Research Article

Efficacy of Risperidone Orally Disintegrating Tablets Combined with Oxazepam in the Treatment of Schizophrenia

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Objective. To explore the efficacy of risperidone orally disintegrating tablets combined with oxazepam in the treatment of schizophrenia.

Methods. From May 2019 to May 2021, 60 patients with schizophrenia treated in our hospital were recruited and assigned into an observation group (risperidone orally disintegrating tablets combined with oxazepam treatment) and a control group (alprazolam combined with chlorpromazine treatment) according to the random number table method. The positive and negative symptom score (PANSS), quality of life score (QOL-75), ability of daily living score (ADL), clinical efficacy, incidence of adverse reactions, and disease recurrence were compared between the two groups before and after treatment.

Results. The PANSS scores were similar in the two groups before treatment (P > 0.05). The two groups presented a declining trend in PANSS score after treatment, whereas a remarkable lower score in the observation group was observed (P < 0.05). The QOL scores of the two groups before treatment was not significantly different (P > 0.05). Both groups witnessed improvements one month and three months after treatment, with considerable improvements being obtained in the observation group (all P < 0.05). The ADL scores of the two groups did not differ before treatment (P > 0.05). At 1 month and 3 months after treatment, the ADL scores of the two groups were improved, with a higher score in the observation group (P < 0.05). The observation group had a markedly higher total effective rate as compared to the control group (X^2 = 5.455, P = 0.020). Adverse reaction occurred in both groups, with milder results in the observation group. The recurrence rate of the two groups was not statistically different one month after treatment (P > 0.05), while two and three months after treatment, they were lower than those of the control group (all P < 0.05). Conclusion. Risperidone orally disintegrating tablets combined with oxazepam shows potential in the treatment of schizophrenia by relieving patients’ mental symptoms, improving quality of life and activities of daily living, and minimizing the incidence of adverse reactions.

1. Introduction

Schizophrenia is a common clinical mental disease characterized by the distortion and abnormality of individual thinking, perception and behavior, unresponsiveness, aggressive behavior, and disordered thinking. Schizophrenia is one of the most debilitating disorders worldwide, and is associated with high costs for hospital admissions, unemployment, and loss of productivity. In addition, relationships are often jeopardised and it might give rise to suicide. All these have an impact in terms of burden for patients, families, and society. It is highly prevalent in younger populations and is associated with genetics, environment, and the brain structure [1]. As the disease progresses, patients are prone to negative emotions such as anxiety and depression, and even suicidal tendencies, aggression, and violent tendencies.

Antipsychotic drugs are the mainstay of the clinical treatment of schizophrenia, and the efficacy is remarkable [2]. Nevertheless, a bulk of evidence shows that the traditional treatment option of alprazolam and chlorpromazine produced a somber outcome that cannot satisfy clinical needs.

Additionally, traditional Chinese medicine treats it based on syndrome differentiation in clinical practice. Zhang divided schizophrenia patients into five syndrome types...
through TCM syndrome differentiation: phlegm and fire disturbing the heart type, qi stagnation and blood stasis type, phlegm-damp internal resistance type, yin deficiency and fire prosperous type, and yang deficiency type [3]. The treatment using syndrome differentiation can significantly improve the cognitive function and social participation of schizophrenia patients [4]. With this background, we attempted to investigate the effectiveness of risperidone orally disintegrating tablets combined with oxazepam.

2. Materials and Methods

2.1. Participants. A total of 60 cases of schizophrenia was evenly assigned into two groups using the random table methods. In the observation group, there were 19 males and 11 females; aged 18–68 years, with an average age of 39.59 ± 4.32 years; the course of the disease was 7 months to 10 years, with an average course of disease of 5.35 ± 1.16 years; in the control group, there were 18 males and 12 females; aged 19–69 years, with a mean age of 39.56 ± 4.57 years; the course of disease was 10 months to 9 years, with a mean course of disease of 5.32 ± 1.13 years. The two groups presented similar baseline data. Prior to the study commencement, the patients and their family members were informed of the research purpose and significance, and signed the informed consent form voluntarily. The medical ethics committee reviewed and approved the study (QS-201904).

2.2. Inclusion and Exclusion Criteria. The participants were assessed as eligible if they (1) met the diagnosis criteria of post schizophrenia depression (Li et al., 2022); (2) could communicate and cooperate with the study; (3) had complete clinical data. Whereas patients who met the following were excluded: (1) with severe damage to important organs; (2) with other types of mental illness; (3) cancer patients; (4) with systemic infectious diseases; (5) poor coordination or failure to finish the study; (6) with intolerance to the treatment or allergic reactions; (7) with immune system diseases or blood coagulation disorders; (8) pregnant women; (9) with a history of drug abuse.

