

Observation on Efficacy of *Chaihu Jia Longgu Muli* Decoction in the Treatment of Schizophrenia

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Abstract: *Objective:* Efficacy of Chaihu Jia Longgu Muli Decoction in the Treatment of Patients with Schizophrenia. *Methods:* Sixty patients with schizophrenia treated at Baotou Mental Health Center were enrolled and randomly divided into an observation group and a control group (30 cases in each group). The control group received oral risperidone at a dose of 4mg. The observation group was additionally administered Chaihu Jia Longgu Muli Decoction, one dose daily, prepared by water decoction, 200 mL each time, twice daily orally. After 4 consecutive weeks of treatment, psychiatric symptoms were evaluated using the Positive and Negative Syndrome Scale (PANSS) and the Brief Psychiatric Rating Scale (BPRS). Blood glucose, blood lipid, electrocardiogram (ECG), and alanine aminotransferase levels were detected. Therapeutic efficacy was determined by the BPRS reduction rate, and adverse reactions were assessed using the Treatment Emergent Symptom Scale (TESS). *Results:* PANSS and BPRS scores decreased in both groups, with significantly greater reductions in the observation group compared with the control group ($p < 0.05$). Levels of blood glucose, blood lipid, and alanine aminotransferase were significantly reduced ($p < 0.05$), and the ECG abnormality rate was significantly lower in the observation group (13.3% vs 36.7%, $p < 0.05$). The total effective rate was 93.33% in the observation group, significantly higher than 66.67% in the control group ($p < 0.05$). The TESS score was lower in the observation group than in the control group ($p < 0.05$). *Conclusion:* Chaihu Jia Longgu Muli Decoction can significantly improve the psychiatric symptoms, metabolism, and liver function of patients with schizophrenia, reduce the incidence of electrocardiographic abnormalities, markedly enhance clinical efficacy, and decrease adverse reactions.

Keywords: *Chaihu Jia Longgu Muli* Decoction; Schizophrenia; Clinical efficacy; PANSS; BPRS; TESS

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1. Introduction

Patients with schizophrenia (SCZ) primarily exhibit severe impairments in thinking, emotions, perception, and behavior, resulting in significantly compromised quality of life and social functioning. The condition is characterized by a long duration and a high likelihood of recurrence. The pathogenesis of schizophrenia is complex, involving dysfunction of neurotransmitters, abnormalities in neural circuits, immune-inflammatory responses, and genetic predisposition. In recent years, due to objective factors such as increased social stress

and chronic disease burdens, the prevalence of SCZ has been on the rise annually, posing a significant threat to public health.

Traditional Chinese Medicine (TCM) attributes the pathogenesis of schizophrenia to liver Qi stagnation and phlegm-heat disturbance, or imbalance of yin and yang and depletion of the heart spirit. Treatment primarily focuses on soothing liver Qi, resolving phlegm, opening orifices, and calming the spirit. Chaihu Jia Longgu Muli Decoction, originating from Zhang Zhongjing's "Treatise on Febrile Diseases" in the Eastern Han Dynasty, has the effects of harmonizing the Shaoyang channel, calming the heart and spirit, and resolving phlegm and disturbance. Extensive research has demonstrated that Chaihu Jia Longgu Muli Decoction regulates neurotransmitter balance and bodily functions through multi-target mechanisms, improving relevant symptoms in patients and showing potential in the treatment of mental disorders ^[1-4].

Currently, the pharmacological treatment of schizophrenia primarily relies on atypical antipsychotic drugs, with risperidone being widely used clinically to improve both positive and negative symptoms effectively ^[5]. However, long-term monotherapy often yields unsatisfactory results and can lead to adverse reactions such as metabolic abnormalities, weight gain, electrocardiogram abnormalities, and liver function damage, affecting patient compliance and making it difficult to consolidate therapeutic effects ^[6,7]. Traditional Chinese Medicine has demonstrated outstanding effects in the treatment of mental illnesses. Studies indicate that TCM can regulate inflammatory responses and improve neurotransmitter imbalances through multiple pathways, thereby synergistically enhancing the efficacy of antipsychotic drugs and reducing adverse reactions ^[8].

