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SHORT COMMUNICATION

CLINICAL OBSERVATION ON PALIPEDDONE SUSTAINED RELEASE TABLET IN THE TREATMENT OF SCHIZOPHRENIA

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Abstract

Objective of this study was to evaluate the efficacy and adverse drug reactions (ADR) of palipeddone sustained release tablet in the treatment of schizophrenia in outpatients. Outpatients with schizophrenia treated with palipeddone sustained release tablet (observation group) in our hospital from Apr. to Sep. in 2009 were followed up and compared with those treated with risperidone (control group) during the same period. PANSS and TESS were applied to evaluate efficacy and ADR. Results suggest that the cure rates were 42.4% for control group and 49.6% for observation group. The effective rates were 74.8% for control group and 80.3% for observation group ($P < 0.05$). As compared with control group, observation group showed slightly ADR with low frequency. In summary palipeddone sustained release tablet which has sound effect on schizophrenia with slightly ADR suits for outpatient treatment.

Key words: Palipeddone sustained release tablet; Risperidone; Outpatient; Schizophrenia

1. INTRODUCTION

Palipeddone is the main metabolite of risperidone. Similar to other antipsychotics, the action mechanism of palipeddone is still unclear. However, it is currently confirmed that the action mechanism is mediated by a combined antagonistic activity of central dopamine receptor (D2) and 5-HT (2A). Studies have indicated that this new type antipsychotic, i.e., palipeddone sustained release tablet can effectively control schizophrenia symptoms and improve the schizophrenia patient's social functions measured by the Personal and Social Performance Scale (PSP). Palipeddone sustained release tablet has received official approval from the Food and Drug Administration of the United States since September 2008. Although there are several clinical trials of this antipsychotic in other countries (Kane et al., 2007; Lehman et al., 2004), there are very limited studies regarding its effect and use in China. In order to explore the clinical effect of palipeddone and accumulate data in China, the investigators of this present study carried out the follow-up observation from the outpatients with schizophrenia treated with palipeddone sustained release tablet in The Third People's Hospital of Yichun,

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China from April to September in 2009 with the control observation from the outpatients treated with risperidone.

2. METHOD

2.1. Participant inclusion criteria

(1) Observation group included the outpatients with schizophrenia treated with paliperidone sustained release tablet from the hospital from April to September in 2009, while control group was the outpatients with schizophrenia treated with risperidone during the same time; (2) The diagnosis of schizophrenia patients was based upon the standard in the Chinese Classification of Mental Disorders Version 3 (CCMD-3); (3) The Positive and Negative Syndrome Scale (PANSS) score for both groups was required to be ≥ 50 ; (4) The patients' age was between 14 and 60, and there was no restriction on gender; (5) Any patient with cardiac, hepatic or renal disorders was excluded; (6) Informed agreements were obtained from all patients.

2.2. Participant demographics

The observation group consisted of 62 males and 44 females between the age of 14-56 (Mean = 28.6, SD = 12.5). The disease course of these participants was 1-38 months (Mean = 9.6, SD = 3.7). In the observation group, 33 participants were diagnosed with schizophrenia first time whereas 73 participants were relapse patients with schizophrenia. For the control group, there were 60 males and 42 females between the age of 14-60 (Mean = 29.2, SD = 14.6). The disease course of these participants was 1-36 months (Mean = 10.6, SD = 4.1). Thirty-two participants were diagnosed with schizophrenia first time and 70 participants were relapse patients. The PANSS baseline score, age, disease course, and number of gender from the two groups did not show any statistically significant differences ($p > .05$), so both groups were comparable.

2.3. Intervention method

In the observation group, patients were given paliperidone sustained release tablet with the initial dosage of 3 mg/d or 6 mg/d once per day. After 7 days, the dosage was changed to 3-9 mg/d for maintenance therapy. For the control group, patients were given risperidone with the initial dosage of 1 mg/d twice per day. After 7 days, the dosage was changed to 2-4 mg/d for maintenance therapy. The period of treatment for both groups was 8 weeks. Patients with insomnia were treated with oral administration of alprazolam 0.4~0.8 mg.