3. Method

The control group received alprazolam combined with chlorpromazine: alprazolam (Jinling Pharmaceutical Co., Ltd., Nanjing Jinling Pharmaceutical Factory, approval No. H32024413, specification 0.4 mg) was administered at a starting dose of 1.2 mg/d and chlorpromazine (Diao Group Chengdu Pharmaceutical Co., Ltd., approval No. H51021169, specification 25 mg) was administered at an initial dosage of 100 mg/d; the dosage was adjusted according to the patient’s condition and the treatment lasted for 3 months. The observation group was given risperidone orally disintegrating tablets (Jilin West Point Pharmaceutical Technology Development Co., Ltd., approval No. H20060283, specification 1 mg) at an initial dosage of 1 mg/d and gradually increased to 4 mg/d within 2 weeks, and oxazepam (Beijing Yimin Pharmaceutical Co., Ltd., approval No. H11020894, specification 15 mg) at an initial dosage of 15 mg/d, and the maximum should not exceed 45 mg/d; the treatment lasted for 3 months.

3.1. Outcomes

1) Positive And Negative Syndrome Scale (PANSS) score: the scale was used to evaluate the positive and negative symptoms of patients, and includes a total of 30 items. Each item scores from 1 to 7, and the higher the score, the more severe the psychiatric symptoms [5].

2) Quality of Life -75 Scale (QOL-75) score: the scale was scored from four dimensions of material, physical, psychological, and social, with a total score of 100 for each item. A high score indicates a better quality of life [6].

3) Abilities of Daily Life (ADL) Scale score: the ADL scale was used to assess the daily living ability, it comprises 10 items and each component has a score that ranges from 0 to 10 points. The scores of the 10 components will be summed to yield a global score ranging from 0 to 100. High scores represent better activities of daily living [7].

4) Efficacy: after treatment, if the symptoms disappear and the PANSS score is reduced by ≥75%, it is deemed as markedly effective; if all symptoms are relieved after treatment, and the PANSS score is reduced by 35% to 74%, it is considered effective; if the symptoms are not mitigated or even aggravated, it is considered ineffective. The total effective rate = percentage of markedly effective + effective [8].

3.2. Statistical Analysis. All statistical analyses were done by the SPSS22.0 software package. The counting data and measurement data were expressed as (%) and (x ± s), respectively, and analyzed by the chi-square and t-test, respectively. Significance was assumed at a P-value of <0.05.

4. Results

4.1. Comparison of the PANSS Scores. The PANSS scores of the two groups before treatment were similar (P > 0.05). After treatment, the PANSS scores in both groups showed a downward trend, while the scores in the observation group were significantly lower (P < 0.05, Table 1).

4.2. Comparison of QOL-75 Scores. There was no significant difference in QOL-75 scores between the two groups before treatment (P > 0.05). Both groups improved at 1 month and 3 months after treatment, and the observation group showed a significant improvement (P < 0.05, Table 2).
Table 1: Comparison of PANSS scores between the two groups (x ± s, point).

| Groups          | N  | Positive symptoms | Negative symptoms | Psychopathology | Total score |
|-----------------|----|-------------------|-------------------|-----------------|-------------|
| Observation group | 30 | 30.85 ± 5.23 | 20.68 ± 4.42 | 39.32 ± 4.22 | 91.04 ± 8.65 |
| Control group   | 29.74 ± 5.52 | 21.07 ± 4.34 | 38.59 ± 4.14 | 92.35 ± 7.89 |
| Before treatment | t  | 0.800           | 0.345            | 0.676           | 0.613       |
|                 | P  | 0.427           | 0.732            | 0.502           | 0.542       |

Note. Compared with the same group before treatment, *P < 0.05.

Table 2: Comparison of QOL-75 scores between the two groups (x ± s, point).

| Groups          | n  | Before treatment | One month after treatment | Three months after treatment |
|-----------------|----|-----------------|--------------------------|-----------------------------|
| Observation group | 30 | 52.32 ± 5.32 | 74.53 ± 7.57             | 82.12 ± 5.53                |
| Control group   | 30 | 51.55 ± 5.43 | 63.49 ± 6.43             | 70.63 ± 5.45                |
| T               | —  | 0.555          | 6.088                    | 8.106                       |
| P               | —  | 0.581          | ≤0.001                   | ≤0.001                      |

4.3. Comparison of ADL Scores. There was no significant difference in ADL scores between the two groups before treatment (P > 0.05). At 1 month and 3 months after treatment, the ADL scores of the two groups were improved, and the observation group had a higher score (P < 0.05, Table 3).