2. Materials and methods

2.1. General information

This study included 60 patients with schizophrenia diagnosed and hospitalized at the Baotou Mental Health Center from January to December 2024. During the follow-up period, 4 patients dropped out, including 2 in the observation group (1 male and 1 female) and 2 in the control group (both females). To ensure the integrity of the study, eligible patients were supplemented during the research process, resulting in 30 patients in each group. The control group consisted of 19 males and 11 females, aged 16 to 49 years, with an average age of (35.23 ± 8.04) years and a disease duration of (5.94 ± 3.44) years. The observation group consisted of 16 males and 14 females, aged 20 to 60 years, with an average age of (39.63 ± 10.82) years and a disease duration of (5.80 ± 4.29) years. There were no statistically significant differences between the two groups in terms of gender ($\chi^2 = 0.617, p = 0.432$), age ($t = -1.79, p = 0.08$), or disease duration ($t = 0.14, p = 0.89$) ($p > 0.05$), and the study was approved by the Medical Ethics Committee.

2.2. Inclusion criteria

- (1) Diagnosis of schizophrenia according to the "Chinese Classification and Diagnostic Criteria for Mental Disorders" and in a stable phase of the illness ^[9];
- (2) TCM diagnosis based on relevant disease manifestations in "Internal Medicine of Traditional Chinese Medicine" and "Integrated Traditional Chinese and Western Medicine Diagnostics for Mental Disorders" ^[10,11];
- (3) Patients treated according to the protocol provided in this study without changing the treatment plan halfway and able to provide complete clinical data before and after treatment.

2.3. Exclusion criteria

- (1) Patients with severe somatic diseases or organic mental disorders of the brain;
- (2) Patients with drug abuse or infectious disease carriers;
- (3) Patients with blood system diseases;
- (4) Patients with other organ failure or malignancies;
- (5) Patients with unstable vital signs;
- (6) Patients with incomplete clinical data;
- (7) Patients allergic to the drugs or devices used in the study;
- (8) Guardians refusing to accept the study protocol.

2.4. Treatment methods

- (1) Control group

Oral administration of risperidone tablets (Xian Janssen Pharmaceutical Ltd., National Medical Products Administration Approval Number H20010310), 2 mg per dose, twice daily, taken 30 minutes after lunch and at 20:00 in the evening.

- (2) Observation group

In addition to the control group's treatment, Chaihu Jia Longgu Muli Decoction (12 g of Chaihu, 15 g of Fuling, 9 g of Huangqin, 10 g each of Banxia and Renshen, 6 g of Shengjiang, 6 g of Dazao, 20 g each of Shenglonggu and Muli, and 6 g each of Guizhi and Dahuang) was administered, decocted and concentrated to 200 mL per dose, twice daily. Both groups of patients received continuous treatment for 4 courses, with each course lasting 7 days.

2.5. Observation indicators

2.5.1. Assessment of mental status

The PANSS and BPRS scores of patients in both groups before and after treatment were compared using the Positive and Negative Syndrome Scale (PANSS) and the Brief Psychiatric Rating Scale (BPRS) to evaluate their mental status^[12,13]. The PANSS consists of 30 items, while the BPRS includes five dimensions, thought disturbance, lack of vitality, anxiety-depression, activation, and hostility-suspiciousness, comprising a total of 18 items.

2.5.2. Blood glucose, lipids, ECG, and alanine aminotransferase levels

Blood glucose, lipid profiles, electrocardiogram (ECG) results, and alanine aminotransferase (ALT) levels were measured before treatment, at 2 weeks, and at the end of 4 weeks of treatment to evaluate the impact of the treatment regimen on metabolic function and liver function.

2.5.3. Clinical efficacy

The reduction rate in the total BPRS score was used as the primary indicator of therapeutic efficacy: a reduction rate of $\geq 75\%$ indicated recovery, 50–74% indicated significant improvement, 25–49% indicated improvement, and $< 25\%$ indicated no effect. Recovery, significant improvement, and improvement were collectively considered as the overall effective rate, calculated as follows: Overall Effective Rate = (Number of recovered cases + Number of significantly improved cases + Number of improved cases) / Total number of cases $\times 100\%$.

2.5.4. Adverse reactions

The Treatment Emergent Symptom Scale (TESS) was used to compare adverse reactions between the two groups during treatment ^[14].

2.6. Statistical methods

Statistical analysis was performed using SPSS 25.0. Continuous data are presented as mean $\pm$ standard deviation (s) and analyzed using paired-sample *t*-tests. Categorical data are presented as frequencies and percentages [n (%)], with differences between groups compared using the χ^2 test. A *p*-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of PANSS and BPRS scores between the two groups

After 4 weeks of treatment, scores in both groups decreased from baseline. Further analysis revealed that the PANSS and BPRS scores in the observation group were significantly lower than those in the control group ($p < 0.01$), as shown in **Table 1**.

