printed porous titanium alloy cervical cages and artificial vertebral bodies are used in the treatment of spinal degeneration, tumors, and deformity correction. Their porous structure can promote early osseointegration while reducing subsidence and migration [4]. Representative examples of guide-assisted spinal surgeries in clinical practice include spinal fusion and spinal deformity correction. The use of 3D printing-assisted cervical pedicle screw internal fixation has demonstrated advantages such as reduced surgical trauma and blood loss during the procedure, effectively restoring cervical stability and promoting spinal fusion [5]. A study involving 60 cases of cervical screw placement confirmed the significant superiority of 3D-printed guides, showing that they can shorten screw placement time, improve accuracy and safety, and lead to better recovery of cervical function [6]. In congenital scoliosis, 3D-printed full-spine models can visually present the curvature angle, vertebral rotation,

and vertebral developmental abnormalities. They enable accurate measurement of the Cobb angle, pedicle width, and pedicle channel, as well as preoperative simulation of osteotomy, fusion levels, and correction angles. During surgery, they facilitate the safe and relatively rapid placement of foundation screws, thereby achieving better treatment outcomes [7].

3.2. Trauma orthopedics

In trauma orthopedics, 3D printing is primarily used for the treatment of challenging intra-articular fractures, complex diaphyseal fractures, and malunited fractures. 3D-printed fracture models can reproduce articular surface collapse and fracture fragment displacement, and are used preoperatively to simulate reduction and pre-bend plates to match the patient's anatomical curvature. During surgery, personalized 3D-printed guides can be used to achieve minimally invasive fixation. This technology can significantly shorten operative time, reduce blood loss, improve the accuracy of articular surface reduction, minimize soft tissue damage, lower the incidence of postoperative post-traumatic arthritis, enhance the fit of internal fixation, and lead to better functional recovery [8].

In the context of the hip joint and pelvis, 3D-printed models can enhance understanding of acetabular fracture morphology, thereby facilitating the determination of the optimal surgical approach, reduction technique, and the positioning and fixation of implants. Additionally, 3D-printed guides assist in percutaneous screw placement, improving screw placement accuracy [9]. Furthermore, studies have shown that 3D printing-assisted surgery not only reduces intraoperative blood loss and operative time in pelvic fracture surgery, but also improves the reduction quality of comminuted and complex fractures [10]. For fractures such as tibial plateau fractures, acetabular fractures, pelvic fractures, and spinal fractures, the accuracy of fracture reduction is significantly enhanced, achieving precise implantation and improved outcomes [11].

Meanwhile, the integration of 3D printing technology with robot-assisted surgery has opened new frontiers in orthopedic surgery. By creating patient-specific anatomical models and preoperative planning tools, 3D printing enables a higher degree of customization, ensuring that the surgical approach aligns with the patient's unique anatomy. Combined with the high precision of robotic systems, this approach significantly improves screw placement accuracy, shortens operative time, and reduces surgical complications and intraoperative radiation exposure [12].

3.3. Joint surgery

In joint revision surgery, accurate assessment of bone defects is critical for selecting the appropriate reconstruction method. 3D-printed models can visually present the morphology, extent, and relationship of bone defects to critical anatomical structures, providing a basis for selecting impaction bone grafting, metal augments, or customized prostheses. In ankle arthrodesis for the treatment of end-stage ankle arthritis, 3D printing enables the customization of fusion cages or locking plates that match the morphology of the distal tibia and talus, thereby improving the fusion rate and the accuracy of mechanical axis reconstruction [13]. For bone defects around the shoulder and elbow joints, such as humeral head necrosis and post-traumatic arthritis of the elbow, 3D printing allows for the customization of prosthetic humeral heads, glenoid augments, or elbow prostheses to achieve anatomical reconstruction.

In total hip arthroplasty (THA), the anteversion and abduction angles of the acetabular prosthesis, as well as the rotational alignment of the femoral stem, influence the dislocation rate and long-term survival rate. 3D-printed patient-specific instruments (PSI) can assist in acetabular reaming positioning, femoral neck osteotomy, and

rotational alignment of the femoral stem. For patients with Crowe type IV developmental dysplasia of the hip (DDH), characterized by an extremely shallow acetabulum, severe shortening and rotational deformity of the proximal femur, and contracture of the surrounding soft tissues, traditional surgery is extremely challenging. Using 3D printing technology to design an integrated acetabular prosthesis (IAP) that matches the size and shape of the acetabular bone defect in DDH enables perfect fit with the defect, ensuring the integrity of the hip joint and restoring its center of rotation. In addition, it reduces micromotion and friction between multiple components, ultimately enhancing the long-term stability of the acetabular prosthesis, making acetabular reconstruction in DDH more reliable and safer [14].

In total knee arthroplasty (TKA), restoration of lower limb mechanical alignment and soft tissue balance are key factors determining long-term outcomes. Traditional surgery relies on intramedullary or extramedullary alignment guides and intraoperative measurements, which are associated with a certain degree of error. 3D-printed patient-specific instruments (PSI) can precisely guide distal femoral osteotomy, tibial plateau osteotomy, and rotational alignment, enabling individualized mechanical axis reconstruction. Customized porous tantalum implants and spacers can promote bone ingrowth, reduce the loosening rate, help restore skeletal integrity and joint stability, and significantly improve function and alleviate pain [15].

3.4. 3D printed orthoses

Traditional manufacturing techniques make custom devices costly and inaccessible to many patients, whereas 3D printing enables the rapid production of personalized prostheses and orthotic devices, significantly reducing costs and improving accessibility. In addition, custom designs can be easily modified and adjusted, enhancing comfort and functionality for patients with limb differences or orthopedic conditions. 3D-printed orthoses offer numerous significant advantages during the treatment process. Three-dimensional scaffolds can effectively reduce swelling and excessive tension in the muscles of the wrist, while improving motor function and the ability to extend the arm [16]. Their nearly perfect fit also reduces friction between the material and the skin. Overall, 3D-printed orthoses surpass traditional alternatives in terms of comfort, pain relief, and convenience in daily use. They provide greater mobility and improved motor function, which is particularly important for patients with limited mobility. One study showed that after four weeks of using a three-dimensional orthosis, pain was significantly reduced compared with the plaster cast and traditional orthosis groups, as assessed by the PRWE and VAS scales [17]. 3D printing has also opened new possibilities for the design and fabrication of prostheses, offering more customized, lightweight, and cost-effective solutions to improve patients' quality of life. However, in certain cases, traditional materials may be more effective, indicating that there is still room for improvement and optimization in orthopedic 3D printing technology.

3.5. Others

3D-printed porous scaffolds (e.g., PCL/HA, PLGA/β-TCP) can mimic trabecular bone structure and be loaded with growth factors such as BMP-2 and VEGF to promote osteogenesis and vascularization [18]. Bioprinting involves loading MSCs and iPSCs into hydrogels to achieve cartilage and bone tissue construction [19]. Incorporating antibiotics (e.g., vancomycin, gentamicin), metal nanoparticles (e.g., Ag, Zn), or chitosan into 3D-printed materials can confer local antimicrobial properties to implants, thereby reducing the risk of periprosthetic infection [20]. 3D-printed anatomical models and surgical simulators can be used for the training of medical students and residents, enhancing anatomical understanding and surgical skills.

The integration of AI with 3D printing is driving transformative innovations in orthopedics, particularly in the fabrication of casts, implants, and prostheses. AI enhances the 3D printing process through real-time continuous monitoring of material properties, layer alignment, and thickness, reducing material usage in line with sustainable practices [21]. AI-driven systems can analyze large volumes of patient data and medical images, enabling the customization of implants based on individual anatomical and biomechanical needs, thereby improving surgical outcomes and reducing complications [22].

4. Conclusion

3D printing technology has transitioned from the laboratory to clinical practice, demonstrating significant value in spinal surgery, trauma orthopedics, joint surgery, orthotics, and medical education. Currently, the next-generation 4D printing technology has emerged, introducing the dimension of time. Leveraging the ability of shape-memory materials to self-deform in vivo, it holds promise for minimally invasive implantation and self-expansion to its predefined configuration, thereby better meeting patient needs. Although challenges remain in areas such as materials, cost, and regulation, with the deepening of multidisciplinary collaboration, advances in materials science, and the integration of AI, 3D printing is expected to become one of the core technologies in orthopedic precision medicine, driving orthopedic treatment toward greater personalization, efficiency, and sustainability.

Disclosure statement

The authors declare no conflict of interest.

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Epidemiology and Demographic Patterns of Co-infections with Eight Respiratory Pathogens: A Large-Scale Retrospective Study

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Abstract: *Background*: Respiratory tract infections (RTIs) pose a significant global health burden, with etiology complicated by frequent pathogen co-infections. Comprehensive data on the epidemiology of co-infections across broad age and demographic spectra remain limited. *Methods*: This large-scale retrospective study analyzed 9,908 patients with suspected RTIs at a single hospital. Detection of IgM antibodies against eight common pathogens (Influenza A/B, Respiratory syncytial virus, Adenovirus, *Mycoplasma pneumoniae*, Parainfluenza virus, Coxsackievirus B, *Chlamydia pneumoniae*) was performed using rapid colloidal gold kits. Positivity rates, co-infection patterns, and their associations with age and gender were analyzed. *Results*: The overall pathogen detection rate was 33.1%. Influenza A was the most frequently detected pathogen overall, while Influenza B was most common among single infections. Notably, 33.1% of positive cases involved co-infections, with dual infections being most prevalent. The most frequent co-infection pattern was Influenza A with RSV. Age-stratified analysis revealed the highest proportion of co-infections in preschool children (48.3%) and older adults (40.3%), with adults having the lowest rate (28.5%). Significant gender-based differences were observed within specific age groups, such as higher Adenovirus rates in adult males and higher Mycoplasma pneumoniae rates in adult females. *Conclusion*: This study highlights the high frequency and specific demographic patterns of respiratory pathogen co-infections, underscoring the complexity of RTI etiology. The findings emphasize the need for considering multiple pathogens in clinical diagnosis and suggest that both age and gender may influence infection susceptibility and co-infection risk, informing future surveillance and management strategies.

Keywords: Respiratory virus; Co-infection; IgM antibody; Multiplex panels detection

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1. Introduction

Respiratory tract infections (RTIs) are a leading cause of global morbidity and mortality, imposing a substantial burden on healthcare systems worldwide. Notably, lower respiratory infections rank among the top five causes contributing to global mortality inequality [1]. The clinical presentation of RTIs is often nonspecific, yet they can be caused by a diverse spectrum of pathogens, including influenza viruses (Flu A, Flu B), respiratory syncytial virus (RSV), adenovirus (ADV), *Mycoplasma pneumoniae* (MP), parainfluenza virus (PIV), coxsackievirus B (COXB), *Chlamydia pneumoniae* (CP) and others [2,3]. Accurate and timely etiological diagnosis is crucial for guiding appropriate clinical management, infection control measures, and understanding epidemiological trends [4].

A significant challenge in managing and studying RTIs is pathogen co-infection, where multiple pathogens are detected simultaneously. Co-infections are common and may alter disease severity, complicate presentation, and impact outcomes [5]. For instance, RSV co-infection with other viruses increases the risk of asthma exacerbation in young children, and viral co-infections in children with SARS-CoV-2 have been associated with severe outcomes [5,6]. While some studies describe age and seasonal variations in single pathogen epidemiology, comprehensive data on co-infection patterns across broad demographic strata, including age and gender, remain limited [3,7,8]. Existing research often focuses on specific subgroups, such as hospitalized children, leaving gaps in understanding co-infection dynamics across the entire age spectrum and in outpatient settings [7,8]. Furthermore, while rapid point-of-care diagnostics like colloidal gold-based IgM assays are widely used in clinical practice, studies reflecting real-world pathogen detection profiles from such methods are needed.

To address these critical knowledge gaps, we conducted a large-scale retrospective study. The primary aim was to elucidate the detection profile of eight common respiratory pathogens via rapid IgM assays in a cohort of patients with suspected RTIs, determining both overall and pathogen-specific positivity rates. Furthermore, we sought to characterize the frequency, distribution, and specific combinatorial patterns of pathogen co-infections. Finally, we aimed to assess whether the rates of single infections, co-infections, and infection by specific pathogens varied significantly across different age groups and between genders. By investigating these aspects, our findings are intended to offer valuable insights for refining diagnostic approaches and enhancing the understanding of the complex epidemiology of respiratory pathogens in a diverse clinical population.

2. Methods

2.1. Study design and population

This retrospective study included 9,908 patients with suspected respiratory tract infections who underwent testing for eight respiratory pathogens (Flu A, Flu B, ADV, MP, PIV, RSV, COXB, CP) at West China Fourth Hospital of Sichuan University from January 1, 2021, to August 31, 2025. The cohort comprised 6838 hospitalized patients and 3070 outpatients. There were 5609 males and 4298 females, with an age range of 2–102 years and a median age of 54 years.

2.2. Pathogen detection

Testing was performed using two commercially available colloidal gold-based rapid IgM antibody detection kits (Innovita, China). The “Respiratory Virus Three” kit was used for the qualitative detection of IgM antibodies against Influenza A virus, Influenza B virus, and Parainfluenza virus. The “Respiratory Virus Five” kit was used for the qualitative detection of IgM antibodies against Mycoplasma pneumoniae, Chlamydia pneumoniae, Respiratory Syncytial Virus, Adenovirus, and Coxsackievirus B group. Both kits operate on an immunocapture principle, where the presence of pathogen-specific IgM antibodies in serum or whole blood samples leads to the

formation of a visible purple band at the corresponding test line (T) on the nitrocellulose membrane. All testing and interpretation of results were performed strictly according to the manufacturers' instructions, with results read within 15–25 minutes of sample application.

2.3. Statistical analysis

All statistical analyses were performed using R software (version 4.4.2). Descriptive statistics were used to summarize patient demographics and the detection rates (positive rates) for each individual pathogen. Co-infection was defined as the simultaneous detection of IgM antibodies for two or more pathogens in a single patient. The frequency and patterns of co-infections were analyzed. Group comparisons (e.g., positive rates between genders or across different age groups) were conducted using the Chi-square test or Fisher's exact test, as appropriate. A two-sided p-value of less than 0.05 was considered statistically significant.

2.4. Ethical considerations

This retrospective study was approved by the Ethics Committee at West China Fourth Hospital of Sichuan University (Approval No. HXSY-EC-2023025). The requirement for written informed consent was waived, as the study involved the analysis of anonymized, pre-existing clinical data and did not affect patient welfare or rights. All procedures were conducted in accordance with the relevant guidelines and regulations.

