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Comparative Study on the Treatment of Schizophrenia Patients with Paliperidone and Risperidone Orally Disintegrating Tablets

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Abstract: *Objective:* To evaluate the therapeutic effects of paliperidone and risperidone orally disintegrating tablets on schizophrenia (SCH). *Methods:* A total of 66 hospitalized SCH patients admitted between April 2022 and October 2023 were selected. They were randomly divided into two groups using a random number table. The study group was treated with paliperidone, while the control group was treated with risperidone orally disintegrating tablets. Differences in efficacy, symptom scores, and adverse reaction rates were compared between the two groups. *Results:* The overall efficacy rate in the study group was similar to that of the control group ($P > 0.05$). After three months of treatment, Positive and Negative Syndrome Scale scores in both groups were significantly lower than those before treatment, with the study group exhibiting lower symptom scores than the control group ($P < 0.05$). The adverse reaction rate in the study group was lower than that in the control group ($P < 0.05$). *Conclusion:* Paliperidone demonstrates therapeutic efficacy for SCH patients comparable to risperidone orally disintegrating tablets. However, paliperidone significantly improves disease symptoms and reduces medication-related side effects.

Keywords: Paliperidone; Risperidone orally disintegrating tablets; Schizophrenia; Symptom scores; Adverse reactions

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1. Introduction

Schizophrenia (SCH) is a chronic psychiatric disorder caused by the combined effects of psychological factors, genetic predisposition, and neurotransmitter dysfunction. Its symptoms include emotional apathy, slowed thinking, and self-directed speech, often accompanied by self-harming or violent behaviors [1]. The conventional treatment approach involves oral medications, primarily risperidone orally disintegrating tablets, which antagonize serotonin (5-HT) and dopamine (DA) receptors to alleviate symptoms. However, prolonged use of risperidone is associated with high drug resistance, frequent side effects, and suboptimal efficacy.

Paliperidone, an atypical second-generation therapeutic drug, exhibits strong antagonistic effects on dopamine

D2 receptors (D2R). It effectively alleviates both positive and negative symptoms without significantly inducing extrapyramidal reactions, offering a higher safety and benefit profile [2]. This study evaluated the therapeutic differences between paliperidone and risperidone orally disintegrating tablets in 66 hospitalized SCH patients.

2. Materials and methods

2.1. General information

A total of 66 hospitalized SCH patients treated between April 2022 and October 2023 were selected. The patients were randomly divided into two groups using a random number table. The study group included 33 patients (19 males and 14 females), aged 26–50 years, with a mean age of 38.14 ± 3.35 years. The duration of illness ranged from 9 to 20 years, with a mean of 15.19 ± 3.18 years. Body mass index (BMI) ranged from 18.5 to 28.1 kg/m², with a mean of 22.59 ± 2.64 kg/m². The control group also included 33 patients (20 males and 13 females), aged 27–48 years, with a mean age of 37.81 ± 3.18 years. The duration of illness ranged from 10 to 20 years, with a mean of 15.91 ± 3.25 years. BMI ranged from 18.4 to 28.3 kg/m², with a mean of 22.68 ± 2.77 kg/m². Comparisons of general characteristics between the two groups showed no statistically significant differences ($P > 0.05$), indicating comparability.

Inclusion criteria: Patients presenting typical symptoms such as delusions or slow thinking; adult patients under 80 years of age; stable condition, capable of cooperating with medication; relatively complete clinical data; agreement to participate in the study.

Exclusion criteria: Patients who received related drug treatment within the past month; allergic to study drugs; suffering from malignant tumors or other severe diseases; severely manic and unable to cooperate; SCH caused by trauma or other factors; withdrawal during the study.

2.2. Methods

The study group was treated with paliperidone (produced by Livzon Pharmaceutical Group, National Drug Approval No. H20080217, specification: 4 mg). The initial dose during the first week was 4 mg per dose, administered three times daily. Based on the patient's condition, the dosage could be increased weekly, with an incremental dose of 4 mg per administration. The maximum oral dose per administration was 16 mg, administered three times daily, with a total daily dose of less than 48 mg. The treatment duration was three months.

The control group was treated with risperidone orally disintegrating tablets (produced by Qilu Pharmaceutical, National Drug Approval No. H20070271, specification: 0.5 mg). The initial dose was 1 mg per administration, taken once daily. After one week of treatment, the dosage could be increased to 3–4 mg per administration, taken once daily. The treatment duration was three months.