Table 1. Comparison of PANSS, BPRS scores between the two groups ($\bar{x} \pm s$, $n = 30$)

Group	Time	PANSS score	BPRS score	<i>t</i>	<i>p</i>
Control	Before treatment	88.73 $\pm$ 5.23	64.47 $\pm$ 6.29	19.33	0.00 (PANSS)
	4 weeks after treatment	53.90 $\pm$ 11.72 ^{##}	40.57 $\pm$ 8.65 ^{##}	15.18	0.00 (BPRS)
Observation	Before treatment	90.80 $\pm$ 7.50	65.67 $\pm$ 5.54	26.76	0.00 (PANSS)
	4 weeks after treatment	41.27 $\pm$ 9.52 ^{***}	33.80 $\pm$ 10.46 ^{***}	21.34	0.00 (BPRS)
<i>t</i>		4.58	2.73		
<i>p</i>		0.00	0.008		

Note: Compared with the same group before treatment, ^{##} $p < 0.01$; compared with the control group, ^{***} $p < 0.01$.

3.2. Comparison of blood glucose, blood lipids, electrocardiogram (ECG), and alanine aminotransferase (ALT) levels between the two groups

Before treatment, there were no significant differences in blood glucose, blood lipids, and other test results between the two groups ($p > 0.05$). Specifically, 13 patients (43.3%) in the control group and 12 patients (40.0%) in the observation group had abnormal ECGs, with no statistically significant difference in the normal ECG rates between the two groups ($\chi^2 = 0.07$, $p = 0.79 > 0.05$). After 2 weeks of treatment, patients in the control group showed an increasing trend in blood glucose, blood lipids, and ALT levels compared to before treatment. In terms of ECG results, both groups showed improvement from baseline, but there was no statistically significant difference between the groups ($\chi^2 = 0.74$, $p = 0.39 > 0.05$). After 4 weeks of treatment, patients in the control group continued to exhibit increases in blood glucose, blood lipids, and ALT levels, with significant differences compared to the observation group ($p < 0.01$). Among them, 11 patients (36.7%) in the control group had abnormal ECGs, while only 4 patients (13.3%) in the observation group had abnormal ECGs, showing a statistically significant difference ($\chi^2 = 4.36$, $p = 0.04$). See **Table 2**.

Table 2. Comparison of glucose, lipids, ECG abnormalities, and ALT between two groups ($\bar{x} \pm s/n$ (%), $n = 30$)

Group	Time	Blood glucose (mmol/L)	Blood lipids (mmol/L)	ALT (U/L)	ECG abnormality [n/N (%)]
Control group	Before treatment	4.96 $\pm$ 0.18	1.97 $\pm$ 0.31	37.43 $\pm$ 4.64	13/30 (43.33%)
	2 weeks of treatment	5.07 $\pm$ 0.17	2.17 $\pm$ 0.34	41.17 $\pm$ 5.10	10/30 (33.33%)
	4 weeks of treatment	5.20 $\pm$ 0.30	2.37 $\pm$ 0.37	44.92 $\pm$ 5.57	11/30 (36.67%)
Observation group	Before treatment	4.97 $\pm$ 0.19	2.08 $\pm$ 0.29	38.43 $\pm$ 3.67	12/30 (40.00%)
	2 weeks of treatment	4.63 $\pm$ 0.15	1.45 $\pm$ 0.19	30.73 $\pm$ 1.78	7/30 (23.33%)
	4 weeks of treatment	4.50 $\pm$ 0.18	1.21 $\pm$ 0.21	27.60 $\pm$ 1.35	4/30 (13.33%)*
2 weeks of treatment	<i>t</i>	10.59	10.20	10.58	$\chi^2 = 0.74$
	<i>p</i>	0.000	0.000	0.000	0.39
4 weeks of treatment	<i>t</i>	11.13	14.98	16.56	$\chi^2 = 4.36$
	<i>p</i>	0.00	0.00	0.00	0.04

Note: Compared with the control group, ** $p < 0.01$, * $p < 0.05$.

3.3. Comparison of clinical efficacy between the two groups

Clinical efficacy was calculated based on the reduction rate in BPRS scores. The results showed that the total number of effective cases in the observation group was 28 (93.33%), which was higher than that in the control group (20 cases, 66.67%), with a statistically significant difference ($\chi^2 = 6.67$, $p = 0.01 < 0.05$). See **Table 3**.

Table 3. Comparison of clinical efficacy between the two groups (n (%), $n = 30$)

Group	Cured	Markedly improved	Improved	Ineffective	Total effective
Control group	0 (0)	4 (13.33)	16 (53.33)	10 (33.33)	20 (66.67)
Observation group	2 (6.67)	12 (40)	14 (46.67)	2 (6.67)	28 (93.33)*

Note: Compared with the control group, * $p < 0.05$.