3. Results

Among the eight respiratory pathogens tested (Flu A, Flu B, ADV, MP, PIV, RSV, COXB, CP), a total of 3,277 individuals tested positive, yielding an overall positivity rate of 33.1%. Of these positive cases, 2,191 were attributed to single pathogen positivity, while 1,086 cases demonstrated co-infection. The distribution of co-infections was as follows: 790 cases of dual positivity, 224 cases of triple positivity, 61 cases of quadruple positivity, 8 cases of quintuple positivity, and 3 cases of sextuple positivity. The overall detection rates for each specific pathogen, along with their respective frequencies in single positivity and co-infection, are detailed in **Table 1**. The data reveal that Flu A exhibited the highest overall detection rate among the eight pathogens. However, within the subset of single positivity cases, Flu B constituted the largest proportion. Notably, similar to Flu A, RSV demonstrated a significantly lower rate of single infection compared to its frequency of co-occurrence with other pathogens.

Table 1. Prevalence of IgM antibodies against respiratory pathogens

Pathogen	Total positive n (%)	Detected alone n (%)	Detected in co-infection n (%)
Flu A	1475 (14.89)	628 (6.34)	847 (8.55)
Flu B	1153 (11.64)	706 (7.13)	447 (4.51)
MP	940 (9.49)	564 (5.69)	376 (3.79)
RSV	685 (6.91)	132 (1.33)	553 (5.58)
ADV	277 (2.80)	73 (0.74)	204 (2.06)
COXB	109 (1.10)	37 (0.37)	72 (0.73)
PIV	93 (0.94)	45 (0.45)	48 (0.48)
CP	13 (0.13)	6 (0.06)	7 (0.07)

Subsequent analysis stratified by age and gender further revealed the incidence rates of each pathogen among populations with different demographic characteristics (**Table 2**). The age stratification criteria were defined as follows: infants and preschool children (2–5 years old), school-age children and adolescents (6–17 years old), adults (18–64 years old), older adults (65–79 years old), and the oldest-old (80–102 years old). The results indicate that the preschool children group accounted for a relatively small proportion of the entire study population, and their results should be interpreted with caution. In the school-age children and adolescents' group, the infection rates of Flu B and MP were relatively higher compared to other age groups, while infections with PIV, RSV, COXB, CP, and ADV were less common. Similarly, in the oldest-old group, infections with PIV, COXB, and CP was also relatively uncommon.

Table 2. Pathogen-specific infection rates stratified by age and gender

Age	Gender	Total	Flu A n (%)	Flu B n (%)	ADV n (%)	MP n (%)	PIV n (%)	RSV n (%)	COXB n (%)	CP n (%)
2–5	Female	20	4 (20)	7 (35)	0 (0)	9 (45)	0 (0)	0 (0)	0 (0)	0 (0)
	Male	26	4 (15.38)	9 (34.62)	0 (0)	13 (50)	1 (3.85)	0 (0)	0 (0)	0 (0)
6–17	Female	121	14 (11.57)	31 (25.62)	0 (0)	41 (33.88)	0 (0)	0 (0)	0 (0)	1 (0.83)
	Male	143	16 (11.19)	29 (20.28)	1 (0.7)	54 (37.76)	0 (0)	1 (0.7)	0 (0)	1 (0.7)
18–64	Female	2697	357 (13.24)	257 (9.53)	50 (1.85)	396 (14.68)	19 (0.7)	96 (3.56)	33 (1.22)	3 (0.11)
	Male	3291	420 (12.76)	287 (8.72)	99 (3.01)	272 (8.26)	30 (0.91)	177 (5.38)	32 (0.97)	5 (0.15)
65–79	Female	862	129 (14.97)	148 (17.17)	24 (2.78)	47 (5.45)	12 (1.39)	84 (9.74)	14 (1.62)	1 (0.12)
	Male	1476	312 (21.14)	173 (11.72)	54 (3.66)	61 (4.13)	11 (0.75)	192 (13.01)	19 (1.29)	1 (0.07)
80–102	Female	597	105 (17.59)	91 (15.24)	19 (3.18)	17 (2.85)	7 (1.17)	65 (10.89)	4 (0.67)	0 (0)
	Male	672	114 (16.96)	121 (18.01)	30 (4.46)	29 (4.32)	13 (1.93)	70 (10.42)	7 (1.04)	1 (0.15)

Chi-square tests conducted across age and gender strata revealed statistically significant differences in pathogen positivity rates between males and females within specific age groups. Among adults, significant gender-based disparities were observed for ADV and MP, with males showing a higher infection rate of ADV, while females exhibited a significantly higher positivity rate for MP. In the elderly population, significant differences were also found for Flu A and RSV, with males demonstrating higher infection rates for both pathogens compared to females.

Subsequent analysis of co-infection patterns and their proportional distribution among all co-infected cases revealed that dual infection with Flu A and RSV was the most frequent combination. This was followed by Flu B and MP, as well as Flu A and Flu B. Among triple infection patterns, the combination of ADV, Flu A, and RSV was the most common, followed by Flu A, Flu B, and RSV, and then Flu A, MP, and RSV. For quadruple infections, the pattern ADV, Flu A, Flu B, and RSV ranked first in frequency, succeeded by ADV, Flu A, MP, and RSV and Flu A, Flu B, MP, and RSV. Further details are provided in **Table 3**.

Table 3. Patterns and frequency of multiple pathogen co-infection

Pattern	Count	Percentage (%)	Pattern	Count	Percentage (%)
Flu A, RSV	270	8.24	CP, PIV	1	0.03
Flu B, MP	138	4.21	ADV, Flu A, RSV	78	2.38
Flu A, Flu B	130	3.97	Flu A, Flu B, RSV	53	1.62
Flu A, MP	108	3.30	Flu A, MP, RSV	30	0.92
ADV, Flu A	33	1.01	Flu A, Flu B, MP	24	0.73
ADV, Flu B	14	0.43	COXB, Flu A, RSV	9	0.27
Flu B, RSV	14	0.43	COXB, Flu A, Flu B	4	0.12
COXB, Flu A	12	0.37	Flu A, PIV, RSV	4	0.12
COXB, MP	11	0.34	ADV, Flu A, Flu B	3	0.09
Flu A, PIV	10	0.31	COXB, Flu B, MP	3	0.09
ADV, RSV	9	0.27	ADV, Flu A, MP	2	0.06
COXB, Flu B	8	0.24	ADV, Flu B, MP	2	0.06
MP, PIV	6	0.18	ADV, MP, RSV	2	0.06
MP, RSV	6	0.18	COXB, Flu A, MP	2	0.06
Flu B, PIV	5	0.15	Flu A, Flu B, PIV	2	0.06
ADV, MP	3	0.09	ADV, COXB, RSV	1	0.03
COXB, RSV	3	0.09	COXB, Flu B, RSV	1	0.03
PIV, RSV	3	0.09	CP, Flu B, PIV	1	0.03
ADV, PIV	2	0.06	Flu A, MP, PIV	1	0.03
CP, Flu A	2	0.06	Flu B, MP, PIV	1	0.03
COXB, PIV	1	0.03	Flu B, MP, RSV	1	0.03
CP, Flu B	1	0.03			

Table 3 (continued). Patterns and frequency of multiple pathogen co-infection

Pattern	Count	Percentage (%)
ADV, Flu A, Flu B, RSV	19	0.58
ADV, Flu A, MP, RSV	14	0.43
Flu A, Flu B, MP, RSV	9	0.27
ADV, COXB, Flu A, RSV	6	0.18
ADV, COXB, Flu A, Flu B	2	0.06
ADV, Flu A, PIV, RSV	2	0.06
COXB, Flu A, Flu B, RSV	2	0.06
Flu A, MP, PIV, RSV	2	0.06
ADV, COXB, MP, RSV	1	0.03
ADV, Flu B, MP, RSV	1	0.03
COXB, Flu A, MP, RSV	1	0.03

Table 3 (Continued)

Pattern	Count	Percentage (%)
CP, Flu A, PIV, RSV	1	0.03
Flu A, Flu B, PIV, RSV	1	0.03
ADV, Flu A, Flu B, MP, RSV	3	0.09
ADV, COXB, CP, Flu A, PIV	1	0.03
ADV, COXB, Flu A, Flu B, RSV	1	0.03
ADV, COXB, Flu A, PIV, RSV	1	0.03
ADV, Flu A, MP, PIV, RSV	1	0.03
Flu A, Flu B, MP, PIV, RSV	1	0.03
ADV, COXB, Flu A, Flu B, MP, RSV	2	0.06
ADV, Flu A, Flu B, MP, PIV, RSV	1	0.03

The statistical results regarding single and co-infection patterns across different age groups reveal that the proportion of co-infections among total infection cases was highest in preschool children (48.28%), followed by older adults (40.25%). In contrast, adults exhibited the lowest proportion of co-infections (28.52%). See more details in **Table 4**.

Table 4. Composition of single and co-infections by age group

Age	Total positive	Detected alone n (%)	Detected in co-infection n (%)
2–5	29	15 (51.72)	14 (48.28)
6–17	135	83 (61.48)	52 (38.52)
18–64	1834	1311 (71.48)	523 (28.52)
65–79	815	487 (59.75)	328 (40.25)
80–102	463	294 (63.50)	169 (36.50)

The overall chi-square test comparing the composition of infection types across age groups yielded a significant result ($\chi^2 = 43.87$, $p = 2.45 \times 10^{-8}$). This indicates a statistically significant difference in the distribution of single versus co-infections among the different age strata. Post-hoc pairwise comparisons with Bonferroni correction revealed specific significant differences between the following groups: adults versus the oldest-old ($p = 0.015$), and adults versus the older adults ($p = 4.79 \times 10^{-8}$.

4. Discussion

This large-scale retrospective study delineates a detailed epidemiological profile of eight common respiratory pathogens detected via rapid IgM assays in a diverse cohort of 9,908 patients with suspected RTIs. The overall pathogen positivity rate of 33.1% aligns with the broad spectrum reported in multi-pathogen surveillance studies, which varies considerably based on population, setting, and diagnostic methodology [9,10]. Flu A was identified as the most frequently detected pathogen overall, consistent with its established role as a major cause of seasonal

respiratory morbidity. A notable finding was the predominance of Flu B among cases of single pathogen detection, which may reflect specific local circulation dynamics or period-specific susceptibility patterns warranting further investigation.

A central and significant finding is the high frequency of pathogen co-detection, with one-third of all positive cases involving multiple pathogens. This underscores the etiological complexity of RTIs and highlights a critical limitation of single-pathogen diagnostic approaches in clinical practice. Dual infections were the most common co-infection type. The most frequent specific combination was Flu A with RSV, a pattern previously observed that raises important questions about potential viral interference, altered clinical severity, or overlapping seasonal peaks [11,12]. Other prevalent patterns, such as Flu B with MP and Flu A with Flu B, illustrate the common mixing of viral and atypical bacterial pathogens, as well as co-circulation within virus families. These patterns suggest that in clinical scenarios where influenza is suspected, concurrent testing for RSV and MP should be strongly considered, and vice versa [13].

Stratified analysis revealed crucial demographic patterns. The proportion of co-infections among all positive cases was highest in preschool children (2–5 years) at 48.3%, followed by older adults (65–79 years) at 40.3%. This is consistent with the known higher frequency of multiple pathogen exposures in young children due to immature immunity and dense social contact, and in older adults potentially due to immunosenescence and comorbid conditions [13,14]. In contrast, adults exhibited the lowest co-infection proportion (28.5%), a statistically significant difference confirmed by post-hoc analysis, likely reflecting more robust immune function and different exposure networks.

Our analysis also revealed statistically significant gender-based differences in pathogen positivity within specific age groups. Among adults, males had a higher infection rate of ADV, while females exhibited a significantly higher positivity rate for MP. In the elderly population, males demonstrated higher infection rates for both Flu A and RSV. These findings contrast with some previous reports which concluded that respiratory pathogen infection rates vary primarily by age and season, but not by gender [15,16]. However, they align with other studies noting gender disparities, such as higher MP and ADV rates in boys within pediatric cohorts [17]. It is important to note that the pediatric subgroup (2–17 years) in our study constituted a relatively small proportion of the total positive cases. Therefore, conclusions regarding infection patterns in children, while suggestive, should be interpreted with caution, and reference to larger, dedicated pediatric studies is recommended for more definitive insights [9,17,18].

Several limitations must be acknowledged to contextualize our findings. First, the reliance on IgM antibody detection, while offering rapid, point-of-care utility, has inherent constraints including potential cross-reactivity, interference from rheumatoid factor, and the inability to precisely distinguish between recent, past, or persistent infection within the serological window. This may lead to an overestimation of active simultaneous co-infections compared to direct molecular methods like PCR [10]. Second, as a single-center retrospective study, the generalizability of our findings to other geographical regions or healthcare settings may be limited. Third, the lack of detailed, prospectively collected clinical metadata (e.g., symptom severity, comorbidities, treatment, and outcomes) precluded analysis of the correlation between specific pathogen or co-infection patterns and disease severity, progression, or healthcare burden. Finally, our predefined panel, though covering major pathogens, did not include other common agents such as rhinovirus, SARS-CoV-2, metapneumovirus, or typical bacteria, which undoubtedly contributes to the overall etiology of RTIs and may lead to an underestimation of co-infection complexity [10,15] .

5. Conclusion

Despite these limitations, this study provides valuable real-world epidemiological data on the co-circulation and demographic distribution of key respiratory pathogens using a widely available diagnostic method. The findings emphasize the necessity of moving beyond single-pathogen diagnostic paradigms in both clinical and public health contexts. Future research should employ prospective, multi-center designs that integrate highly sensitive molecular multiplex panels (e.g., PCR-based syndromic testing) with comprehensive clinical and epidemiological data collection. This approach will enable a more precise determination of active co-infection rates and a robust assessment of their clinical and public health impact. Furthermore, investigating the immunological mechanisms, such as viral interference or synergistic pathogenesis, underlying high-frequency co-infection patterns like Flu A/RSV, is a crucial direction [12,13]. Ultimately, such refined insights are essential for developing more nuanced diagnostic algorithms, guiding targeted therapeutic and preventive strategies, and strengthening surveillance systems to mitigate the burden of respiratory infections across diverse populations.

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Disclosure statement

The authors declare no conflict of interest.