2.3. Observation indicators

(1) Symptom scores: Assessed using the Positive and Negative Syndrome Scale (PANSS), which includes positive symptoms (7–49 points), general psychopathology symptoms (16–112 points), and negative symptoms (7–49 points). The total score ranges from 30 to 210 points, with higher scores indicating more severe symptoms.

(2) Adverse reactions: Observed the incidence of side effects such as weight gain, insomnia, extrapyramidal reactions, nausea, and elevated prolactin levels.

2.4. Criteria for evaluating efficacy

(1) Cured: Reduction in PANSS score > 80%.

(2) Significant improvement: Reduction in PANSS score between 50–80%.

(3) Initial improvement: Reduction in PANSS score between 25–49%.

(4) No improvement: Reduction in PANSS score < 25%.

2.5. Statistical analysis

Data were processed using SPSS 28.0. Measurement data were expressed as (mean ± standard deviation) and compared using *t*-tests. Count data were expressed as [*n* (%)] and compared using χ^2 tests. Statistical significance was set at $P < 0.05$.

3. Results

3.1. Comparison of efficacy between the two groups

Table 1 shows that the total effective rate of treatment in the study group was comparable to that of the control group ($P > 0.05$).

Table 1. Comparison of efficacy between the two groups [*n* (%)]

Group	*n*	Cured	Significant improvement	Initial improvement	No improvement	Total effective rate
Study group	33	15 (45.45)	10 (30.30)	6 (18.18)	2 (6.06)	31 (93.94)
Control group	33	12 (36.36)	11 (33.33)	5 (15.15)	5 (15.15)	28 (84.85)
χ^2	-	-	-	-	-	1.438
P	-	-	-	-	-	0.230

3.2. Comparison of symptom scores between the two groups

After treatment, symptom scores in both groups were significantly lower than before treatment. The study group exhibited significantly lower symptom scores compared to the control group ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of symptom scores between the two groups (mean ± SD, points)

		Study group (*n* = 33)	Control group (*n* = 33)	*t*	*P*
Positive symptoms	Before treatment	31.42 ± 3.59	31.40 ± 3.55	0.023	0.982
	After treatment	10.15 ± 1.98	14.09 ± 2.07	7.901	< 0.001
	t	29.803	24.198	-	-
	P	< 0.001	< 0.001	-	-
General psychopathology symptoms	Before treatment	40.19 ± 4.82	40.77 ± 4.91	0.484	0.630
	After treatment	20.53 ± 2.98	25.74 ± 3.46	6.554	< 0.001
	t	19.930	14.374	-	-
	P	< 0.001	< 0.001	-	-

Table 2 (Continued)

		Study group (n = 33)	Control group (n = 33)	t	P
Negative symptoms	Before treatment	23.77 ± 3.06	23.91 ± 3.15	0.183	0.855
	After treatment	9.88 ± 1.52	12.43 ± 1.60	6.638	< 0.001
	t	23.353	18.666	-	-
	P	< 0.001	< 0.001	-	-
Total score	Before treatment	95.38 ± 7.12	96.08 ± 7.25	0.396	0.694
	After treatment	40.56 ± 5.83	52.26 ± 6.11	7.959	< 0.001
	t	34.221	26.550	-	-
	P	< 0.001	< 0.001	-	-

3.3. Comparison of adverse reaction rates between the two groups

Table 3 shows that the adverse reaction rate in the study group was significantly lower than in the control group (P < 0.05).

Table 3. Comparison of adverse reaction rates between the two groups [n (%)]

Group	n	Weight gain	Insomnia	Extrapyramidal reaction	Nausea	Elevated prolactin	Incidence
Study group	33	0	1 (3.03)	0	1 (3.03)	0	2 (6.06)
Control group	33	1 (3.03)	3 (9.09)	1 (3.03)	2 (6.06)	1 (3.03)	8 (24.24)
χ^2	-	-	-	-	-	-	4.243
P	-	-	-	-	-	-	0.039

4. Discussion

The pathogenesis of SCH involves genetic, environmental, and biological factors, resulting from a combination of these influences. SCH is characterized by complex clinical manifestations and a prolonged disease course, which significantly affect patients' cognitive function, emotional perception, thought patterns, language expression, and behavioral habits [3]. SCH typically presents with positive symptoms such as disorganized speech, hallucinations, or delusions, which may lead to abnormal behaviors. Over time, these behaviors often give rise to negative symptoms like emotional apathy and lack of motivation. Additionally, many SCH patients experience cognitive symptoms such as memory impairment and difficulty concentrating, severely impacting their daily lives.