3.4. Comparison of adverse reactions between the two groups

After the treatment, the TESS (Treatment Emergent Symptom Scale) score of patients in the control group was higher than that in the observation group ($p < 0.01$). See **Table 4**.

Table 4. Comparison of TESS scores between two groups ($\bar{x} \pm s$, $n = 30$)

Group	Time	TESS score	<i>t</i>	<i>p</i>
Control group	4 weeks of treatment	3.43 $\pm$ 1.25	6.73	0.00
Observation group		1.43 $\pm$ 1.04		

4. Discussion

Schizophrenia is a severe mental disorder characterized by a long course and a tendency to recur. Its occurrence is related to dysfunction of neurotransmitters such as dopamine and serotonin, as well as factors such as immune-inflammatory responses, oxidative stress, and abnormal regulation of neural circuits^[15]. Currently, antipsychotic drugs remain the primary means of clinical treatment, effectively improving positive symptoms and some negative symptoms. However, long-term medication use can lead to issues such as weight gain,

abnormal blood glucose and lipid levels, liver function damage, and electrocardiogram abnormalities, thereby affecting patient compliance and sustained treatment outcomes. Therefore, on the premise of ensuring the efficacy of antipsychotic treatment, how to reduce drug-related adverse reactions and improve the overall condition of patients is a critical concern in the treatment of schizophrenia.

In traditional Chinese medicine, manifestations related to schizophrenia are mostly classified under categories such as “mania” and “insanity”. Its occurrence is often associated with emotional imbalance, internal disturbance of phlegm-fire, stagnation of Qi, disharmony of Zang-fu organ functions, and depletion of brain nourishment. Chaihu Jia Longgu Muli Decoction, originating from the Treatise on Febrile Diseases, has the effects of harmonizing the lesser yang, calming the spirit, purging heat through the intestines, and strengthening the body’s resistance. In this formula, Chaihu (Bupleurum) soothes the liver and relieves Qi stagnation while harmonizing the lesser yang; Guizhi (Cinnamomum) warms and unblocks the meridians and harmonizes the Yingwei; Dahuang (Rheum) purges heat through the intestines, providing an outlet for stagnant heat; Longgu (Fossilia Ovis Mastodi) and Muli (Ostreae Concha) calm the spirit and subdue liver yang; Fuling (Poria) strengthens the spleen and calms the heart; Banxia (Pinellia) harmonizes the stomach, reverses Qi counterflow, and resolves phlegm and nodules; Renshen (Ginseng) and Dazao (*Ziziphi Jujubae Fructus*) replenish Qi, strengthen the body’s resistance, and harmonize the spleen and stomach. When combined, these herbs act to soothe the liver and relieve Qi stagnation, resolve phlegm and purge heat, calm the spirit and stabilize the will, and strengthen the body’s resistance and regulate the middle, aligning well with the characteristics of schizophrenia, which involves the interplay of “phlegm, fire, stagnation, and deficiency”. Modern pharmacological research suggests that Chaihu Jia Longgu Muli Decoction has effects such as regulating neurotransmitters, improving sleep, anti-inflammatory and antioxidant actions, and protecting liver function ^[16,17]. The results of this study show that after 4 weeks of treatment, the observation group exhibited more significant decreases in PANSS and BPRS scores and a higher overall effective rate compared to the control group, suggesting that the combination of Chaihu Jia Longgu Muli Decoction and risperidone can further improve psychiatric symptoms and enhance clinical efficacy. Meanwhile, the observation group had lower levels of blood glucose, lipids, and alanine aminotransferase, as well as a lower incidence of electrocardiogram abnormalities and adverse reaction scores, indicating that this combination regimen may help reduce risperidone-related metabolic abnormalities, liver function damage, and cardiovascular adverse effects ^[18,19].

5. Conclusion

In summary, Chaihu Jia Longgu Muli Decoction demonstrates significant advantages in improving symptoms of schizophrenia, enhancing the efficacy of antipsychotic drugs, and ameliorating metabolic abnormalities and adverse reactions, reflecting the clinical potential and promotional value of traditional Chinese medicine in the management of schizophrenia. However, this study had limitations, including a small sample size, short follow-up period, lack of placebo uses in the control group, and failure to conduct stratified analysis based on different disease courses or subtypes. Future research should involve multicenter studies to validate further the efficacy and mechanism of action of Chaihu Jia Longgu Muli Decoction combined with risperidone in the treatment of schizophrenia.

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Disclosure statement

The authors declare no conflict of interest.

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