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A Competency-Mapping-Based Instructional Model for Health Assessment Education in Nursing

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Abstract: Health assessment represents a fundamental component of professional nursing practice and forms the starting point of the nursing process. As healthcare systems become increasingly complex and patient needs more diverse, nursing education has gradually shifted toward competency-based training models. International professional organizations, including the International Council of Nurses (ICN), the American Association of Colleges of Nursing (AACN), and the American Nurses Association (ANA), have proposed competency frameworks that define the knowledge, skills, and professional attributes required of registered nurse. However, translating these broad competency standards into specific curriculum structures and teaching strategies remains a challenge in nursing education. Drawing on the AACN Essentials framework and incorporating elements from the ICN competency framework and ANA practice standards, this study develops a competency-mapping-based instructional model for health assessment education. The model integrates the Knowledge–Skill–Attitude (KSA) structure and a progressive competency development pathway. Three levels of competency are described: foundational assessment and data collection, integrated analysis and preliminary clinical judgment, and advanced clinical reasoning in complex clinical situations. Previous studies have suggested that nursing competence develops progressively through education and clinical experience. The proposed model aligns learning activities with competency outcomes through a mapping matrix linking curriculum content, teaching strategies, and evaluation approaches. Simulation training, case-based learning, standardized patient encounters, and clinical observation are incorporated to facilitate competency development. By clarifying how competency standards can be translated into teaching practice, the model contributes to bridging the gap between competency frameworks and nursing curriculum implementation. The framework may provide a useful reference for curriculum development, clinical training design, and competency evaluation in nursing education. Future research should further examine the effectiveness of this instructional model through empirical studies and longitudinal assessment of student competency development.

Keywords: Registered nurse competency; Health assessment; Nursing education; Competency mapping; Instructional design

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1. Introduction

Health assessment is widely regarded as one of the most essential components of professional nursing practice. As the first step of the nursing process, it provides the foundation for identifying patient problems, determining priorities of care, and developing individualized nursing interventions. Accurate and comprehensive assessment enables nurses to understand patients' physiological conditions as well as psychosocial and environmental factors that may influence health outcomes.

In recent decades, nursing education has increasingly adopted competency-based approaches to ensure that graduates are adequately prepared for contemporary clinical practice. Several international organizations have developed competency frameworks to guide nursing education and professional regulation. For example, the International Council of Nurses (ICN) proposed a competency framework that outlines professional, ethical, and care-related competencies required for nursing practice [1]. Similarly, the American Association of Colleges of Nursing (AACN) introduced The Essentials: Core Competencies for Professional Nursing Education, which defines ten competency domains and eight key concepts expected of nursing graduates [2]. In addition, the American Nurses Association (ANA) has published standards of nursing practice that emphasize systematic assessment as a central element of professional nursing care [3].

Previous research has emphasized that nursing competence is a multidimensional construct involving knowledge, skills, professional attitudes, and clinical judgment [4]. The development of professional competence is also considered a progressive process that evolves through education and clinical experience [5].

Although these frameworks provide valuable guidance, nursing educators often face difficulties in translating abstract competency requirements into specific curriculum structures and teaching strategies. Health assessment courses provide a particularly suitable context for competency integration because they involve knowledge application, communication skills, clinical reasoning, and patient-centered care.

Therefore, developing a competency-mapping-based instructional model may help bridge the gap between competency frameworks and curriculum implementation.

2. Theoretical foundations and literature review

2.1. Competency frameworks for registered nurses

Nursing competence is commonly understood as the integration of knowledge, technical skills, professional attitudes, and clinical judgment required to deliver safe and effective nursing care. Previous research suggests that nursing competence develops progressively through education and clinical experience. Cowan et al. described competence as a complex concept involving knowledge, clinical performance, and professional responsibility [4]. Benner's well-known "novice to expert" theory further illustrates that professional competence develops gradually through experience and clinical exposure [5]. More recent studies have continued to examine the conceptual structure of nursing competence and its implications for nursing education [6–8].

The AACN Essentials framework has become a widely recognized benchmark for undergraduate nursing education. It identifies ten competency domains including knowledge for nursing practice, person-centered care, population health, quality and safety, and leadership development [2]. Similarly, the ICN competency framework emphasizes systematic health assessment and care planning as core competencies for registered nurses [1].

The ANA standards of nursing practice provide operational guidance for nursing activities across the care continuum. These standards emphasize assessment, diagnosis, planning, implementation, and evaluation as core

components of nursing practice. Among these standards, patient assessment is considered the foundation for subsequent clinical decision-making [3].

2.2. Challenges in health assessment education

Traditional health assessment teaching often focuses heavily on procedural skills such as physical examination techniques and the sequence of assessment steps. While such training is necessary, an excessive emphasis on technical procedures may result in fragmented learning experiences. Students may acquire isolated technical skills without fully understanding how assessment findings contribute to clinical reasoning and patient-centered care.

Consequently, there is increasing recognition that health assessment education should move beyond mechanical skill training and instead emphasize integrated competency development. Teaching models that combine knowledge acquisition, communication competence, and clinical reasoning are therefore needed.

3. Development of a competency-mapping-based teaching model

3.1. Design principles

The proposed teaching model was developed according to three guiding principles.

First, an integration principle was adopted, combining competency elements from the ICN, AACN, and ANA frameworks.

Second, a progressive development principle was applied, organizing competencies into hierarchical levels that reflect gradual development of knowledge and clinical reasoning abilities.

Third, a practice-oriented principle was emphasized, ensuring that competency descriptions correspond to realistic clinical situations.

3.2. Design rationale and framework overview

The instructional model proposed in this study is grounded in the integration of the Knowledge–Skill–Attitude (KSA) framework with a progressive competency development pathway. The model draws primarily on two authoritative competency frameworks in nursing education.

First, the International Council of Nurses (ICN) competency framework for registered nurses serves as an important reference. Within the category of care provision and management, the subdomain of assessment and care planning explicitly highlights key competencies such as conducting systematic health assessments and collaborating with patients in the development of individualized care plans.

Second, the American Association of Colleges of Nursing (AACN) framework, The Essentials: Core Competencies for Professional Nursing Education, provides a structured foundation for competency-based nursing education. The framework identifies ten competency domains that guide the design of nursing curricula. In the context of health assessment education, several domains are particularly relevant:

(1) Domain 2

Person-centered care, which emphasizes comprehensive and individualized assessment and care planning.

(2) Domain 1

Knowledge for nursing practice and Domain 3: Clinical judgment, which provide the theoretical knowledge base and higher-level cognitive processes necessary for effective assessment.

(3) Domain 8

Informatics and healthcare technologies, which highlights the role of information technology and digital tools in modern health assessment practices.

Based on these frameworks, a three-level competency structure is proposed to represent the progressive development of health assessment capabilities.

3.2.1. Level 1: Foundational assessment and data collection competence

This level focuses on the ability to perform systematic health assessments according to standardized procedures and accurately collect both subjective and objective patient data.

3.2.2. Level 2: Integrated analysis and preliminary clinical judgment competence

At this level, students are expected to integrate and interpret assessment findings, identify potential health problems or risks, formulate preliminary nursing diagnoses or problem lists, and participate in the development of nursing care plans.

3.2.3. Level 3: Advanced clinical reasoning and management of complex situations

This level involves higher-level clinical reasoning in complex or uncertain clinical situations, including leading interprofessional assessment processes and coordinating care planning adjustments. In the present instructional model, Levels 1 and 2 are the primary focus of undergraduate education, while Level 3 is considered a long-term developmental goal.

3.3. Level 1 competency teaching model

3.3.1. Core competency description

At this level, students are expected to perform a basic health assessment independently according to standardized procedures, including health history taking and physical examination of adult patients. Assessment procedures should be accurate, systematic, and properly documented.

3.3.2. Teaching objectives

Students should demonstrate standardized health assessment skills, identify normal and abnormal findings, and record assessment data accurately. Refer **Table 1**.

Table 1. Level-1 competency structure for health assessment education

Competency dimension	Knowledge	Skills	Professional attitudes
Systematic health assessment process	Principles and ethical considerations of health assessment, including privacy protection and informed consent; components and sequence of health assessment	Conduct interviews and physical examinations following standardized procedures; accurately measure and record vital signs	Responsibility for accurate assessment and cumentation; respect for patient autonomy and cultural diversity
Communication and health interview	Principles of therapeutic communication, such as active listening and open-ended questioning; components of health history including chief complaint and past history	Establish initial nurse–patient relationships through therapeutic communication; conduct effective health interviews	Empathy and patient-centered care; attention to patients' experiences and concerns

Table 1 (Continued)

Competency dimension	Knowledge	Skills	Professional attitudes
Physical examination	Basic anatomy and physiology of body systems; principles of inspection, palpation, percussion and auscultation	Perform systematic physical examination; correctly use assessment tools such as stethoscopes and blood pressure monitors	Professional rigor and attention to detail; adherence to infection control principles
Technology- assisted assessment	Basic interpretation of laboratory tests and diagnostic reports	Utilize electronic health records, bedside monitoring devices, and digital health technologies during assessment	Data security awareness and responsible use of healthcare technology
Basic clinical judgment	Recognition of normal and abnormal findings; interpretation of common laboratory values	Identify deviations from normal findings; recognize potential health risks	Application of critical thinking and evidence- based reasoning
Documentation	Principles of standardized nursing	Record assessment data accurately	Professional integrity and accountability in

3.4. Level 2 competency teaching model

3.4.1. Core competency description

Students at this level should be able to interpret and integrate assessment data collected in Level-1, identify potential health problems, prioritize nursing issues, and participate in the development of individualized nursing care plans.

3.4.2. Teaching objectives

Students should demonstrate the ability to analyze assessment findings, formulate nursing diagnoses or health problems, and develop evidence-based nursing plans in collaboration with patients and healthcare teams. See **Table 2**.

Table 2. Level 2 competency structure for health assessment education

Competency dimension	Knowledge	Skills	Professional attitudes
Data integration and pattern recognition	Pathophysiological mechanisms of common diseases; clinical significance of abnormal assessment findings	Integrate subjective and objective data to develop a comprehensive patient profile	Application of critical thinking in data interpretation
Nursing diagnosis and problem identification	Classification systems of Nursing diagnoses (e.g., NANDA-I); principles of priority setting	Formulate appropriate nursing diagnoses based on assessment data; prioritize patient problems	Evidence-based reasoning and analytical thinking
Care planning	Components of nursing care plans; principles of SMART goal setting	Collaboratively develop patient-centered care plans; select evidence-based interventions	Collaboration and advocacy for patient participation
Preliminary clinical judgment	Basic principles of differential diagnosis and risk identification	Determine when immediate intervention or further assessment is required	Commitment to patient safety and awareness of professional limitations

3.5. Curriculum implementation pathway

The implementation of the competency-based teaching model follows a spiral curriculum structure.

Competencies are gradually reinforced across different semesters. For example, early courses focus primarily on Level 1 competency such as system-based physical examination, while later courses emphasize Level 2 competencies including data integration and clinical reasoning.

Evaluation methods include both formative and summative assessments.

Formative assessments may include:

(1) Objective Structured Clinical Examinations (OSCE)

(2) Case analysis reports

(3) Group presentations of nursing care plans

Summative assessments may include:

(1) Comprehensive clinical performance evaluations

(2) Written examinations covering theoretical knowledge and clinical reasoning.

3.6. Competency-teaching activity mapping matrix

Through competency mapping, macro-level competency frameworks are translated into teachable and assessable knowledge-skill-attitude components. This instructional model provides a structured blueprint for health assessment education and promotes alignment between nursing curriculum design and professional competency requirements. See **Table 3**.

Table 3. Mapping of teaching activities and competency outcomes

Teaching activity	Competency level	Corresponding AACN / ICN competency domains	Evaluation focus
Standardized patient interview and physical examination	Level 1	AACN Domain 2: Person-centered care; ICN competency: Therapeutic communication and systematic assessment	Procedural accuracy, communication effectiveness, data completeness
Complex case discussion seminars	Level 2	AACN Domain 1: Knowledge for nursing practice; Domain 3: Clinical judgment	Depth of data analysis and logical reasoning
Nursing care plan workshops	Level 2	AACN Domain 2: Person-centered care; ICN competency: collaborative care planning	Feasibility of goals, relevance of interventions, patient involvement
Clinical observation under supervision	Level 1–2 integration	Multiple competency domains	Comprehensive clinical Performance and teamwork

4. Discussion

The competency-mapping model developed in this study offers several potential advantages for nursing education.

First, it provides a structured framework that links competency standards with teaching activities and evaluation methods. By clarifying expected learning outcomes, the model may improve consistency in curriculum design and teaching practice.

Second, competency mapping helps students understand the relationship between classroom learning and future professional responsibilities. This alignment may strengthen students' professional identity and motivation to develop clinical competence.

Third, the framework may also support clinical training programs by providing guidance for competency evaluation and professional development planning.

However, several challenges should also be considered. Implementing competency-based education requires faculty development and training in innovative teaching strategies such as simulation-based education and problem-based learning. In addition, evaluating higher-level competencies such as clinical reasoning and ethical decision-making remains methodologically challenging.

Future research may examine the effectiveness of this instructional model through pilot implementation and longitudinal evaluation of student competency development.

5. Conclusion

This study presents a competency-mapping-based instructional model for health assessment education grounded in international nursing competency frameworks. By integrating elements from the ICN, AACN, and ANA standards, the model provides a structured approach for translating competency frameworks into curriculum design and teaching practice.

The framework clarifies competency development pathways from basic assessment skills to more advanced clinical reasoning abilities. Adoption of this model may contribute to improving the effectiveness of health assessment education and support the preparation of competent nursing professionals capable of delivering safe and high-quality patient care.

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Disclosure statement

The authors declare no conflict of interest.

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LncRNA MALAT1 as a Competitive Endogenous RNA in Osteoarthritis: Mechanisms and Therapeutic Prospects

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Abstract: Osteoarthritis (OA) is a complex degenerative joint disease characterized by articular cartilage degeneration, synovial inflammation, and osteophyte formation, with its exact pathogenesis not yet fully elucidated. In recent years, competing endogenous RNA (ceRNA) regulatory networks, particularly the role of long non-coding RNAs (LncRNAs) within them, have garnered increasing attention. This review focuses on LncRNA MALAT1, summarizing its ceRNA mechanism in the initiation and progression of OA. The article systematically elaborates on how MALAT1 acts as a molecular sponge to adsorb specific microRNAs (miRNAs), thereby relieving the inhibition of downstream target genes, and consequently regulating key pathological processes such as chondrocyte metabolism, extracellular matrix homeostasis, inflammatory response, and cell apoptosis. Furthermore, this review summarizes the potential value and latest research progress in targeting the MALAT1-ceRNA axis for early OA diagnosis, disease monitoring, and the development of novel therapeutic strategies, aiming to provide a new theoretical basis and perspective for the precise diagnosis and treatment of OA.

Keywords: Osteoarthritis; Competing endogenous RNA; LncRNA MALAT1; Chondrocytes; ceRNA network; Molecular mechanism

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1. Introduction

Osteoarthritis is the most common joint disease worldwide, imposing a heavy socioeconomic burden. Its pathological process involves multiple interacting factors, including chondrocyte dysfunction, imbalance between extracellular matrix degradation and synthesis, chronic low-grade inflammation, and abnormal subchondral bone remodeling [1]. Traditional treatment strategies primarily focus on symptom relief and cannot reverse disease progression; therefore, in-depth exploration of the molecular mechanisms underlying OA is crucial. In recent

years, research on non-coding RNAs has revealed their central role in gene expression regulation [2]. Among these, the ceRNA hypothesis proposes that RNA transcripts (such as LncRNAs and circular RNAs) can competitively bind miRNAs through shared miRNA response elements, thereby relieving the miRNA-induced inhibition of target messenger RNAs, forming a complex post-transcriptional regulatory network [3].

