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To Explore the Clinical Efficacy and Safety of Lithium Carbonate Combined with Magnesium Valproate Sustained-release Tablets in the Treatment of Acute Manic Episodes in Patients with Bipolar Disorder

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Abstract: *Objective:* To study the clinical efficacy and safety of lithium carbonate combined with magnesium valproate sustained-release tablets in the treatment of acute manic episodes in bipolar disorder. *Methods:* From January to December 2024, 76 patients with acute episodes of mania in bipolar disorder were selected for data research in our hospital. They were divided into groups using a random number table, with 38 patients in each group. The research group was treated with lithium carbonate combined with magnesium valproate sustained-release tablets, and the control group was treated with lithium carbonate. The data between the groups were compared. *Results:* Compared with the control group, the total effective rate of the study group was significantly higher, the MoCA score after treatment was significantly higher, the BRMS score after treatment was significantly lower, the BPRS score after treatment was significantly lower, the BI score after treatment was significantly higher, and adverse reactions were significantly less likely to occur. The data comparison between the groups was statistically significant, $p < 0.05$; comparing the MoCA score, BRMS score, BPRS score, and BI score before treatment between the two groups, there was no statistical significance in the data comparison between the groups, $p > 0.05$. *Conclusion:* The clinical efficacy and safety of lithium carbonate combined with magnesium valproate sustained-release tablets in the treatment of patients with acute manic episodes of bipolar disorder are high, and it is worthy of clinical use and promotion.

Keywords: Lithium carbonate; Magnesium valproate sustained-release tablets; Bipolar disorder; Acute manic episode; Clinical efficacy; Safety

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1. Introduction

Bipolar disorder is a severe mental disorder whose core feature is alternating episodes of mania and depression. The typical manifestations of an acute episode of mania are elevated mood, erratic thinking, and impulsive behavior. The patient's cognitive function and social adaptability are seriously damaged, and adverse events are prone to occur, such as impulsive

injury to others and self-injury. Epidemiological surveys suggest that the lifetime prevalence of bipolar disorder is 1–2%, among which acute manic episodes account for more than 20% of acute psychiatric hospitalizations [1]. Therefore, clinical attention is paid to optimizing the treatment plan for patients with acute manic episodes of bipolar disorder in psychiatric settings. Lithium carbonate is a mood stabilizer that can regulate neurotransmitters and ion balance in the patient's brain and play a clinical therapeutic role. However, the effect of single use is not ideal. Not only does it take effect slowly, but long-term use also requires vigilance for problems such as nephrotoxicity and thyroid dysfunction [2]. Clinical research shows that magnesium valproate sustained-release tablets can help patients stabilize their mood. After taking the drug, it plays a therapeutic role by enhancing gamma-aminobutyric acid neurotransmission and inhibiting neuronal over-excitation. When the above two drugs are used together, they can form complementary mechanisms of action and produce synergistic effects. However, there are currently not many relevant studies and in-depth analysis is needed. This article selected 76 patients to study the clinical efficacy and safety of lithium carbonate combined with magnesium valproate sustained-release tablets in the treatment of acute manic episodes of bipolar disorder.

2. Materials and methods

2.1. Information

From January to December 2024, 76 patients with acute episodes of mania in bipolar disorder were selected for data research in our hospital. They were divided into groups using a random number table, with 38 patients in each group. The study group was 20/18 men and women, aged 21–62 (38.25 ± 6.35) years old, and the control group was 21/17 men and women, aged 20–68 (38.21 ± 6.34) years old. Comparison of the two sets of data resulted in $p > 0.05$.

2.1.1. Inclusion criteria

Consistent with disease diagnostic criteria; no use of relevant drugs 7 days before hospitalization; informed consent.

2.1.2. Exclusion criteria

Serious physical illness or organ disease, such as malignant tumors, hematopoietic system diseases, etc.; alcohol dependence; intellectual disability; sensitivity to drugs, serious suicidal thoughts and behaviors; lactation or pregnancy; missing clinical data; withdrawal midway, and loss of follow-up.

2.2. Method

The control group was treated with lithium carbonate. The initial dose was 250 mg orally once a day. After one week, the dose was increased to 500–750 mg twice a day.

The research group was treated with lithium carbonate combined with magnesium valproate sustained-release tablets, which was increased based on the treatment in the control group: the initial dose was 250 mg orally per day, and the dose was increased to 250–500 mg per day after one week. Both groups continued to take medication for 8 weeks.

2.3. Observation indicators

(1) Compare the total effectiveness of the two groups. If the symptoms are significantly relieved or disappear after treatment, it is judged to be effective; if the symptoms are relieved, it is considered effective; otherwise, it is considered ineffective. Total efficiency = 100% – inefficiency.

