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Clinical Efficacy and Safety of Brexitan in the Treatment of Children with Epilepsy and Sleep Disorders

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Abstract: This study primarily investigates the clinical efficacy and safety of brivaracetam in treating children with epilepsy combined with sleep disorders. A total of 84 pediatric patients meeting the inclusion criteria from June 2023 to June 2025 were selected as the study subjects and randomly divided into an observation group and a control group, with 42 cases in each group. The control group received conventional levetiracetam treatment, while the observation group was administered brivaracetam along with a standardized sleep hygiene guidance program. Both groups underwent systematic intervention for six months. By comparing data such as total effective rates, changes in the Children's Sleep Habits Questionnaire (CSHQ) scores, polysomnography indicators, electroencephalogram (EEG) characteristics, and adverse reaction frequencies, the study verified significant differences in efficacy, EEG changes, and sleep conditions between the observation and control groups. The results showed that the observation group had a total effective rate of 90.5% and an EEG improvement rate of 83.3%, significantly higher than the control group's 71.4% and 61.9%, respectively. Additionally, the observation group's CSHQ scores, total sleep duration, sleep efficiency, nocturnal awakenings, and latency were all superior to those of the control group, with an adverse reaction incidence of 11.9%, markedly lower than the control group's 31.0%. This study confirms that brivaracetam effectively controls epileptic seizures and significantly improves sleep quality in children, demonstrating good safety and practicality.

Keywords: Epilepsy; Sleep disorders; Brivaracetam; Children; Safety

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1. Introduction

Epilepsy is one of the most common neurological diseases, with a prevalence second only to stroke [1]. Children are at high risk, and recurrent seizures not only damage neurological function but also often lead to multiple comorbidities. Sleep disorders are a common but easily overlooked category among them. Research has shown that anxiety is an independent risk factor for epilepsy patients with sleep disorders. The SPECT/CT findings of patients with epilepsy and sleep disorders during the interictal phase of seizures show reduced

blood flow in multiple brain functional areas, indicating a neurological basis for their comorbidity [2].

Compared to children without epilepsy, children with epilepsy have a much higher incidence of sleep disorders. Seizures can seriously disrupt an individual's normal sleep structure, and the decrease in sleep quality can in turn worsen the speed of improvement in epilepsy and clinical prognosis [3]. The two are mutually causal and can easily form a vicious cycle; how to improve sleep while controlling seizures has become a practical challenge in the management of childhood epilepsy. As a third-generation antiepileptic drug, Bristol Myers Squibb has both good efficacy and tolerability, providing a new option for solving this problem. This study observed the efficacy and safety of its treatment for such children, and the report is as follows.

2. Data and methods

2.1. General information

A total of 84 children with epilepsy complicated by sleep disorders admitted to the Department of Neurology from June 2023 to June 2025 were selected as the research objects. They were randomly divided into an observation group and a control group, with 42 cases in each group. There were 24 males and 18 females in the observation group; The average age was (7.82 ± 2.35) years, and the average course of disease was (2.46 ± 1.12) years; In the control group, there were 25 males and 17 females; The average age was (7.95 ± 2.41) years, and the average course of disease was (2.53 ± 1.08) years. There was no significant difference in baseline data between the two groups after statistical testing ($p > 0.05$), and the groups were homogeneous and comparable. This research protocol has been reviewed and approved by the medical ethics committee of the hospital, and the written informed consent of all guardians has been obtained.

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Meet the diagnostic criteria of epilepsy, confirmed by video EEG;

(2) The total score of the Children's Sleep Habits Questionnaire (CSHQ) was more than 41, and the diagnosis was complicated by sleep disorders;

(3) The age ranged from 3 to 14 years.

2.2.2. Exclusion criteria

(1) Patients with intracranial organic lesions or severe liver and kidney dysfunction;

(2) Allergic to the study drug;

(3) Unable to cooperate with the evaluator.