LncRNA MALAT1 (metastasis-associated lung adenocarcinoma transcript 1) has been confirmed as a key ceRNA regulator in various diseases. In the field of OA, accumulating evidence indicates that MALAT1 is aberrantly expressed and extensively participates in the pathophysiological processes of OA through ceRNA mechanisms [4]. This review will delve into the specific mechanisms of LncRNA MALAT1 as a ceRNA in OA, outline the key signaling pathways it regulates, and explore the potential of diagnostic biomarkers and novel therapeutic strategies based on this mechanism.

Studies have shown that MALAT1 expression is upregulated in the subchondral bone and chondrocytes of OA patients, closely correlating with joint inflammation and degeneration [5]. For instance, in the subchondral bone of OA patients, MALAT1 expression levels positively correlate with serum concentrations of DKK1 and galectin-1, suggesting its involvement in bone metabolism regulation [5]. Functional studies further confirmed that knocking down MALAT1 in osteoblasts from OA patients leads to significant expression changes in 155 genes, including PTGS2, and enhances basal and IL-1β-induced prostaglandin E2 secretion, indicating that MALAT1 plays a crucial role in regulating subchondral bone inflammation in OA [5]. Additionally, an allele-specific expression imbalance analysis based on a genome-wide association study identified MALAT1 as a key long intergenic non-coding RNA within an OA risk locus, where its expression imbalance is significantly associated with OA risk [6]. These findings collectively establish the central role of MALAT1 in OA pathogenesis.

As a ceRNA, MALAT1 primarily regulates downstream miRNA and target gene expression through a "sponge" adsorption effect, thereby influencing multiple pathological aspects of OA. For example, MALAT1 can competitively bind miR-146a, relieving its inhibition of target genes, ultimately reducing IL-1β-induced articular chondrocyte apoptosis and extracellular matrix degradation [7]. In human synovial mesenchymal stem cells (hSMSCs), MALAT1 has been shown to act as a ceRNA, adsorbing miR-212-5p and subsequently regulating its target gene MyD88, thereby inhibiting the chondrogenic differentiation of hSMSCs; conversely, inhibiting MALAT1 promotes chondrogenic differentiation and reduces joint degeneration in a rat OA model [8]. Another study revealed that the MALAT1/miR-15b-5p axis influences lipopolysaccharide-induced chondrocyte damage by regulating the Wnt/β-catenin signaling pathway [9]. These studies clearly outline the complex molecular landscape through which MALAT1 regulates OA progression via the ceRNA network.

Based on its ceRNA mechanism, MALAT1 demonstrates significant potential in the diagnosis and treatment of OA. In diagnostics, studies have found that MALAT1 expression levels in the serum of OA patients are altered and correlate with postoperative chronic pain, suggesting its potential as a circulating biomarker [10]. Therapeutically, targeting MALAT1 or its ceRNA network has emerged as a novel strategy. For instance, extracellular vesicles derived from human mesenchymal stem cells overexpressing MALAT1 can inhibit IL-1β-induced chondrocyte inflammation and apoptosis, alleviating cartilage degeneration in a rat OA model [11]. Traditional Chinese medicine formulas, such as Tougu Xiaotong Capsules, have also been shown to regulate the MALAT1/miR-16-5p ceRNA axis, ameliorating "cholesterol-iron" metabolic disorders in OA chondrocytes, thereby delaying OA progression [12]. Furthermore, docosahexaenoic acid (DHA) exerts anti-inflammatory, chondroprotective, and chondrogenic effects by downregulating MALAT1 levels [13]. These studies provide a solid theoretical basis and experimental foundation for developing novel OA therapies targeting MALAT1.

2. Biological characteristics of LncRNA MALAT1 and its expression regulation in OA

2.1. Basic structure and function of MALAT1

MALAT1 is a highly conserved long non-coding RNA, initially discovered in non-small cell lung cancer, with a transcript length exceeding 200 nucleotides [14]. As a nuclear-retained lncRNA, MALAT1 plays a crucial role in transcriptional regulation and alternative splicing within the nucleus [4]. In addition to its nuclear functions, MALAT1 has also been shown to shuttle to the cytoplasm, where it functions as a competing endogenous RNA (ceRNA). In the cytoplasm, MALAT1 can act as a molecular sponge, binding and inhibiting the activity of specific microRNAs (miRNAs), thereby relieving the inhibitory effect of these miRNAs on their downstream target genes, participating in the regulation of various cellular processes [15]. In the pathological context of osteoarthritis (OA), the expression level of MALAT1 is closely related to the severity of cartilage degeneration. Multiple studies have indicated that MALAT1 expression is generally significantly upregulated in OA articular tissues, suggesting its role as a molecular factor promoting OA progression [3]. For example, MALAT1 expression is upregulated in chondrocytes from OA patients, exacerbating cartilage destruction by regulating inflammatory pathways and extracellular matrix metabolism [7].

2.2. Regulation of MALAT1 expression by the OA pathological microenvironment

The pathological microenvironment of OA, particularly its various pathogenic factors, can significantly regulate MALAT1 expression in chondrocytes. Inflammatory factors constitute a core component of the OA microenvironment. Key pro-inflammatory cytokines such as interleukin-1β (IL-1β) and tumor necrosis factor-α (TNF-α) have been shown to induce the upregulation of MALAT1 expression in chondrocytes [3]. For instance, MALAT1 expression levels significantly increase in IL-1β-treated chondrocyte models [16]. Besides inflammatory factors, epigenetic modifications also participate in the transcriptional regulation of MALAT1. Mechanisms such as DNA methylation and histone modifications can affect the chromatin state of the MALAT1 locus, thereby modulating its transcriptional activity in OA chondrocytes [4]. Additionally, the hypoxic microenvironment commonly found in OA cartilage tissue is another critical factor regulating MALAT1 expression. Hypoxia can promote MALAT1 transcription by activating transcription factors like hypoxia-inducible factor-1α (HIF-1α) [3]. This upregulated MALAT1 can further exacerbate inflammatory responses and extracellular matrix degradation, forming a positive feedback loop that continuously drives cartilage destruction in OA [7].

3. Molecular mechanisms of MALAT1 as a ceRNA regulating chondrocyte metabolic homeostasis in OA

3.1. The MALAT1/miRNA/target gene axis regulating extracellular matrix synthesis and degradation

MALAT1, acting as a competing endogenous RNA, plays a key regulatory role in the balance between synthesis and degradation of the extracellular matrix in osteoarthritic chondrocytes by adsorbing specific microRNAs and relieving the inhibition of downstream target genes. Studies have shown that MALAT1 expression is upregulated in OA cartilage tissue and is closely associated with matrix degradation [7]. Specifically, MALAT1 acts as a molecular sponge for miR-146a, competitively binding to it, thereby relieving the inhibitory effect of miR-146a on its target gene, ADAMTS5. ADAMTS5 is a crucial aggrecanase; its upregulation accelerates

the degradation of the core proteoglycan in the extracellular matrix, directly promoting cartilage destruction [7]. Furthermore, another important regulatory pathway involves the adsorption of miR-150-5p by MALAT1. By sponging miR-150-5p, MALAT1 upregulates the expression of its target gene, matrix metalloproteinase 13 (MMP13), thereby enhancing the breakdown of type II collagen and compromising the integrity of the cartilage structure [17]. Under OA pathological conditions, the aberrant expression of MALAT1 also affects pro-synthesis pathways. For instance, MALAT1 can act as a ceRNA for miR-127-5p, theoretically promoting the expression of SOX9, a key transcription factor for chondrogenesis, by relieving miR-127-5p inhibition, which would favor extracellular matrix synthesis. However, in the inflammatory environment of OA, this pro-synthesis pathway is often suppressed, leading to an imbalance between synthesis and degradation, ultimately exacerbating cartilage degeneration [18].

3.2. Role of the MALAT1-ceRNA network in regulating chondrocyte apoptosis and autophagy

The MALAT1-ceRNA network also deeply participates in regulating the survival and death processes of chondrocytes, including apoptosis and autophagy. In terms of apoptosis regulation, MALAT1 sponges miR-181a-5p, upregulating the expression of its target gene Bcl-2, thereby inhibiting the mitochondrial pathway of apoptosis and exerting a protective effect on chondrocytes [19]. However, under OA pathological conditions, the aberrant high expression of MALAT1 may produce dual effects through complex networks. For example, some studies suggest that MALAT1 might promote apoptotic signals via other miRNAs (such as miR-20b), indicating the context-dependent regulation of apoptosis by MALAT1 in OA [20]. Regarding autophagy regulation, MALAT1 also plays a significant role as a ceRNA. MALAT1 acts as a molecular sponge for miR-142-3p, influencing the expression of autophagy-related genes like ATG7, thereby interfering with the autophagic flux in chondrocytes under stress conditions [21]. Autophagy is a crucial mechanism for maintaining cellular homeostasis, and dysregulation of autophagic flux is directly linked to decreased chondrocyte survival in OA. Therefore, through the ceRNA mechanism regulating miR-142-3p and its downstream targets, MALAT1 influences chondrocyte autophagic activity and thus participates in OA disease progression. These studies collectively reveal that MALAT1 plays a key role in the fine-tuning of chondrocyte apoptosis and autophagy by constructing a complex ceRNA network, and its expression imbalance is a significant factor contributing to the disruption of chondrocyte metabolic homeostasis in OA.

4. OA Synovial inflammation and subchondral bone remodeling mediated by the MALAT1-ceRNA axis

4.1. Regulation of inflammatory responses in synovial fibroblasts

In the pathological process of osteoarthritis (OA), chronic inflammation of the synovial tissue is a critical factor exacerbating joint destruction. Long non-coding RNA MALAT1 is highly expressed in OA synovial tissue and drives the inflammatory response in synovial fibroblasts by regulating downstream signaling pathways through competing endogenous RNA (ceRNA) mechanisms. Studies indicate that MALAT1 acts as a molecular sponge for microRNA-150 (miR-150). By adsorbing miR-150, it relieves the inhibition of downstream target genes, subsequently activating the nuclear factor κB (NF-κB) signaling pathway [3]. Activation of the NF-κB pathway prompts synovial fibroblasts to release large quantities of pro-inflammatory cytokines such as interleukin-6

(IL-6), interleukin-8 (IL-8), and tumor necrosis factor-α (TNF-α), significantly intensifying the inflammatory microenvironment within the joint cavity and creating a vicious cycle [3]. Furthermore, MALAT1 participates in the phenotypic transformation of synovial cells through the MALAT1/miR-145/signal transducer and activator of transcription 1 (STAT1) axis. This axis has been shown to promote abnormal proliferation of synovial cells and induce their transformation into a pro-inflammatory phenotype, thereby driving the chronic inflammatory process in OA [4]. These findings reveal that MALAT1 finely regulates synovial inflammation through a multi-dimensional ceRNA network, acting as a crucial molecular driver in the pathogenesis and progression of OA synovitis.

4.2. Influence on osteoclast differentiation and subchondral bone sclerosis

The characteristic pathological changes in OA extend beyond cartilage and include abnormal subchondral bone remodeling, with excessive osteoclast activation and subchondral bone sclerosis being central components. MALAT1 plays a significant role in this process through ceRNA mechanisms. In bone marrow mesenchymal stem cells or pre-osteoclasts, MALAT1 can act as a molecular sponge for microRNAs such as miR-214, thereby regulating the balance between the receptor activator of nuclear factor κB ligand (RANKL) and osteoprotegerin (OPG) system [3]. Dysregulation of the RANKL/OPG ratio directly promotes osteoclast differentiation and activation, leading to abnormal bone resorption, a key feature of typical subchondral bone remodeling in OA [3]. On the other hand, MALAT1 also indirectly promotes subchondral bone sclerosis by regulating osteogenesis-related signaling pathways such as Wnt/β-catenin. Aberrant activation of the Wnt/β-catenin pathway enhances osteoblast activity and accelerates bone formation, leading to thickening and sclerosis of the subchondral bone plate [3]. Such alterations in bone structure significantly impact the joint's biomechanical environment, increasing the stress on articular cartilage and further exacerbating cartilage wear and degradation. Therefore, the MALAT1-ceRNA axis profoundly participates in the complex regulatory network underlying abnormal subchondral bone remodeling in OA by simultaneously influencing both osteoclastic and osteoblastic processes.

5. Perspectives on OA diagnosis and treatment strategies targeting the MALAT1-ceRNA network

5.1. MALAT1 as a biomarker for OA diagnosis and prognosis assessment

Studies have found that the expression level of MALAT1 in the articular cartilage tissue of osteoarthritis (OA) patients is significantly higher than that in healthy controls, and its expression changes correlate with disease progression. One study showed that in OA articular cartilage, the relative expression level of MALAT1 is elevated, while the expression level of microRNA-146a (miR-146a) is decreased, with a significant negative correlation between the two [7]. This expression pattern suggests that MALAT1 may be involved in the pathological process of OA. Furthermore, another study compared the expression of MALAT1 in peripheral blood mononuclear cells (PBMCs) and fibroblast-like synoviocytes (FLSCs) from patients with rheumatoid arthritis (RA), OA, and traumatic arthritis (TA). It found that MALAT1 expression levels in PBMCs and FLSCs of OA patients were significantly higher than those in RA patients but lower than those in TA patients [22]. This disease-specific expression difference, combined with its negative correlation with the expression of inflammatory factors (such as IL-2, IL-6, TNF-α), highlights the potential value of MALAT1 as a biomarker reflecting OA disease activity and inflammatory status. Further studies using bioinformatics analysis to construct ceRNA networks suggest that MALAT1 can be linked to specific miRNAs (e.g., hsa-miR-22-3p) and their downstream target genes (e.g., PTEN,

ESR1). These networks may have specific utility in distinguishing OA from other skeletal disorders, such as osteoporosis [23]. Therefore, combining the detection of MALAT1 with key regulatory molecules within its ceRNA network could potentially constitute a more precise diagnostic panel, enhancing the specificity and sensitivity of early OA diagnosis and disease assessment.