(2) Compare the MoCA scores, BRMS scores, BPRS scores, and BI scores of the two groups. The Montreal Cognitive Assessment (MoCA), Beck-Ravanson Mania Scale (BRMS), Brief Psychiatric Symptom Rating Scale (BPRS), and Barthel Index (BI) were used to evaluate.

(3) Compare the adverse reactions of the two groups.

2.4. Statistics

Use SPSS 28.0 software, use mean ± standard deviation ($\bar{x} \pm s$) to describe measurement data, *t* test; use rate (%) to describe count data, χ^2 test, $p < 0.05$, statistically significant.

3. Results

Compared with the control group, the total effective rate of the study group was significantly higher, the MoCA score after treatment was significantly higher, the BRMS score after treatment was significantly lower, the BPRS score after treatment was significantly lower, the BI score after treatment was significantly higher, and adverse reactions occurred significantly less. The data comparison between the groups was statistically significant, $p < 0.05$; comparing the MoCA score, BRMS score, BPRS score, and BI score before treatment between the two groups, the data comparison between the groups had no statistical significance, $p > 0.05$. See **Table 1**, **2** and **3**.

Table 1. Comparison of the total effective rate (%) between the two groups

Group	Effective	Valid	Invalid	Always efficient
Research group (n = 38)	22 (57.89)	14 (36.84)	2 (5.26)	94.74
Control group (n = 38)	10 (26.32)	19 (50.00)	9 (23.68)	76.32
χ^2	-	-	-	5.2084
p	-	-	-	< 0.05

Table 2. Comparison of MoCA scores, BRMS scores, BPRS scores, and BI scores between the two groups (points)

Group	MoCA score		BRMS score		BPRS score		BI score	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Research group (n = 38)	19.11 ± 2.33	25.67 ± 3.05	28.45 ± 3.36	9.12 ± 1.27	55.34 ± 4.28	24.06 ± 1.32	60.05 ± 12.12	92.92 ± 17.81
Control group (n = 38)	19.26 ± 2.41	23.36 ± 2.62	28.26 ± 3.28	15.41 ± 2.18	55.65 ± 4.31	34.25 ± 1.27	60.85 ± 12.33	83.78 ± 15.27
t	0.2758	3.5415	0.2494	15.3686	0.3146	34.2926	0.2852	2.4017
p	> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05

Table 3. Comparison of adverse reactions between the two groups (%)

Group	Weakness in limbs	Gastrointestinal reactions	Lethargy	Total
Research group (n = 38)	0	0	1 (2.63）	1 (2.63)
Control group (n = 38)	2 (5.26)	2 (5.26)	3 (7.89)	7 (18.42)
χ^2	-	-	-	5.0294
p	-	-	-	< 0.05

4. Discussion

Patients with bipolar disorder have a high disability rate and are prone to relapse. Therefore, effective intervention in patients with acute episodes of mania can improve the patient's prognosis. Clinical research on the classic mood stabilizer lithium carbonate found that a single drug has delayed onset of action and limited improvement in patient cognition, and long-term use has safety risks [3]. Clinical research on magnesium valproate sustained-release tablets can produce multi-target effects, with the gamma-aminobutyric acid (GABA) energy system as the core, providing a theoretical basis for combination with lithium carbonate. The results of this study confirm that the clinical efficacy and safety of lithium carbonate combined with magnesium valproate sustained-release tablets in the treatment of patients with acute manic episodes of bipolar disorder are high, and the results of this study can support this.

The results of this study suggest that the total effective rate of the study group is 94.74%, which is significantly higher than that of the control group. The results confirm that patients can effectively control symptoms through combined treatment. The core reason is that the mechanism of action of lithium carbonate combined with magnesium valproate sustained-release tablets is synergistic and complementary. Lithium carbonate can inhibit the activity of sodium-potassium ATPase and reduce intracellular sodium ion concentration, and inhibit the release of excitatory transmitters such as norepinephrine and dopamine, serotonergic transmission is enhanced, but post-synaptic membrane receptor regulation is insufficient [4]. Magnesium valproate is used for the patient to inhibit GABA transaminase to increase the concentration of GABA in the brain, and to inhibit the sodium-calcium channel to reduce glutamate release. The patient's manic episode is blocked from different links. The two form a multi-target regulatory network, and the patient's therapeutic response rate is significantly improved, especially the patient's core symptoms can be quickly controlled [5].