2.3. Treatment methods

All subjects received standardized sleep hygiene interventions, including regular work and rest time, avoiding stimulating behavior before going to bed, and optimizing the sleep environment. The control group was treated with levetiracetam; the initial dose was 10 mg/(kg · d), increased every 1 to 2 weeks, and finally maintained in the range of 20 to 40 mg/(kg · d). The experimental group used brexitan as an intervention drug; the initial dose was set at 1 mg/(kg · d) and gradually adjusted according to the progress of the disease and individual differences. The target maintenance dose was 2 mg/(kg · d), and the upper limit of a single

dose was no more than 100 mg. All subjects were divided into two doses, and the whole course lasted for 6 months.

2.4. Observation indexes

The curative effect evaluation system is as follows:

(1) The criteria for judging the antiepileptic effect are: no seizures are judged to be cured; If the attack frequency decreased by ≥ 50% compared with the baseline after treatment, it was evaluated as effective; Otherwise, it is regarded as invalid, and the total effective rate is calculated as (number of cured + number of good revolutions)/total sample size × 100%.

(2) The analysis of sleep quality was based on the comprehensive evaluation of the CSHQ scale and polysomnography. The higher the total score, the more significant the potential disorder was. The monitoring indicators include total duration, effectiveness index, number of wake-ups at night, and length of incubation period.

(3) The change trend of EEG was based on the reduction of epileptic discharge ≥ 50% before and after treatment.

(4) The safety investigation involved the occurrence and proportion of common adverse reactions such as drowsiness, dizziness, mood swings, and anorexia.

2.5. Statistical methods

This study used SPSS 26.0 software to analyze the data. For the measurement data, the mean ± standard deviation was used to express the data, and the differences between groups were compared by an independent-samples t-test; The counting data were presented in the form of number of cases (percentage), and the correlation between variables was explored by the χ^2 test. When the *p*-value is less than 0.05, the result is considered to be statistically significant.

3. Results

3.1. Comparison of seizure control effect between the two groups

After 6 months of treatment, in the observation group, 24 cases were controlled, 14 cases were effective, and 4 cases were ineffective; the total effective rate was 90.5% (38/42). In the control group, 16 cases were controlled, 14 cases were effective, and 12 cases were ineffective. The total effective rate was 71.4% (30g42). The observation group was higher than the control group *($p < 0.05$)*.

3.2. Comparison of sleep quality between the two groups

Before treatment, the CSHQ score and polysomnography monitoring indices of the two groups were similar ($p > 0.05$). After treatment, the CSHQ score of the observation group was (38.14 ± 4.22), which was lower than (43.57 ± 4.86) of the control group; The total sleep time and sleep efficiency were (512.40 ± 38.60) min and (88.60 ± 5.30)%, respectively, which were higher than those in the control group (476.80 ± 41.20) min and (82.40 ± 6.10)%; The times of night awakening and sleep latency were (2.60 ± 1.10) times and (16.80 ± 5.20) min respectively, which were lower than (4.30 ± 1.50) times and (24.50 ± 6.80) min in the control group, and the differences were statistically significant ($p < 0.05$).

3.3. Comparison of EEG improvement between the two groups

EEG improved in 35 cases (83.3%) in the observation group and 26 cases (61.9%) in the control group, which was higher in the observation group than in the control group ($p < 0.05$).

3.4. Safety comparison between the two groups

During the treatment, the observation group had 2 cases of somnolence, 1 case of dizziness, 1 case of irritability, 1 case of anorexia, and the incidence of adverse reactions was 11.9% (5g42); In the control group, there were 5 cases of somnolence, 3 cases of dizziness, 3 cases of irritability, and 2 cases of anorexia, with an incidence of 31.0% (13g42). The observation group was lower than the control group ($p < 0.05$). The adverse reactions were transient and relieved after slow titration or symptomatic treatment. There were no serious adverse reactions or drug withdrawal cases [4].