5.2. Therapeutic intervention strategies based on the MALAT1-ceRNA axis

Gene silencing strategies represent a significant therapeutic direction targeting the MALAT1-ceRNA axis. Research has confirmed that specifically knocking down MALAT1 expression in vivo and in vitro can effectively delay OA progression. For instance, inhibiting MALAT1 expression in human synovial mesenchymal stem cells (hSMSCs) promotes their chondrogenic differentiation and exerts a chondroprotective effect via the miR-212-5p/MyD88 axis [8]. In animal models, MALAT1 inhibition similarly alleviated OA progression in rats [8]. This provides experimental evidence for gene therapy utilizing techniques such as small interfering RNA (siRNA) or short hairpin RNA (shRNA). Beyond direct MALAT1 silencing, oligonucleotide competition strategies based on its ceRNA mechanism also show promise. As MALAT1 acts as a molecular sponge for specific miRNAs (e.g., miR-146a, miR-15b-5p), thereby relieving the inhibition of their target genes [7,9], designing and delivering "decoy" sequences or anti-miRNA oligonucleotides (AMOs) that share the miRNA response elements with MALAT1 could competitively restore the function of the sponged miRNAs, correcting downstream signaling pathway abnormalities, such as excessive activation of the Wnt/β-catenin pathway [9].

To enhance the targeting and bioavailability of therapeutic agents and reduce off-target effects, developing efficient nanocarrier delivery systems is crucial. Currently, nanocarriers based on liposomes, exosomes, or polymeric materials are research hotspots. They can efficiently and specifically deliver MALAT1 inhibitors (e.g., siRNA) or protective miRNA mimics to articular chondrocytes [3]. Additionally, the modulatory effects of active ingredients from traditional Chinese medicine offer new perspectives for OA pharmacotherapy. For example, the natural compound quercetin (QUE) has been shown to directly target and downregulate MALAT1 expression, subsequently affecting the MALAT1/miR-9/NF-κB axis, thereby inhibiting cartilage damage and chondrocyte apoptosis in OA mice [16]. Similarly, Tougu Xiaotong Capsules (TGXTC) have been found to regulate the MALAT1/miR-16-5p ceRNA network, ameliorating "cholesterol-iron" metabolic disorders in OA chondrocytes, thus exerting a therapeutic effect [12,24]. These studies not only reveal novel mechanisms of action for traditional medicines but also provide valuable candidate molecules for developing new OA treatment strategies based on the MALAT1-ceRNA axis.

6. Conclusion

In summary, LncRNA MALAT1 plays a pivotal role in the initiation and progression of osteoarthritis (OA). Its upregulation is not an isolated event; rather, by acting as a competing endogenous RNA (ceRNA) that sponges specific microRNAs such as miR-140 and miR-146a, MALAT1 constructs a broad and complex regulatory network. This network acts as a sophisticated molecular hub, tightly interconnecting the three core pathological hallmarks of OA: chondrocyte metabolic imbalance, chronic synovial inflammation, and abnormal subchondral bone remodeling. Specifically, the MALAT1-ceRNA axis profoundly influences OA pathogenesis by finely regulating a series of key effector molecules and their associated signaling pathways, including ADAMTS5 and MMP13 (affecting extracellular matrix degradation), SOX9 (influencing chondrocyte differentiation and

homeostasis), NF-κB (mediating inflammatory responses), and RANKL (regulating bone remodeling). This positions MALAT1 beyond the scope of a single functional molecule, establishing it as a critical intersection point for understanding the multi-factorial, multi-stage pathogenic mechanisms of OA.

From an expert perspective, the discovery of MALAT1 signifies an important paradigm shift in OA research. Traditionally viewed primarily as a "degenerative" disease driven by mechanical wear, with treatments largely focused on symptom relief, research on MALAT1 and its ceRNA network redirects attention towards epigenetic regulation and complex molecular crosstalk. It emphasizes OA as an active disease driven by multiple cellular and molecular events. This perspective helps balance earlier viewpoints that might have overemphasized single factors (such as inflammatory cytokines or matrix-degrading enzymes), offering a more integrated systems biology view. It reveals that beneath the surface of "degeneration" lies an active, targetable dysregulation of molecular processes, laying a theoretical foundation for intervening at the root cause of the disease.

Based on its core mechanisms, targeting MALAT1 or its ceRNA network holds immense translational potential. On one hand, detecting MALAT1 expression levels or its associated ceRNA network molecular profiles in synovial fluid or peripheral blood holds promise as novel biomarkers for early OA diagnosis and monitoring disease activity, potentially complementing existing imaging and clinical assessments. On the other hand, and more importantly, it opens up new avenues for developing true disease-modifying osteoarthritis drugs (DMOADs). By specifically inhibiting MALAT1 function through techniques such as small molecule drugs, antisense oligonucleotides (ASOs), or small interfering RNA (siRNA), it is theoretically possible to simultaneously intervene in multiple pathological processes, which includes the cartilage destruction, inflammation, and abnormal bone remodeling, thus achieving a transition from "symptom management" to "disease-modifying intervention".

However, translating this potential into clinical reality faces significant challenges. Future research urgently requires employing cutting-edge technologies like single-cell sequencing and spatial transcriptomics to precisely map the dynamic spatiotemporal landscape of the MALAT1-ceRNA network across different OA stages and joint tissues (e.g., superficial vs. deep chondrocytes, synovial fibroblast subpopulations, bone cells). This would clarify the most critical intervention windows and cellular targets. Furthermore, achieving efficient, specific delivery of therapeutic agents to diseased joint tissues while ensuring long-term safety and efficacy remains a major obstacle between basic research and clinical application. Overcoming these challenges necessitates deep integration of materials science, pharmaceutical science, clinical medicine, and fundamental research.

In conclusion, LncRNA MALAT1 serves as a key ceRNA regulatory hub within the OA pathological network. Its study not only deepens our understanding of the molecular mechanisms underlying OA but also points towards new directions for diagnosis and treatment. Future efforts should focus on refining the precision of mechanistic insights and vigorously tackling the technical bottlenecks in clinical translation, potentially leading to revolutionary therapeutic options for OA patients.

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Analysis of the Effect of Gua Sha Combined with Cupping Therapy in TCM Nursing for Patients with Shoulder Periarthritis

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Abstract: Shoulder periarthritis is a common disease characterized by shoulder joint pain and dysfunction, which seriously affects patients' quality of life. In the clinical treatment of shoulder periarthritis, external therapies of Traditional Chinese Medicine (TCM) have unique advantages. This paper focuses on the TCM nursing model of Gua Sha combined with cupping therapy. By systematically elaborating on the operational process and detailed requirements of this nursing model, it further compares with conventional nursing to analyze its clinical effects in relieving pain, improving shoulder joint mobility, and enhancing quality of life. The results show that Gua Sha combined with cupping TCM nursing can effectively dredge the meridians and Qi-blood in the shoulder, dispel cold and dampness, and relieve muscle spasm. Its analgesic and functional recovery effects are significantly superior to simple conventional nursing, with high safety, and it is worthy of popularization and application in clinical nursing.

Keywords: Shoulder periarthritis; Gua Sha; Cupping therapy; TCM nursing; Pain; Joint function

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1. Introduction

Shoulder periarthritis, also known as "fifty-year-old shoulder" or "frozen shoulder", is one of the common diseases in middle-aged and elderly groups, mainly characterized by pain around the shoulder joint and limited mobility in all directions. In the context of modern medicine, the treatment of shoulder periarthritis mostly adopts conventional methods such as analgesic drugs, physical therapy, and functional exercises, but some of these patients face problems such as limited curative effect or easy recurrence. According to TCM theory, shoulder periarthritis belongs to the category of "Bi Syndrome", which is mainly caused by the invasion of wind-cold-damp pathogens, strain and trauma, or insufficient Qi and blood, leading to obstruction of meridians and stagnation of Qi-blood in the shoulder [1]. In traditional TCM external treatment techniques, the combined use of Gua Sha and cupping therapy is often adopted to achieve the effects of promoting blood circulation to remove blood stasis, relaxing tendons and dredging meridians, dispelling wind and cold, etc. In recent years, the number of practical

cases of combining Gua Sha and cupping therapy in the nursing of shoulder periarthritis has been increasing. This paper systematically sorts out the process, constructs a detailed nursing plan of Gua Sha combined with cupping therapy, and evaluates its clinical effect, aiming to provide standardized practical reference and basis for TCM characteristic nursing of shoulder periarthritis.

2. Application process of Gua Sha combined with cupping TCM nursing in the clinical treatment of patients with shoulder periarthritis

2.1. Pre-operation evaluation and preparation

2.1.1. Patient evaluation

First, detailed communication was conducted with the patient to understand their medical history and specific symptoms, so as to perform TCM syndrome differentiation and classification, and clarify whether the patient belongs to wind-cold-damp Bi type, Qi stagnation and blood stasis type, or Qi and blood deficiency type. Second, systematically evaluated and recorded the patient's symptoms, including the location, nature and degree of shoulder joint pain; if conditions permit, the scoring was completed using methods such as VAS (Visual Analog Scale) [2]. Third, the patient's shoulder mobility was measured and tested, such as detecting and recording the range of anterior flexion, posterior extension, abduction, internal rotation and external rotation of the shoulder joint. Finally, the patient's overall condition was observed to confirm that there are no skin lesions, infections, bleeding tendencies, etc., and verify that there are no contraindications such as severe cardiovascular diseases, excessive weakness or empty stomach.

2.1.2. Environment preparation

The nursing operation was performed in the treatment room. The treatment room was required to be quiet, warm and windproof, and the central air conditioning is adjusted to ensure the temperature is maintained at 26–28 ℃ to avoid the patient catching cold.

2.1.3. Article preparation

First, disinfected Gua Sha boards, special Gua Sha oil, glass cups or air extraction cups were prepared. Among them, ox horn or stone needle materials were preferred for Gua Sha boards, and Gua Sha oil was replaced with similar media [3]. Second, prepare commonly used equipment such as 95% alcohol cotton balls, hemostats, sterile gauze, lighters, and treatment towels. In addition, ensure that all instruments were used by one person and disinfected once [4].

2.1.4. Patient preparation

The patient was communicated before diagnosis and treatment. On the one hand, explain the process and purpose of the treatment operation in detail, and let the patient understand the possible feelings such as soreness and distension, and the appearance of sha during the treatment, so that the patient can be mentally prepared [5]. On the other hand, patient's informed consent was collected and the patient was assisted to choose a suitable posture, such as a comfortable sitting position or a contralateral recumbent position, to ensure that the shoulder and part of the neck and back areas are fully exposed [6].

2.2. Selection of acupoints and areas

2.2.1. Principles of acupoint and area selection

The treatment should follow the principle of "where the meridian passes, the treatment reaches", focusing on selecting acupoints of the Three Yang Meridians of the Hand and local Ashi Points [7]. The Three Yang Meridians of the Hand include the Large Intestine Meridian of Hand-Yangming, the Triple Burner Meridian of Hand-Shaoyang, and the Small Intestine Meridian of Hand-Taiyang [8].

2.2.2. Main meridians and areas for Gua Sha

Two main meridians were selected for Gua Sha: one is from Fengchi Point on the neck along Jianjing Point to the acromion; the other is from Tianzhu Point at the root of the neck along the medial edge of the scapula to the posterior axillary line. The key scraping areas were divided into four parts: first, near Zhongfu Point in the front of the shoulder; second, near Jianzhen Point behind the shoulder; third, the area of Jianyu and Jianliao Points on the lateral side of the shoulder; fourth, the lateral side of the upper arm.

2.2.3. Main acupoints for cupping

Four main acupoints were selected for cupping: Jianyu, Jianliao, Jianzhen and Ashi Points, among which Ashi Point is the tender point. In addition, auxiliary acupoints should be reasonably selected according to syndrome differentiation. For example, Fengmen and Dazhui were selected for wind-cold-damp Bi type; Geshu can be selected for Qi stagnation and blood stasis type; Zusanli and Qihai can be selected for Qi and blood deficiency type.

2.3. Specific operational steps

2.3.1. Gua Sha operation

First, Gua Sha oil was evenly applied to the area to be scrapped. Second, hold the Gua Sha board at a 45° angle to the skin, and a one-way scraping method was adopted. The scraping force was gradually increased from light to heavy, but it needs to be adjusted individually based on the patient's tolerance and the occurrence of soreness and distension [9]. Third, the scraping order was clarified: first scrape the neck and upper back, then the area around the shoulder joint. For areas with obvious pain in the patient, such as Ashi Points, heavy techniques or point pressing methods should be used for key stimulation. Fourth, the scraping time was clarified: the duration of each area should be controlled according to the actual situation, usually scraping until uniform red-purple sha spots or plaques appear (sha formation), generally scraping each area 20–30 times, with the total time was controlled at 15–20 minutes.

2.3.2. Cupping operation

First, after the Gua Sha operation, the residual Gua Sha medium on the local skin was cleaned. Second, the cupping operation was started, usually selecting the flash-fire method or air extraction method to adsorb the cups on the selected acupoints. The cupping time should also be based on the actual situation, with the degree of redness, purple red or a small amount of ecchymoses on the patient's local skin, generally between 10–15 minutes. In addition, for patients with severe cold-damp or blood stasis, the moving cupping method can also be used: apply medium to the patient's shoulder pain area, and after the cup is adsorbed, slowly move it up, down, left and right along the direction of the muscles several times until the skin appears flushed [10]. Third, during the cupping process, it is necessary to observe the patient's situation in real time, including the changes of the skin inside the cup and the patient's own reaction.

2.3.3. Cup removal and arrangement

First, the skin at the cup mouth was pressed gently with the thumb to let air enter the cup, the pressure was released and the cup was slowly removed. Second, the skin was gently wiped with sterile gauze and check whether there are blisters or lesions in the cupping area. If small blisters appear, no treatment is needed, and the patient was absorb and recover by themselves. If large blisters appear, sterile treatment is required to avoid infection [11]. Third, after the cupping operation, the patient was communicated, they were advised to avoid getting cold water on the cupping area within 4–6 hours, keep warm, and drink an appropriate amount of warm boiled water.

2.4. Nursing plan and course of treatment

2.4.1. Plan

A combined nursing plan of Gua Sha and cupping therapy was adopted, emphasizing Gua Sha first and then cupping. The function of Gua Sha was used to open the interstitial spaces and initially promote blood circulation, creating conditions for cupping to dispel pathogens more deeply.

2.4.2. Frequency and course of treatment

The specific treatment frequency needs to be personalized according to the severity of the patient's condition. For most patients, treatment was performed 2–3 times a week. Patients with obvious pain in the acute phase can choose a frequency of once every two days in the early stage, and reduce the frequency to 1–2 times a week after the pain is relieved. One course of treatment consists of 7–10 nursing sessions, with a rest of 3–5 days between courses, and usually 2–3 courses as the treatment period.

2.5. Precautions and contraindications

During the treatment period, the operator was required to pay attention to the following matters and avoid various contraindications. First, the choice of operation force must be individualized, try to keep it within the patient's comfortable tolerance, and avoid using brute force. Second, the appearance of ecchymoses after sha formation or cupping is a normal phenomenon, which should be explained to the patient, and it will subside on its own in about 3–7 days. Third, after the treatment, remind the patient to keep the shoulder warm during the entire course of treatment, avoid blowing wind and catching cold; at the same time, encourage the patient to cooperate with gentle active functional exercises, such as pendulum exercises. Fourth, clarify the contraindications of this nursing treatment plan: when the patient's shoulder skin has ulcers, lesions, rashes, etc., or the shoulder is a tumor location, this plan should be used with caution; when the patient has symptoms such as high fever, convulsions, hemorrhagic diseases, etc., this plan should be avoided; when the patient is pregnant or menstruating, this plan should be used with caution [12]. When the patient has underlying diseases such as severe heart disease and hypertension, heavy techniques and strong stimulation should be used with caution.