The results of this article suggest that the important goal of treatment for acute mania is the improvement of cognitive function and social function. After treatment, the MoCA score (25.67 ± 3.05) of the study group was significantly higher than that of the control group, and the BI score (92.92 ± 17.81) was also higher than that of the control group. In the control group, analyze the reasons: using lithium carbonate for the patient can inhibit the activity of glycogen synthase kinase-3β (GSK-3β) and promote neurogenesis in the hippocampus, but single drug treatment has a weak effect on improving the executive function of the patient's prefrontal cortex. Magnesium valproate is used to slow down the patient's prefrontal cortex. The release of tablets upregulates the expression of brain-derived neurotrophic factor (BDNF), strengthens the synaptic connection strength between the prefrontal cortex and the hippocampus, and the patient significantly improves core cognitive domains such as attention and executive function [6]. After the drug is used, it has a regulating effect on the GABAergic system, and the patient's impulsive behavior during manic episodes is significantly reduced, creating conditions for the patient to restore his daily life ability. Analysis of the above two drugs, superimposed neuroprotective effects, the patient accelerates the repair of cognitive function, improves self-care, social interaction and other abilities, and the social function score increases significantly.

The results of this article suggest that the indicator that further proves the advantages of combined treatment is the symptom assessment scale score. After treatment, the BRMS score (9.12 ± 1.27) and BPRS score (24.06 ± 1.32) of the research group were significantly lower than those of the control group. Analyzing from the perspective of pharmacological mechanism, the use of lithium carbonate for patients has the effect of regulating the dopaminergic system and can reduce the patient's manic mood and behavior. The symptoms were significantly improved. The patient was treated with magnesium valproate, which can regulate the serotonergic system. The patient's psychotic symptoms were significantly improved. The patient was treated with magnesium valproate. Its pharmacokinetic characteristics can stabilize the patient's blood concentration and avoid the recurrence of symptoms caused by fluctuations in blood concentration during the single use of lithium carbonate [7]. Therefore, the study group's scale score improved more significantly.

The results of this article suggest that the core consideration of clinical medication is safety. The incidence of adverse reactions in the study group was only 2.63%, which was significantly lower than that in the control group. One case of drowsiness symptoms occurred in the study group. The analysis of its mechanism involves two aspects, one is drug metabolism, and the other is dosage adjustment. Analyzing the adverse reactions of lithium carbonate and related to blood

drug concentration, patients need a higher dose to achieve the efficacy of monotherapy, and are prone to gastrointestinal irritation, kidney damage and other adverse reactions. After patients are combined with magnesium valproate, the synergistic effect of the two significantly reduces the risk of adverse reactions related to blood lithium in patients. Clinical studies on the adverse reactions of magnesium valproate itself, the spectrum of adverse reactions is narrow, including mild gastrointestinal reactions and drowsiness, with a low incidence [8]. After lithium carbonate combined with magnesium valproate sustained-release tablets, patients will not experience significant pharmacokinetic interactions. Analysis of drug metabolism, mainly renal excretion, shows that there is no significant competition in metabolic pathways between the two, so the overall incidence of adverse reactions is reduced. No serious adverse reactions occurred in this study, confirming that the medication of lithium carbonate combined with magnesium valproate sustained-release tablets is safe and controllable.

Analyzing from the perspective of clinical practice, the innovative point of this research is to study recent cases in 2024. The random number table method was used when grouping, and a small sample clinical controlled study was conducted. The inclusion and exclusion criteria strictly controlled confounding factors such as comorbidities and drug dependence. The research results are reliable and timely. This study has limitations. It conducted a single-center study with a sample size of 76 cases. In addition, the sample source is geographically limited, and the extrapolation of the results is affected. In addition, the follow-up time is 8 weeks, and there is no evaluation of the long-term efficacy and recurrence rate of the patients. The core of the treatment of bipolar disorder is to prevent recurrence, so long-term follow-up is required in the future. In this study, the patient's blood drug concentration, BDNF, GSK-3β and other biological indicators before and after treatment were not tested, and the mechanism of action of the patient's combined medication was not further verified at the molecular level. In addition, this study did not conduct a detailed analysis of subgroups of different ages and disease durations, and did not clarify the differences in the efficacy of combined treatment in specific groups. In future research, the above directions will be improved.

In summary, the clinical efficacy and safety of lithium carbonate combined with magnesium valproate sustained-release tablets in the treatment of patients with acute manic episodes of bipolar disorder are high and worthy of clinical promotion. The patients' MoCA scores were significantly higher after treatment, their BRMS scores were significantly lower after treatment, their BPRS scores were significantly lower after treatment, and their BI scores were significantly higher after treatment.

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Disclosure statement

The author declares no conflict of interest.

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