Treatment for SCH involves a comprehensive approach, including psychotherapy, social support, and pharmacotherapy. The primary goal is to alleviate symptoms, minimize the impact of the disease on quality of life, and reduce relapse rates. Currently, antipsychotic medications are the standard treatment, primarily working as D2R antagonists to improve both positive and negative symptoms and stabilize the condition [4].

Risperidone is a commonly used antipsychotic derived from benzisoxazole. It has a high affinity for 5-HT and DA receptors and binds to α1-adrenergic receptors, exerting its antipsychotic effects. Lacking cholinergic receptor activity, risperidone effectively alleviates positive symptoms due to its strong D2R antagonism. Its orally disintegrating tablet (ODT) formulation dissolves rapidly in saliva, requiring minimal water for swallowing,

offering significant convenience. With a high oral bioavailability, peak plasma concentration occurs 1–2 hours post-administration, and its half-life is approximately 24 hours, allowing stable therapeutic effects [5]. However, long-term use of risperidone ODT may cause adverse effects such as electrocardiogram abnormalities, nausea, vomiting, and insomnia, which can reduce medication adherence and efficacy.

Paliperidone, a novel medication for SCH, acts as a D2R antagonist and modulates DA and 5-HT balance, thus addressing cognitive and negative symptoms. With a dual antagonistic mechanism for DA and 5-HT receptors, it improves neurotransmitter secretion [6]. Specifically, D2R inhibition prevents stereotypical behaviors induced by substances like apomorphine, enhancing central nervous function. Similarly, 5-HT receptor inhibition counteracts abnormal behaviors induced by compounds like para-chloramphetamine and tryptamine, alleviating disease symptoms [7]. Paliperidone also disrupts DA metabolic pathways, exerting stronger effects on the striatum and reducing extrapyramidal reactions.

The results indicate that the total effective treatment rate in the study group was comparable to that in the control group ($P > 0.05$). A detailed analysis suggests that both medications are multi-receptor agents. Risperidone ODT lacks anticholinergic activity, modulating DA and 5-HT receptor expression to achieve stable therapeutic effects [8]. Similarly, paliperidone acts on these receptors, sharing a similar mechanism of action with risperidone, which accounts for their comparable efficacy. However, paliperidone upregulates DA concentrations in the prefrontal cortex, enhancing cognitive function and achieving a slightly higher total effective rate than risperidone [9].

Symptom scores in the study group were significantly lower than those in the control group after treatment ($P < 0.05$). D2R, a neurotransmitter receptor, regulates emotional behavior and motor function. Its genetic polymorphisms are associated with SCH pathogenesis and clinical outcomes. Paliperidone's pronounced D2R antagonism modulates DA levels, improving emotional and motor control and alleviating related symptoms [10]. Furthermore, its D2R inhibitory effect is stronger than that of conventional drugs like risperidone, leading to significant improvements in both positive and negative symptoms.

The adverse reaction rate in the study group was lower than that in the control group ($P < 0.05$). A specific analysis indicates that prolonged risperidone ODT use affects the extrapyramidal system, leading to extrapyramidal reactions. In contrast, paliperidone exhibits a higher affinity for 5-HT receptors, reducing interference with the extrapyramidal system and thereby minimizing adverse reactions [11]. Additionally, paliperidone has a shorter half-life, with faster distribution and metabolism, reducing the likelihood of drug accumulation and associated adverse effects. Consequently, it demonstrates fewer long-term adverse reactions.

However, SCH patients present with individual differences in constitution, disease progression, and drug tolerance. During pharmacotherapy, regular monitoring of coagulation function, liver and kidney function, and other indicators is necessary to assess improvement and adjust dosages appropriately, avoiding overmedication [12]. Additionally, patients should be observed for discomfort during treatment. In cases of adverse effects such as nausea or akathisia, the underlying cause should be identified, and discontinuation or targeted interventions should be considered to prevent severe reactions.

5. Conclusion

In conclusion, paliperidone demonstrates comparable efficacy to risperidone ODT in the treatment of SCH but offers superior symptom improvement and a lower risk of adverse effects, making it a more advantageous therapeutic option.

Disclosure statement

The author declares no conflict of interest.

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