3. Effect performance of Gua Sha combined with cupping TCM nursing for patients with shoulder periarthritis

3.1. Significant and rapid pain relief effect

The TCM nursing model of Gua Sha combined with cupping therapy has a significant effect in relieving patients' pain. According to practical cases, most patients reported that after 1–2 sessions of combined nursing, the sense of

heaviness and tightness in the shoulder was relieved, and their pain was significantly reduced, especially in terms of night rest pain and activity pain. According to the comparison of VAS scores before and after treatment, it can be determined that under this treatment plan, the pain reduction range of patients is usually greater than that of simple conventional nursing methods such as oral non-steroidal anti-inflammatory drugs, simple hot compress or low-frequency electrotherapy.

From the perspective of TCM theory, Gua Sha directly acts on the skin and meridians, which can effectively and quickly relieve the tension of local muscle fascia; at the same time, cupping therapy can further stretch the deep muscle tissue of the patient's shoulder through negative pressure suction, thereby promoting the absorption and metabolism of inflammatory substances [13]. The synergistic use of the two can achieve the conditioning goal of "pain disappears when meridians are unblocked" faster. Conventional nursing usually chooses a single target for treatment, while the combined therapy quickly intervenes in the pain pathway from multiple levels, thus showing a better pain relief effect.

3.2. Obvious improvement of shoulder joint mobility

The TCM nursing model of Gua Sha combined with cupping therapy also has a significant effect in improving shoulder joint mobility. According to patient feedback, after 1–2 courses of treatment, the range of anterior flexion, abduction, posterior extension and rotation of their shoulder joints gradually increases, and the shoulder mobility is significantly enhanced, and the impact on daily actions such as combing hair, dressing and touching the back is also greatly reduced. The results of joint function scores such as Constant-Murley show that the improvement rate of the combined nursing model is better than that of the control group receiving only conventional functional exercises.

It is not difficult to find that the combined therapy not only has an analgesic effect, but also can continuously dredge the meridians and Qi-blood, eliminate the soft tissue adhesion in the patient's shoulder, thereby increasing local blood circulation and nutritional supply, and creating a good internal environment for the recovery of joint function [14]. In addition, due to the significant pain reduction effect of the combined nursing model, the effect of improving mobility is more lasting and stable, which can effectively reduce the aggravation of joint "freezing" caused by the patient's fear of pain.

3.3. Superior comprehensive curative effect and high patient satisfaction

The combined Gua Sha and cupping nursing model has a more prominent comprehensive curative effect and is highly praised by the majority of patients. On the one hand, most patients reported that their sleep quality improved and their overall comfort increased after combined nursing. On the other hand, in the evaluation of TCM syndrome scores, the patients' evaluations of pain, tenderness, mobility, fear of cold, etc. are also higher than those of the conventional nursing group. In addition, since the combined nursing method is a non-drug, external physical therapy, it can avoid side effects on the patient's gastrointestinal tract and other parts.

Overall, the combined nursing method of Gua Sha and cupping fully follows the theoretical basis of TCM "holistic concept" and "syndrome differentiation and nursing" [15]. It can not only relieve local symptoms, but also act on the regulation of the body's overall Qi-blood state, especially for shoulder periarthritis of wind-cold-damp type and Qi stagnation and blood stasis type. In addition, this nursing method has the characteristics of comprehensiveness, safety and naturalness, so it has more advantages in patient acceptance and long-term rehabilitation management.

4. Conclusion

In summary, in the treatment and nursing of patients with shoulder periarthritis, this paper organically combines Gua Sha and cupping therapy to form a standardized process from evaluation, acupoint selection, operation to course management. This combined nursing plan gives full play to the synergistic effect of Gua Sha and cupping therapy: Gua Sha can "open the interstitial spaces and expel excess pathogens, and initially promote blood circulation", while cupping therapy can "disperse cold-dampness and activate deep tissues", thus jointly achieving the purposes of dispelling pathogens and dredging meridians, promoting Qi and blood circulation, relieving spasm and pain. Clinical effect observation shows that it has clear effects in relieving pain, restoring joint function and improving patients' overall quality of life, which is superior to some conventional nursing methods. It has the characteristics of simple operation, few side effects and good patient compliance, and has the value and significance of wide promotion and application.

Disclosure statement

The author declares no conflict of interest.

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Exploration of the Application of Humanistic Care in High-Quality Nursing Services of Gastroenterology Department

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Abstract: *Objective*: To explore the application effect of humanistic care in high-quality nursing services of the gastroenterology department. *Methods*: A total of 40 patients in the gastroenterology department admitted to our hospital from July 2024 to July 2025 were randomly divided into two groups. The experimental group (20 cases) received high-quality nursing services integrated with humanistic care, while the control group (20 cases) only received high-quality nursing services. *Results*: The scores of depression (SDS) and anxiety (SAS) in the control group were significantly higher than those in the experimental group; the understanding and mastery of dietary health knowledge in the control group were significantly lower than those in the experimental group; the satisfaction degree of the control group was significantly lower than that of the experimental group, and the differences between the groups were statistically significant ($p < 0.05$). *Conclusion*: The application of humanistic care in high-quality nursing services of the gastroenterology department can not only promote the rapid recovery of the body, but also improve patients' compliance, effectively alleviate their negative emotions, guide patients to develop good dietary and living habits, and effectively improve their quality of life. Therefore, it has high clinical application value and is worthy of vigorous promotion and active reference.

Keywords: Humanistic care; Gastroenterology department; High-quality nursing services; Application

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1. Introduction

In recent years, with the continuous advancement of medical models and the increasing emphasis on patient-centered care, the integration of humanistic care into clinical nursing practice has gained widespread attention. High-quality nursing services aim to improve patient outcomes through standardized and meticulous nursing interventions. However, the specific role of humanistic care within such services, particularly in specialized departments such as gastroenterology, remains to be further explored. Gastroenterology patients often experience physical discomfort and negative emotions, making comprehensive nursing support essential. This study aims to investigate the application effect of humanistic care in high-quality nursing services for gastroenterology patients,

providing a reference for optimizing clinical nursing strategies.

2. Materials and methods

2.1. General information

A total of 40 patients in the gastroenterology department admitted to our hospital from July 2024 to July 2025 were selected as the research subjects, and they were randomly divided into the experimental group and the control group, with 20 cases in each group.

(1) Control group

11 males and 9 females; aged 19–78 years, with an average age of (45.31 ± 5.14) years.

(2) Experimental group

7 males and 13 females; aged 20–77 years, with an average age of (45.17 ± 5.22) years. There were no statistically significant differences in general data between the two groups ($p > 0.05$), so they were comparable.

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria for related diseases in the gastroenterology department;

(2) Aged 18 years and above, able to communicate normally;

(3) Patients or their family members fully informed, voluntarily participating and signing the informed consent form, etc.

2.1.2. Exclusion criteria

(1) Unable to cooperate with nursing and research;

(2) With severe underlying diseases;

(3) Incomplete clinical data, etc.

2.2. Nursing methods

The control group only received high-quality nursing services, mainly including routine content such as observation of adverse reactions, basic nursing operations, medication guidance, and environmental maintenance [1].

On the basis of high-quality nursing intervention, the experimental group integrated humanistic care into the nursing content. The specific measures are as follows:

(1) Daily care

Medical staff guide patients to attach great importance to infection prevention, conduct careful cleaning and disinfection, ensure personal food hygiene, and avoid cross-infection. At the same time, correct patients' mentality, ensure they have sufficient sleep, and develop healthy living habits [2].

(2) Psychological care

Patients in the gastroenterology department have complex and recurrent conditions, leading to easy occurrence of negative emotions such as depression and irritability, and their compliance with treatment and nursing also decreases accordingly. Medical staff understand and respect patients' emotional fluctuations, increase face-to-face communication opportunities with patients, guide them to express their anxiety and pressure, and take effective measures to comfort their emotions in a timely manner [3]. For

example, tell patients about successful cases to enhance their self-confidence, enable them to maintain a positive attitude, and actively participate in nursing and treatment [4].

(3) Medication care

When administering medication to patients, nurses should strictly follow the doctor's advice and repeatedly emphasize to patients the serious harm of arbitrarily discontinuing medication; after patients take the medication, nurses need to carefully observe whether patients have adverse reactions and inquire about their feelings in a timely manner. If any abnormalities occur, they should feed back to the attending doctor immediately for corresponding adjustments and treatment [5].

(4) Dietary guidance

Medical staff formulate personalized dietary plans for patients based on their specific conditions, eating habits and nutritional status. First, explain in detail the close relationship between diet and disease rehabilitation to patients, and emphasize the importance of a reasonable diet. For example, for patients with gastric ulcers, explain the reasons for avoiding spicy, too cold, overheated and irritating foods, as well as the benefits of regular eating and small frequent meals [6]. Secondly, specifically guide patients to choose appropriate types of food. For example, encourage patients with weak digestive function to intake easily digestible liquid or semi-liquid foods, such as rice porridge, noodle soup, steamed eggs, etc.; for cirrhotic patients who need to limit protein intake, inform them the detail appropriate daily protein intake and sources of high-quality protein, such as lean meat, fish, soy products, etc., and remind them to avoid rough and hard foods to prevent bleeding from esophageal varices. At the same time, patiently correct patients' bad eating habits, such as advising patients to quit smoking and limit alcohol, and reduce the intake of high-oil, high-sugar and high-salt foods [7].

(5) Health education and humanistic care

The purpose of humanistic care is to transform the learned nursing knowledge into basic care and emotional dedication to patients, which belongs to the scope of cultural nursing. In practice, nurses should not only have necessary nursing skills, but also provide services to patients from emotional, spiritual and cultural levels, which can not only show care for life, but also ensure that patients' physical and mental health needs are fully met. Therefore, humanistic care should be reflected in all links of high-quality nursing services, improve nurses' humanistic care ability, and create a people-oriented nursing atmosphere in the hospital, so that patients can feel the care and respect from nurses. In addition, throughout the nursing process, nurses should always keep a smile, have exquisite nursing skills, kind language and gentle movements, pay attention to transmitting positive energy to patients and gain their trust. Health education is a characteristic activity in high-quality nursing services, which will promote the further improvement of nursing level. Through health education activities implemented by nurses, patients and their family members can abandon unhealthy behaviors and establish the concept of healthy diet and life, which can not only speed up the patients' recovery, but also prevent the recurrence of diseases. In this process, nurses should be good at stimulating the subjective initiative of patients and their family members, explain in detail matters related to the patients' own diseases, enable patients and their family members to have a sufficient understanding of the condition, independently adjust their mentality, develop healthy dietary and living habits, and form stable and lasting healthy behaviors [8,9].

2.3. Observation indicators

(1) Anxiety and depression scoring indicators

The Self-Rating Anxiety Scale (SAS) and Self-Rating Depression Scale (SDS) were used to evaluate the psychological status of the two groups of patients before and after nursing. The higher the standard score of the SAS scale, the more serious the anxiety. Among them, 50–59 points were mild anxiety, 60–69 points were moderate anxiety, and 70 points and above were severe anxiety. The higher the standard score of the SDS scale, the more serious the depression. 53–62 points were mild depression, 63–72 points were moderate depression, and 73 points and above were severe depression.

(2) Nursing satisfaction scoring indicators

A self-designed nursing satisfaction questionnaire was used for evaluation. Among them, 90–100 points were very satisfied, 80–89 points were satisfied, 60–79 points were average, and below 60 points were dissatisfied. After the nursing, the investigators explained the questionnaire filling requirements to the patients in detail, guided the patients to complete it independently and collected it on the spot.

(3) Health education scoring indicators

Mainly including patients' understanding and cognition of dietary health knowledge, such as dietary methods and precautions. Each item was scored out of 100 points.

2.4. Statistical methods

All data in this study were processed using SPSS 26.0 statistical software. Measurement data were expressed as mean ± standard deviation ($\overline{x} \pm s$), and inter-group comparison was performed using independent sample *t*-test; count data were expressed as rate (%), and inter-group comparison was performed using χ^2 test. A p-value < 0.05 was considered statistically significant [10].

3. Results

3.1. Comparison of SAS and SDS scores between the two groups

In terms of SAS and SDS scores, the control group was higher than the experimental group, and the differences between the groups ($p < 0.05$) were statistically significant, as shown in **Table 1**.

Table 1. Comparison of SAS and SDS scores between the two groups ($\overline{x} \pm s$, points)

Group	n	SAS score		SAS score	
		Before intervention	After intervention	Before intervention	After intervention
Experimental group	20	58.47 ± 6.71	43.06 ± 3.82	65.79 ± 5.38	42.83 ± 4.19
Control group	20	59.81 ± 6.64	33.47 ± 4.06	66.86 ± 5.44	30.42 ± 5.16
t	–	0.7774	9.4225	0.7659	10.2261
p	–	0.4400	0.0000	0.4468	0.0000

3.2. Comparison of nursing satisfaction scores between the two groups

In terms of nursing satisfaction, the control group was significantly lower than the experimental group, and the difference between the groups ($p < 0.05$) was statistically significant, as shown in **Table 2**.

Table 2. Comparison of nursing satisfaction scores between the two groups [n(%)]

Group	n	Very satisfied	Satisfied	Dissatisfied	Total satisfaction
Experimental group	20	11	8	1	19(95.00)
Control group	20	8	7	5	15(75.00)
χ^2					4.3242
p					0.0375

3.3. Comparison of dietary health education scores between the two groups

In terms of dietary health education, the scores of the experimental group in dietary methods, the importance of diet and dietary precautions were significantly higher than those of the control group, and the difference between the groups ($p < 0.05$) was statistically significant, as shown in **Table 3**.

Table 3. Comparison of dietary health education scores between the two groups ($\overline{x} \pm$ s, points)

Group	n	Dietary methods	Importance of diet	Dietary precautions
Experimental group	20	97.53 ± 1.31	96.37 ± 2.55	94.65 ± 3.16
Control group	20	78.51 ± 2.43	76.45 ± 3.51	80.67 ± 4.32
t		37.7368	25.1483	14.3060
p		0.0000	0.0000	0.0000

4. Discussion

First, in terms of improving the negative emotions of patients in the gastroenterology department, the research results show that the scores of the experimental group are much lower than those of the control group, and psychological care in humanistic care plays an important role. Gastroenterological diseases are characterized by easy recurrence and long treatment cycle, so patients are prone to various negative emotions such as depression and anxiety. Nurses in the experimental group communicated face-to-face with patients to understand their anxiety and pressure, and combined with successful cases, the patients' negative emotions were effectively relieved, and their confidence in overcoming the "illness" was greatly increased. Emotional support can reduce the occurrence of negative emotions such as depression and anxiety, correct patients' mentality, and lay a solid foundation for patients' recovery and discharge [11].