4. Discussion

4.1. Brexitan meets the long-term medication needs of children with high safety

Children with epilepsy need long-term standardized medication. Its therapeutic effect and tolerance directly affect compliance and the long-term prognosis of disease management, which constitutes a key challenge in clinical practice. As a derivative of levetiracetam, brexitan has made significant progress in global application. In 2016, the drug was approved by the European Union and the U.S. regulatory authorities for marketing, and emerged through a highly selective mechanism of action on its target, synaptic vesicle protein 2A (SV2A), with an affinity about 15 to 30 times higher than levetiracetam. Research shows that brexitan has excellent bioavailability, rapid onset, and a low risk of drug interactions, which provides an effective solution to the above problems [5]. As an innovative antiepileptic drug, brexitan has not only shown excellent safety and effectiveness in the monotherapy or adjuvant therapy of focal epilepsy, but also received extensive attention due to its less adverse reaction characteristics [6]. The study data confirmed that the incidence of adverse events in the observation group was 11.9%, significantly lower than that in the control group, and all adverse reactions were transient and reversible, which fully reflected the good tolerance of the drug in children.

4.2. Achieving double benefits of Brexitan combined with sleep hygiene intervention

Seizure and sleep are the cause and effect of each other and aggravate each other, which is the second reality dilemma. It is often difficult to obtain an ideal curative effect only by controlling seizures and ignoring sleep. In this study, the simultaneous implementation of Brexitan and sleep hygiene intervention is the combination scheme for it. Brexitan inhibited the abnormal discharge of neurons and reduced nocturnal seizures and sleep fragmentation; The seizure threshold tended to be stable after sleep improvement, which in turn consolidated the anti-seizure effect. The results showed that the total effective rate, EEG improvement rate, and sleep indices of the observation group were better than those of the control group, and the double benefits of controlling seizures and improving sleep were achieved. Previous studies have also suggested that age and depression are independently related factors of sleep disorders in patients with epilepsy, and the degree of daytime sleepiness in patients with epilepsy is significantly positively correlated with seizure frequency and negatively correlated with quality of life [7,8]. Therefore, during treatment, attention should also be paid to the emotional state and daytime functioning of children, and psychological support should be given in a timely

manner to transform the double benefits into the improvement of quality of life.

4.3. Multidimensional assessment and comprehensive management to cope with the risk of missed diagnosis of comorbidities

The third reality dilemma is that children's sleep disorders are hidden, easy to be ignored by parents and doctors, and there may be other causes behind them. Sleep disorder is a common clinical symptom of autoimmune encephalitis, mainly manifested as insomnia, behavior disorder during rapid eye movement sleep, lethargy and so on, which suggests that the diagnosis and treatment of such children should not only focus on the attack control, but also pay attention to the etiology identification, and improve the immunology and other examinations when necessary, so as to avoid missed diagnosis and misdiagnosis [9]. Correspondingly, this study combined CSHQ, polysomnography, and video EEG to evaluate, and included sleep hygiene intervention into the program, forming a management path of assessment, drugs, and behavior, so as to transform sleep problems from neglected comorbidities to quantifiable treatment targets.

4.4. Research limitations and prospects

This study has some shortcomings, such as a single center, small sample size, short follow-up time, etc., which need to be verified by multicenter and large-sample studies in the future. In conclusion, Brexitan in the treatment of such children can not only effectively control seizures, but also improve sleep quality and EEG activity, with fewer adverse reactions and good tolerance, and realize the synergistic benefits of seizure control and sleep improvement, which is worthy of promotion.

5. Conclusion

In conclusion, brexitan combined with standardized sleep hygiene intervention in the treatment of children with epilepsy and sleep disorders can effectively control seizures, improve EEG performance, and significantly improve the sleep quality of children, with fewer adverse reactions and good tolerance, realizing the synergistic benefits of seizure control and sleep improvement. The scheme meets the safety requirements of long-term medication for children, and provides a feasible way for the clinical management of epilepsy comorbid sleep disorder, which is worthy of promotion. However, this study is a single-center, small-sample observation, and the conclusion needs to be further verified by multicenter, large-sample, and long-term follow-up studies.

Disclosure statement

The authors declare no conflict of interest.

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