4.4. Comparison of Clinical Efficacy. The total effective rate of the observation group was significantly higher than that of the control group (X² = 5.455, P = 0.020), as shown in Table 4.

4.5. Comparison of Adverse Reactions. Adverse reactions occurred in both groups, while the proportion in the observation group was smaller, as shown in Table 5.

4.6. Comparison of the Recurrence Rate. There was no significant difference in the recurrence rate between the two groups after 1 month of treatment (P > 0.05). The recurrence rates of the observation group 2 and 3 months after treatment were 3.3% and 6.7%, respectively, which were lower than those of the control group (P < 0.05, Figure 1).

5. Discussion

Schizophrenia is a chronic, severe mental illness that affects 1% of the population throughout their lives, and may lead to a tendency to become chronic or mentally retarded [9]. It is reported that psychiatric disorders are associated with multiple factors such as genetics, environment, brain structure, and neurotransmitters. A good prognosis after treatment may account for 40%, and some patients have symptoms such as anorexia and depression, which are the triggers for patients to commit suicide [10, 11]. In addition, their social functioning and ability of daily living are impaired, thereby affecting the quality of life, and increasing the financial pressure and caregiving burden on families. As a consequence, it is urgent to strengthen efforts to find an efficient and safe treatment strategy.

Traditionally, schizophrenia patients are treated with alprazolam and chlorpromazine. However, despite its certain effect in relieving the positive and negative symptoms of patients, it is associated with poor medication compliance and multiple adverse reactions, restraining the efficacy of the drug [12, 13]. As an atypical antipsychotic drug, risperidone orally disintegrating tablets are derivatives of benzisoxazole, which can effectively block dopamine D2 receptors and serotonin receptors, and can target dopamine receptors and subtypes at multiple sites in the brain [14].

In addition to the abovementioned conventional treatments, traditional Chinese medicine (TCM) can also effectively improve the mental symptoms of schizophrenia patients, improve the quality of life, improve treatment compliance, and reduce the incidence of adverse reactions. According to its clinical symptoms, Chinese medicine classifies it as "madness" and "dementia." Treatment includes syndrome differentiation and prescription according to syndrome type, special prescription treatment, acupuncture treatment, TCM emotional therapy, and TCM exercise therapy [15].

Some scholars have previously revealed that risperidone plays a role in regulating the patient’s dopamine system, thereby inhibiting the adverse reactions of the extraneural system, relieving the patient’s discomfort, and ultimately improving medication compliance [16, 17]. In addition, risperidone orally disintegrating tablets also possess excellent water solubility and can be dissolved in the daily diet, ensuring the efficacy of the drug in the case of poor coordination [18]. Oxazepam, a new generation of benzodiazepines with merits of strong activity and a short half-life, functions well in mitigating patients’ symptoms such as insomnia, anxiety, and convulsions, and has a high safety profile [19, 20, 21].
This study showed that the PANSS score, QOL-75 score, and ADL score of the observation group improved more significantly than those of the control group after treatment. In terms of drug safety, the major adverse reactions such as gastrointestinal reactions and extravertebral adverse reactions of risperidone orally disintegrating tablets and oxazepam are relatively mild, and they can disappear without special treatment. It is mainly attributed to its half-life that if the drug is stopped, the side effects will disappear in about a week to more than half a month [22].

Promisingly, the follow-up showed that the total effective rate in the observation group was higher than that in the control group, and the incidence of adverse reactions was lower than that in the control group. After 3 months of follow-up, the recurrence rate of the observation group was lower than that of the control group, suggesting an ideal efficacy of risperidone orally disintegrating tablets combined with oxazepam. The possible explanation may be that risperidone is a potent D2 antagonist, antagonizing serotonin and dopamine in the central system, adjusting their balance to reduce the occurrence of extrapyramidal side effects, and extending its therapeutic effect to schizophrenia of negative symptoms, affective symptoms, etc.

However, there are several limitations that merit attention. First, the outcome measures are not so comprehensive that long-term indicators failed to be evaluated, such as anxiety, depression, and coordination degree. In addition, depressed patients are often accompanied by anxiety, sleep disorders, etc., which may also affect the presentation of the results, but these patients were not included in this study. In the future, it is suggested that future trials should be planned with a larger sample size and longer period of intervention to make better judgment on the efficacy and safety of this strategy.