Second, in terms of patient satisfaction, the control group was significantly lower than the experimental group. The experimental group integrated humanistic care measures on the basis of high-quality nursing, such as smiling service, exquisite technology, kind language, gentle movements, transmitting positive energy, and making patients feel respected and cared for. Specific as follows: in terms of dietary guidance, nurses formulated personalized dietary plans according to the actual situation of patients and patiently explained relevant precautions; in terms of medication care, nurses administered medication according to the doctor's advice, observed adverse reactions, and fed back abnormalities in a timely manner; in terms of daily care, guided patients to develop healthy habits and ensured they had sufficient sleep, etc. This comprehensive and warm nursing service made patients feel respected and cared for, and their satisfaction also increased accordingly [12]. The control group focused on routine basic nursing and ignored emotional nursing services, resulting in low patient satisfaction. Therefore, nurses

should realize the importance of humanistic care, pay attention to integrating humanistic care into daily nursing, and further improve patient satisfaction [13].

Third, in terms of dietary health education, the scores of the experimental group in dietary methods, the importance of diet and dietary precautions were significantly higher than those of the control group. As an important part of humanistic care, nurses popularized knowledge about gastroenterological diseases to patients and their family members in an easy-to-understand way, corrected their unhealthy behaviors, and helped them establish healthy living awareness [14,15]. Especially in dietary guidance, formulate plans for different diseases and individual conditions. For example, patients with gastric ulcers need to avoid acidic and irritating foods, and emphasize the principles of small frequent meals and balanced nutrition, so that patients can clearly understand the close relationship between diet and disease rehabilitation, thereby actively cooperating with and adopting healthy dietary suggestions. Telephone follow-up after discharge extends health education to home care, which helps patients form stable and lasting healthy behaviors, and is of great significance for preventing the recurrence of old diseases and promoting the recovery of physical health.

5. Conclusion

In conclusion, the implementation of high-quality nursing services with humanistic care for patients in the gastroenterology department can not only effectively relieve their negative emotions, improve patients' treatment compliance, but also improve patients' quality of life, help patients develop good dietary and living habits, and promote the recovery of physical health. It has high clinical application value and can be used for reference and promotion.

Disclosure statement

The author declares no conflict of interest.

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Exploration of Optimizing Hospital Nursing Work in the New Era

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Abstract: Under the background of the new era, with the continuous advancement of the Healthy China strategy, the general public has put forward higher requirements for hospital nursing work. As a bridge between medical services and patient needs, nursing work directly affects medical quality and safety, patients' medical experience, and the sustainable development of the medical and health cause. Based on this, this paper briefly analyzes the connotation and development requirements of hospital nursing work in the new era, as well as the current situation of hospital nursing work, and discusses the optimization paths of hospital nursing work in the new era, aiming to provide certain theoretical support and practical guidance for the improvement of hospital nursing work.

Keywords: New era; Hospital nursing; Optimization paths

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1. Introduction

The new era has endowed hospital nursing work with new connotations and missions. Nursing work is no longer limited to traditional disease care, condition observation, and basic operations, but extends to the entire process of prevention, health care, treatment, rehabilitation, and palliative care, and develops in the direction of personalization, precision, humanization, and intelligence. It requires nursing work to pay more attention to quality and safety, patient experience, connotation construction, and team literacy. Therefore, exploring the optimization paths of hospital nursing work in the new era and improving the quality and level of nursing services have become new issues facing current hospital nursing work.

2. Connotation and development requirements of hospital nursing work in the new era

2.1. Connotation of hospital nursing work in the new era

The connotation of hospital nursing work in the new era is an extension and expansion of traditional nursing.

Its core is to adhere to people's health as the center, take the whole-life cycle health service as the fundamental starting point, and build a nursing service system with full coverage of nursing service objects, all-round nursing service content, and full innovation of nursing service models. First, full coverage of nursing service objects, including healthy people, sub-healthy people, patients, the elderly, rehabilitation groups and other groups at all levels, realizing the whole-process nursing from disease prevention to end-of-life care. Second, all-round nursing service content, including traditional content such as disease care, condition observation, basic nursing, and treatment cooperation, as well as diversified content such as health education, psychological counseling, rehabilitation guidance, nutritional support, palliative care, and community extended nursing [1]. Third, full innovation of nursing service models, breaking the limitations of traditional ward nursing, promoting the extension of nursing services to communities, families, and home settings, and combining intelligent technologies to build a precise, personalized, and convenient nursing service model.

2.2. Development requirements of hospital nursing work in the new era

With the continuous development of medical technology, the complexity and risk of nursing work have been continuously improved, and the management of nursing quality and safety has become more and more strict. In this context, hospital nursing work should strengthen the awareness of quality and safety, improve the management system of nursing quality and safety, standardize nursing operation processes, strengthen the monitoring of nursing quality, and timely detect and eliminate potential nursing safety hazards; strengthen the training of nursing staff on quality and safety, improve their risk prevention ability and emergency response ability, and eliminate the occurrence of nursing errors and accidents [2]. At the same time, hospitals should strengthen the construction of nursing teams, improve the structure of nursing teams, and improve the recruitment, training, assessment, and promotion mechanisms of nursing staff; strengthen the professional training and continuing education of nursing staff, especially the training of professional ethics and communication skills, enhance their sense of responsibility, service awareness, and humanistic care ability, and build a nursing team with political qualification, exquisite professional skills, good work style, and high-quality service.

3. Analysis of the current situation of hospital nursing work

3.1. The construction of nursing teams needs to be improved

The structure of nursing teams in many hospitals is obviously unbalanced. For example, there is a large gap in clinical front-line nursing staff, and the proportion of nursing staff in non-clinical positions such as administration and logistics is relatively high, resulting in a shortage of clinical nursing manpower, excessive workload of nursing staff, and affecting the quality and level of nursing services. In addition, some nursing staff lack systematic training and continuing education, their professional knowledge is not updated in time, they are not proficient in new nursing technologies and new diagnosis and treatment equipment, and cannot provide precise and professional nursing services. At the same time, there is a lack of specialist nursing talents, and there is an insufficient number of nursing talents in specialist fields such as critical care nursing, geriatric nursing, rehabilitation nursing, oncology nursing, and palliative care [3]. In addition, the scientific research ability of nursing staff is generally weak. Most nursing staff have no scientific research awareness and methods, making it difficult to improve nursing quality through scientific research innovation.

3.2. The nursing service model is relatively rigid

At present, the nursing work in some hospitals pays too much attention to disease care and basic operations, ignoring the psychological and social needs of patients. When providing nursing services, nursing staff lack communication with patients, pay insufficient attention to negative emotions such as anxiety and fear of patients, and cannot provide timely psychological counseling and emotional support, which leads to poor patient experience and low satisfaction. In addition, the traditional nursing service model is mainly "one-size-fits-all", lacking pertinence and personalization, and cannot meet the diversified and personalized health needs of the general public in the new era [4]. At the same time, nursing services lack precision. The observation of patients' condition changes and rehabilitation progress is not detailed enough, and nursing interventions are not in place, making it impossible to achieve precise nursing of "one person, one policy", which directly affects the nursing effect and patients' rehabilitation process.

3.3. The level of nursing informatization needs to be strengthened

With the rapid development of digital technology, informatization and intelligence have become the development direction of nursing work in the new era, and also an important way to improve nursing efficiency and quality. However, the level of nursing informatization in some hospitals is relatively low, and the application of intelligence is insufficient, which cannot meet the development needs of nursing work in the new era. On the one hand, due to insufficient investment in the construction of nursing informatization in hospitals, the informatization system is not perfect, and there is a lack of a unified nursing informatization platform, resulting in the inability to share and integrate nursing data, leading to low efficiency of nursing work [5]. On the other hand, the application of intelligent nursing equipment is relatively small, the popularity of intelligent equipment such as intelligent infusion pumps, intelligent monitors, and nursing robots is not high, the informatization literacy of nursing staff is lacking, and they lack the operational ability of informatization systems and intelligent equipment, so they cannot give full play to the role of intelligent technologies and equipment in nursing work.

4. Optimization paths of hospital nursing work in the new era

4.1. Strengthen the construction of nursing teams and implement the responsibilities of nursing staff

Hospitals should formulate scientific and reasonable recruitment and allocation plans for nursing staff according to their own development scale and nursing work needs. In terms of age structure, attach importance to recruiting nursing staff of different age groups, reasonably match young nurses and middle-aged and elderly nurses, give play to the experience advantages of middle-aged and elderly nurses and the vitality advantages of young nurses, and promote the experience inheritance and healthy development of nursing teams ; in terms of educational structure, raise the educational threshold for nursing staff recruitment, focus on recruiting nurses with bachelor's degree or above, strengthen the continuing education and academic improvement training for nurses with low educational background, gradually increase the proportion of nurses with bachelor's degree or above, and improve the professional theoretical level of nursing teams; in terms of post structure, reasonably allocate nursing manpower, reduce the number of nursing staff in non-clinical positions such as administration and logistics, enrich the clinical front-line nursing manpower, and dynamically allocate nursing manpower according to factors such as department characteristics, number of patients, and severity of illness, so as to ensure the supply of clinical nursing manpower

and reduce the workload of nursing staff [6]. In addition, strengthen the construction of grass-roots nursing teams, and improve the quantity and quality of grass-roots nursing staff through paired assistance, talent sinking, training and guidance, so as to promote the balanced distribution of nursing resources. By formulating personalized training plans, on the basis of strengthening the training of basic nursing skills, standardizing nursing operation processes, and improving the basic nursing ability and risk prevention ability of nursing staff, carry out specialist nursing training focusing on specialist nursing, critical care nursing, geriatric nursing, rehabilitation nursing and other key fields, cultivate specialist nursing talents, and improve the professional precision and pertinence of nursing staff.

In addition, formulate clear job descriptions for nursing staff to facilitate their reference, so as to better provide nursing services for patients and shorten the waiting time for patients [7]. At the same time, keep pace with the times and introduce an intelligent scheduling system, which dynamically adjusts the work schedules of medical staff according to the real-time outpatient visit prediction data, ensuring that there are sufficient nursing resources during peak visiting periods.

4.2. Innovate the nursing service model and optimize basic nursing services

Hospital nursing work in the new era should establish a "patient-centered" concept and integrate humanistic care into the whole process of nursing work. Strengthen the training of nursing staff's humanistic literacy, improve their communication ability, empathy, and sense of responsibility, so that nursing staff respect, care for, and understand patients; establish a good nurse-patient communication mechanism. Nursing staff should take the initiative to communicate with patients, patiently listen to their demands, timely answer their questions, alleviate their negative emotions such as anxiety and fear, give them sufficient psychological counseling and emotional support, and strengthen humanistic care [8].

At present, people's health needs are increasingly diversified and personalized. In this regard, hospitals should continuously optimize basic nursing services. For example, assign special nurses at the entrance of each department of the hospital to be responsible for guidance, provide health and medical guidance for patients, guide elderly patients to use self-service machines, help disabled or critically ill patients go through procedures, and improve the efficiency of medical treatment [9]. In addition, nursing staff should break the traditional one-size-fits-all nursing model in practical work and provide personalized and precise nursing services for patients. Nursing staff should formulate personalized nursing plans according to individual differences such as patients' age, gender, condition, psychological state, and living habits, and implement personalized nursing of "one person, one policy". Strengthen the observation of patients' condition changes and rehabilitation progress, adjust the nursing plan in a timely manner, and ensure the timeliness and accuracy of nursing interventions. Take multiple measures to promote the detailed management of nursing services, so that patients can experience the meticulous care and exquisite medical skills of medical staff in every link from admission reception, condition assessment, nursing operations to discharge guidance. For example, in the condition assessment stage, nursing staff comprehensively grasp the patients' physical conditions and potential risks through detailed inquiry and examination, providing accurate basis for the formulation of subsequent nursing plans.

4.3. Improve the nursing management system and improve the quality of nursing staff

Hospital nursing management should abandon the traditional extensive management model, implement refined management concepts and methods, and improve the refinement level of nursing management. First, establish

the management concept of "details determine success or failure", integrate refined management into every link of nursing work, and strengthen the detailed control of various aspects such as nursing quality, nursing processes, nursing manpower, and nursing costs. Second, optimize the nursing service process, simplify the procedures for patients' admission, medical treatment, nursing, discharge and other links, reduce patients' waiting time, and improve the convenience and efficiency of nursing services [10]. Third, strengthen the refined monitoring of nursing quality, establish a scientific and reasonable nursing quality monitoring index system, and use various methods such as daily inspections, random spot checks, and special inspections to conduct all-round and whole-process monitoring of nursing quality, timely discover and solve problems in nursing work, and promote the continuous improvement of nursing quality.

Hospitals should improve the assessment and evaluation system for nursing staff and build a scientific, reasonable, comprehensive and systematic assessment and evaluation system for nursing staff. First, improve the assessment index system, increase the assessment weight of nursing quality, patient satisfaction, professional ability, humanistic care, scientific research achievements and other aspects, and form an assessment model combining process assessment and result assessment, quantitative assessment and qualitative assessment [11]. Second, innovate assessment methods, adopt various assessment methods such as daily dynamic assessment, comprehensive evaluation, patient evaluation, and colleague evaluation to comprehensively, objectively and fairly evaluate the work performance of nursing staff. Finally, strengthen the application of assessment results, directly link the assessment results with nursing staff's salary and benefits, promotion, selection of excellent employees, training and further study, commend and reward nursing staff with excellent assessments, interview and train nursing staff with unqualified assessments, fully mobilize the work enthusiasm and initiative of nursing staff, and stimulate the work vitality of nursing teams [12].

4.4. Improve the construction of nursing informatization and enhance the efficiency of nursing work

Hospitals should increase investment in the construction of nursing informatization and intelligence, promote the development of nursing informatization and intelligence, improve nursing efficiency and quality, and reduce the workload of nursing staff. Establish a unified nursing informatization platform, integrate resources such as nursing data, patient information, and nursing processes, realize the sharing and integration of nursing data, and improve the informatization level of nursing work [13]. At the same time, actively introduce intelligent nursing equipment, such as intelligent infusion monitoring systems, mobile nursing terminals, and nursing robots, and use intelligent tools to automatically collect patients' vital sign data and perform basic nursing operations, reducing human operation errors and repetitive labor. In addition, hospitals should regularly organize training for nursing staff on informatization system operation, data processing, and information security, improve their ability to use informatization tools to carry out work, ensure the efficient application of informatization systems and intelligent equipment in nursing work, and promote the transformation of nursing work from traditional experience-based to intelligent and precise.

In addition, in traditional hospital nursing work, nursing staff need to spend a lot of time and energy on cumbersome documentation such as patient information entry and nursing record filling. These repetitive tasks not only occupy the valuable time of nursing staff, but also may lead to recording errors or omissions due to human factors, thereby affecting nursing quality and patient safety [14,15]. In this regard, hospitals have introduced nursing information systems. Through automated data entry and intelligent information management, they help nursing

staff complete various documentation work accurately and efficiently, enabling nursing staff to devote more time and energy to direct patient care, thereby effectively improving the efficiency of nursing work.

5. Conclusion

In summary, in the context of the new era, the Healthy China strategy is constantly advancing, and the reform of the medical and health system is deepening. While putting forward higher requirements for hospital nursing work, it also brings new opportunities for the development of nursing work. Nursing work is an important part of the medical and health cause, and also a guarantee for meeting the all-round and whole-cycle health needs of the general public. Therefore, hospitals should further strengthen the construction of nursing teams, innovate nursing service models, improve the nursing management system, and improve the construction of nursing informatization, so as to promote the high-quality development of China's nursing cause.

Disclosure statement

The author declares no conflict of interest.

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Application Effect of Hierarchical Nursing Management Model in Hospital Nursing Management

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Abstract: *Objective*: To explore the implementation plan of the hierarchical nursing management model and its application effect in actual hospital work, and propose more effective and guaranteed management measures to provide reference for the improvement of modern medical and nursing service quality. *Methods*: Based on a controlled experiment, 68 nursing staff from our hospital from March 2024 to February 2025 were enrolled and randomly divided into two groups with 34 cases in each group. The control group adopted conventional management, while the observation group implemented the hierarchical nursing management model to form a new working mode. Finally, their performance in work enthusiasm, nursing quality, as well as patient satisfaction and assessment scores were discussed. *Results*: The data of the observation group showed that it was superior to the control group in multiple indicator dimensions (patient satisfaction, work enthusiasm, work efficiency, nursing quality, and assessment scores), and the difference was statistically significant ($p < 0.05$). *Conclusion*: In hospital nursing management work, there is an urgent need to implement modern and effective management models, and the hierarchical nursing management model is one of them. It has truly reversed the concept of nursing staff, making them realize the importance of maintaining work enthusiasm and fulfilling their duties. Moreover, through the penetration of modern management concepts, it has effectively improved the level of professional nursing services and patient satisfaction, and contributed to the harmony of doctor-patient relations.

Keywords: Hierarchical nursing management model; Hospital nursing; Management; Quality; Satisfaction

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1. Introduction

The public pays attention to their own health and puts forward higher requirements for nursing services. Hospitals also keep up with the times, adjust their working modes, and deepen their efforts in nursing management. The hierarchical nursing management model has unique value and connotation, which can give full play to the

maximum potential of nursing staff at different levels and with different abilities, and satisfy patients to achieve a win-win situation. In today's era, with the improvement of economic level, national health awareness is constantly growing, and the demand for health protection, medical experience and nursing quality is rising. In terms of nursing services, it is becoming more professional, continuous, humanistic and refined, forming many unwritten rules and new standards in the industry [1]. Medical institutions at all levels actively adapt to industry development trends and patient needs, take the initiative to optimize service processes, innovate working modes, continue to deepen efforts in the field of nursing management, and constantly promote the transformation of nursing work towards standardization, scientization and efficiency, supporting the improvement of overall medical level with high-quality nursing services. As an important practical model in the modern nursing management system, the hierarchical nursing management model has unique application value and management connotation. Based on the ability and qualifications of nursing staff, it scientifically allocates resources to achieve a management pattern of job-personnel matching, special personnel for special tasks, and division of labor and cooperation. Moreover, the implementation of the hierarchical management model has greatly improved work efficiency, reduced corresponding losses, maximized the strengths of nursing staff, and laid a solid foundation for the transformation and upgrading of the hospital's modern management model [2]. In this way, senior nurses focus on review affairs management, and can also influence more junior nurses, arouse their work enthusiasm, and promote the steady improvement and long-term development of the overall team quality. The optimized resource allocation makes the entire care service process smoother and more personalized, reduces nursing risks, and improves patients' medical experience, which can be described as achieving multiple goals with one action.

2. Materials and methods

2.1. General information

Based on a controlled experiment, 68 nursing staff from our hospital from March 2024 to February 2025 were enrolled and randomly divided into two groups with 34 cases in each group.

(1) Group A (control group)

Included 18 male and 16 female nursing staffs, accounting for 52.94% and 47.06% respectively; the minimum age was 23, the maximum age was 40, with an average of (31.61 ± 0.12) years; educational background: all had college degree or above; professional titles: 2 (5.88%) associate chief nurses, 7 (20.59%) senior nurses, 11 (32.35%) nurses, and 14 (41.18%) junior nurses.

(2) Group B (observation group)

Included 19 male and 15 female nursing staffs, accounting for 55.88% and 44.12% respectively; the minimum age was 21, the maximum age was 36, with an average of (29.53 ± 0.84) years; educational background: all had college degree or above; professional titles: 3 (8.82%) associate chief nurses, 8 (23.53%) senior nurses, 9 (26.47%) nurses, and 14 (41.18%) junior nurses. The baseline data between the two groups were comparable ($p > 0.05$).

2.1.1. Inclusion criteria

(1) Informed and fully supportive of the research;

(2) Aged 21–40;

(3) Working in the hospital for more than 3 years;

(4) Possessing high cognitive, understanding and language expression abilities

2.1.2. Exclusion criteria

(1) Withdrawing midway from the research;
(2) Refusing to participate in the research;
(3) Intern nurses;
(4) Incomplete general data

2.2. Methods

2.2.1. Control group: Implementing traditional nursing management model

Conventional nursing management methods were adopted. The head nurse uniformly arranged work content and generally assigned general work tasks; unified standards were implemented for training and assessment, a flexible scheduling system and work assessment system were implemented, and the work status of nursing staff was regularly inspected. The above were adaptively adjusted according to the nursing needs of each department, the level and work experience of nursing staff, etc.

2.2.2. Observation group: Implementing hierarchical nursing management model

A new hierarchical nursing management model was adopted to clearly divide the levels, powers and responsibilities of nurses with different seniority. For nursing staff at three different levels (high, medium and low), the upper-level nursing staff were responsible for the lower-level ones, and all regulations and requirements on nursing work rules within the level must be followed. At the same time, the lower-level staff should fully cooperate with the upper-level work, obey the leadership and instructions, and work together to make work efficiency more efficient and the working environment and atmosphere more harmonious.

(1) On the basis of fully grasping the actual abilities and work status of nursing staff at all levels, the head nurse should scientifically divide groups according to reasonable principles and select suitable candidates to serve as responsible group leaders and team members.
(2) When setting the responsible group leader, the professional title requirement should be clarified, such as having a nurse or above title, and being a senior nursing staff with rich experience and proficient skills; being able to fully master the professional knowledge and operational skills required by the department and having outstanding daily work performance [3]. Other members of the group should have good compliance and be able to steadily improve their professional quality and operational ability under the guidance of the responsible group leader and responsible nurse.
(3) Combine the actual situation of the hospital to formulate and continuously improve the assessment system to effectively improve the overall work quality of each nursing group and strengthen the comprehensive ability of nursing staff. At the same time, implement a feasible competition mechanism to promote a positive competition atmosphere among nursing staff; conduct regular performance assessments to objectively evaluate the daily work efficiency, skill operation level and nursing service quality of nursing staff.
(4) In the daily treatment of clinical patients, senior nursing staff should not only strengthen the verification of the implementation of medical orders but also play a leading role in guiding intermediate-level nursing staff to complete various nursing tasks with high quality and prevent nursing errors. Junior nursing staff

should regularly summarize and report their daily work content to the head nurse and take the initiative to learn new knowledge and skills emerging in nursing practice.

(5) The head nurse should fully supervise the work implementation of medium and junior nursing staff, timely point out and summarize the problems and deficiencies in their work; through weekly regular meetings, assign work tasks, clarify key content and relevant precautions, and help nursing staff at all levels clearly recognize their own shortcomings [4,5]. For existing problems, the department head nurse should organize special training and assessment, and regularly submit phased work reports to the nursing department; at the same time, implement a reward and punishment system, commend those with outstanding performance, fully mobilize the enthusiasm and initiative of nursing staff, and further promote the optimization and improvement of the clinical nursing management system [6].

2.3. Observation indicators

2.3.1. Patient satisfaction

Questionnaires were distributed in the hospital to evaluate and score the nursing staff of the control group and the observation group by patients in the department. Among them, a score greater than 95 points was rated as very satisfied, a score between 75 and 95 points was rated as satisfied, and a score less than 75 points was regarded as dissatisfied. The scores of nursing staff in groups A and B were counted:

Patient satisfaction = (very satisfied + basically satisfied)/total number of cases × percentage.

2.3.2. Work enthusiasm, work effect and nursing quality level

Evaluations were made by hospital managers, nursing staff, etc. On the basis of the previous scale, more indicators were referred to evaluate the actual work situation of nursing staff in the control group and the observation group, and scores were given from the aspects of work efficiency and quality, work enthusiasm, etc. A higher score indicates that the nursing staff has high work efficiency, enthusiasm and professionalism, and the final nursing quality is good; on the contrary, the work attitude, enthusiasm and quality need to be improved.

2.3.3. Assessment scores

Dynamic monitoring of operations before and after nursing was carried out to evaluate the theoretical and nursing operation levels of nursing staff in the control group and the observation group. Referring to the general examination content, strict scoring was carried out. A higher score indicates that the nursing staff has a high level of knowledge and professional skills; on the contrary, it indicates that the professional ability of the nursing staff needs to be improved.

2.4. Statistical methods

SPSS 18.0 statistical software was used for data analysis. $p < 0.05$ indicated that the difference was statistically significant.

3. Results

3.1. Comparison of nursing satisfaction between the control group and the observation group

Comparing the data in the table, it is obvious that the patient nursing satisfaction of the observation group is

higher, and that of the control group is at a general level, which meets $p < 0.05$. For details, refer to **Table 1**.

Table 1. Comparison of nursing satisfaction between the control group and the observation group [n(%)]

Group	Number of cases	Very satisfied	Satisfied	Dissatisfied	Satisfaction rate
Control group	34	16 (47.06)	10 (29.41)	8 (23.53)	26 (76.47)
Observation group	34	23 (67.65)	10 (29.41)	1 (2.94)	33 (97.06)
χ^2					6.275
p					0.012

3.2. Comparison of work situation and quality between the control group and the observation group

Comparing the data in the table, based on the control group, the observation group had higher scores in this item. It is obvious that the nursing staff in the observation group had higher work efficiency, higher work enthusiasm, and higher nursing quality level, which meets $p < 0.05$. For details, refer to **Table 2**.

Table 2. Comparison of work situation and quality between the control group and the observation group ($\overline{x} \pm s$, points)

Group	Number of cases	Work efficiency	Work quality	Work enthusiasm
Control group	34	86.35 ± 1.56	84.18 ± 2.89	87.51 ± 2.62
Observation group	34	98.77 ± 1.93	97.40 ± 2.51	97.83 ± 3.54
t		29.183	20.138	13.664
p		0.000	0.000	0.000

3.3. Comparison of professional assessment scores between the control group and the observation group

Comparing the data in the table, in the assessment scores before and after nursing management, the levels of both groups of personnel in the control group and the observation group have slightly improved, but the scores of the nursing staff in the observation group are higher, indicating that their professional level is superior to that of the control group, which meets $p < 0.05$. For details, refer to **Table 3**.

Table 3. Comparison of professional assessment scores between the control group and the observation group ($\overline{x} \pm s$, points)

Group	Number of cases	Theoretical knowledge		Operational skills	
		Before nursing management	After nursing management	Before nursing management	After nursing management
Control group	34	62.91 ± 3.62	72.45 ± 2.85	65.28 ± 4.29	82.52 ± 2.23
Observation group	34	63.63 ± 3.84	81.56 ± 2.77	64.80 ± 4.01	92.64 ± 2.95
t		0.796	13.366	0.477	15.957
p		0.429	0.000	0.635	0.000

4. Discussion

Nursing quality is not only directly related to the overall level of medical services but also profoundly reflects the hospital's management ability and treatment effect. Conventional and traditional nursing management models often ignore the differences in qualifications, professional titles and professional abilities of nursing staff, fail to achieve scientific division of labor, resulting in insufficient team collaboration, lack of systematic nursing services, and uneven personnel allocation. Some nurses work overloaded for a long time, affecting service quality and professional satisfaction [7–9]. Therefore, it is particularly necessary to implement the hierarchical management model. It is necessary to emphasize the reasonable stratification and division of responsibilities according to the professional abilities, professional titles and qualifications of nursing staff. While clarifying post responsibilities, optimize the allocation of power and resources to ensure that all work is carried out in accordance with regulations and in an orderly manner. In this way, more systematic, professional and efficient nursing services can be provided to patients, thereby comprehensively improving nursing quality and the overall service level of the hospital [10].

The controlled experiment of this study shows that stratification is crucial in hospital nursing management work. A survey of 68 randomly selected nursing staff in our hospital within one year shows that the observation group performs better than the control group by distinguishing the traditional management model from the implementation of the hierarchical nursing management model. This also indicates that the nursing management model in which the upper level manages the lower level, with mutual cooperation and clear powers and responsibilities, has positive significance. In practice, all levels can give play to their advantages and potential, actively and wholeheartedly engage in nursing work, and consciously maintain a good medical environment and doctor-patient relationship.

5. Conclusion

In conclusion, the implementation of hierarchical nursing management is of special significance for the modern development of hospital management models. Adjustments should be made in future hospital work. With its support in patient satisfaction, nursing staff's work performance and professional ability level, it will surely make positive contributions to the sustainable development of China's medical and health cause.

Disclosure statement

The authors declare no conflict of interest.

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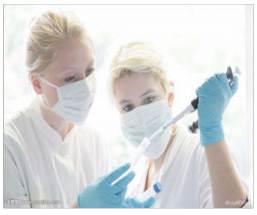


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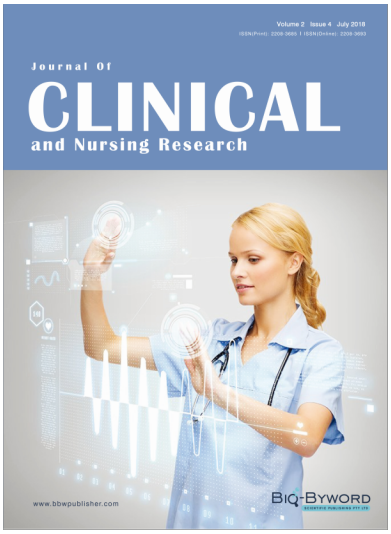
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