6. Conclusion

The combination of risperidone orally disintegrating tablets and oxazepam in the treatment of schizophrenia can reduce the psychotic symptoms of patients, improve the quality of life, and enhance the ability of daily living, with higher safety.

Data Availability

No data were used to support this study.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

References

[1] W. Changhong, L. Liulu, and Y. Fengju, "Epidemiological investigation of mental disorders in Henan Province, analysis
of the prevalence of schizophrenia,” *Chinese Journal of Psychiatry*, vol. 53, pp. 23–28, 2020.

[2] G. Yan, L. Xiuping, and Z. Yuanyuan, “The effect of antipsychotic drugs on the gray matter area of adolescents with first-episode schizophrenia,” *Journal of Psychiatry*, vol. 34, pp. 56–59, 2021.

[3] Y. Zhang, “Efficacy of TCM syndrome differentiation in treating anxiety symptoms in patients with schizophrenia in convalescence,” *China Health Standards Administration*, vol. 13, no. 02, pp. 100–104, 2022.

[4] G. Sun, “Therapeutic effect of TCM syndrome differentiation on anxiety symptoms in patients with schizophrenia in convalescence,” *Journal of Baotou Medical College*, vol. 33, no. 04, pp. 109–110, 2017.

[5] G. Xinwei, J. Haifeng, and Y. Shijian, “The correlation between the concentration of first-episode schizophrenia-related factors and its cognitive function score and PANSS score,” *Chinese Journal of Coal Industry Medicine*, vol. 23, pp. 539–543, 2020.

[6] Y. Jingjing, T. Wenyan, and W. Shubin, “Analysis of quality of life and influencing factors of patients with schizophrenia in Guangdong Province,” *Chongqing Medical Science*, vol. 50, pp. 1199–1204, 2021.

[7] L. Jinyan, L. Feifei, and Z. Jiazi, “The effect of intensive intervention on treatment compliance and ability of daily living in patients with chronic hospitalized schizophrenia,” *Guangdong Medicine*, vol. 41, pp. 2465–2469, 2020.

[8] Y. Jinglan, Z. Xiaorong, and Z. Yuanjia, “Research progress in the involvement of the prefrontal cortex in the pathogenesis of schizophrenia,” *Chinese Journal of Neuromedicine*, vol. 18, pp. 194–198, 2019.

[9] Z. Rui, G. Xuan, and X. Ling, “The effect of aripiprazole combined with risperidone on alleviating violent behavior in patients with schizophrenia,” *Journal of Clinical and Experimental Medicine*, vol. 20, pp. 35–39, 2021.

[10] X. Huiyan and C. Wei, “Disorders of identity and heterosexuality: a neurophenomenological analysis of social perception disorders in schizophrenia,” *Zhejiang Social Sciences*, vol. 12, pp. 90–98, 2020.

[11] J. Yizhou, Z. Weibo, and C. Chunmei, “Research progress on related factors of schizophrenia recurrence,” *Neurological Diseases and Mental Health*, vol. 20, pp. 869–874, 2020.

[12] H. Jianchun, C. Aobo, and L. Xiaoning, “The effects of amisulpride, chlorpromazine, and haloperidol on cognitive function and efficacy analysis of patients with first-episode schizophrenia,” *Journal of Psychiatry*, vol. 32, pp. 268–272, 2019.

[13] Y. Yanhong, W. Xin, and Z. Jun, “Changes in granulocyte levels in patients with first episode mental illness and schizophrenia and its correlation with chlorpromazine equivalent,” *Journal of Clinical Research*, vol. 38, pp. 209–212, 2021.

[14] C. Qingyan, D. Mingjun, and J. Wei, “A comparative study of paliperidone sustained-release tablets and risperidone on improving social function in elderly patients with schizophrenia,” *Journal of Clinical Psychiatry*, vol. 31, pp. 221–223, 2021.

[15] Q. Zhong, Z. Tian, and M. Yan, “Research progress of traditional Chinese medicine in the treatment of schizophrenia (II),” *Jiangxi Chinese Medicine*, vol. 53, no. 06, pp. 67–69, 2022.

[16] D. Handong, C. Chuanqi, and S. Liujuan, “Effects of risperidone, quetiapine, clozapine and olanzapine on QTc interval prolongation in elderly patients with schizophrenia,” *International Journal of Psychiatry*, vol. 48, pp. 233–236, 2021.