2.4. Outcome evaluation

Evaluation of therapeutic effects. PANSS scores were used to assess the efficacy of paliperidone. PANSS scores were evaluated pre treatment and post treatment in 2 weeks/4 weeks /8 weeks, by two psychiatrists who were responsible for the follow-up work. Efficacy was assessed by the PANSS score reduction. A PANSS score reduction $\geq 80\%$ indicated remission, $\geq 50\%$ indicated significant improvement, $\geq 20\%$ indicated improvement, and $< 20\%$ indicated a lack of effect. The cure rate was the percentage determined by the total number of participants who demonstrated either remission or significant improvement divided by the total number of the group participants. The effective rate was the percentage determined by the total number of participants who showed remission, significant improvement or improvement divided by the total number of the group participants.

Evaluation of safety. Treatment-Emergent Signs and Symptoms (TESS) scores were used to assess the side effects. If the TESS score was ≥ 2 , this indicated an adverse reaction. The schedule and the method of the TESS implementation were the same as the PANSS.

Statistical analysis. The SPSS10.0 program was used to carry out the data analysis. The t-test was used for interval/ratio data and the χ^2 test was used for nominal data. The effects of medication efficacy of group comparison were examined with the χ^2 test. Statistical significance was set to $p < .05$.

3. RESULTS

3.1. Follow-up results

In the observation group, among 127 outpatients with schizophrenia treated with palipeddone sustained release tablet, 21 outpatients (16.5%) did not complete the entire treatment period due to various reasons; only 106 outpatients (83.5%) were able to obey the medical orders and comply with 6-8 weeks of follow-up. For the control group, among 139 outpatients treated with risperidone, 37 outpatients (26.6%) also did not complete the entire treatment period; only 102 outpatients (73.4%) were able obey the medical orders and comply with 6-8weeks of follow-up. There was a statistically significant difference in the rate of cooperation between the two groups ($p < .05$). This difference was because the adverse reactions of palipeddone sustained release tablet were less and this drug was easily acceptable by patients with more compliance, supporting the conclusion from Sun and Zhou (2007).

The main reason why the patients could not insist on the maintenance therapy was that the adverse reactions had an influence on their bodies. Since several factors, such as the dosage of antipsychotics, frequency of medications, treatment duration, and medication administration method are highly related to medication compliance, a simple and convenient medication administration method would be easily acceptable by patients with more compliance. This implies that for outpatient follow-up treatment, psychiatrists should select patients with milder symptoms to better acquire their informed agreements and cooperation. We suggested that the patients with uncertain diagnosis or serious, acute symptoms needed hospitalization.

3.2. Therapeutic effects

Table 1 and Table 2 present the comparison of the PANSS scores between the two groups.

Table 1. Comparison of the therapeutic effects between the two groups.

Groups	Sample Size	Remission	Significant Improvement	Improvement	Lack of Effect	Cure Rate (%)	Effective Rate (%)
Observation	127	18	45	39	25	49.6	80.3
Control	139	19	40	45	35	42.4	74.8

Table 2. Comparison of the PANSS and TESS score between the two groups (Mean \pm SD).

Groups	Sample Size	Scale	Pretreatment	2W	4W	8W
Observation	106	PANSS	67.6 \pm 12.5	59.6 \pm 12.5	43.6 \pm 11.4	39.2 \pm 10.6
		TESS	1.8 \pm 1.3	4.2 \pm 2.9	3.9 \pm 2.8	3.2 \pm 2.6
Control	139	PANSS	66.7 \pm 13.3	58.5 \pm 12.5	45.1 \pm 10.8	42.7 \pm 11.4
		TESS	1.8 \pm 1.4	7.2 \pm 3.6	7.9 \pm 3.6	6.7 \pm 3

As seen in Table 1, there were statistically significant differences in both the cure rate and effective rate between the two groups ($p < .05$), which indicated that palipredone sustained release tablet was more efficacious in the treatment of outpatients with schizophrenia than risperidone. As shown in Table 2, the PANSS scores of the two groups significantly decreased after 2-4weeks treatment with similar amount of score reduction and there were no statistically significant differences in the PANSS scores between the two groups ($p > 0.05$). But, there were statistically significant differences in the PANSS scores between the two groups and the scores of the observation group were obviously lower than those of the control group after 6-8weeks treatment ($p < .05$). With regard to TESS, the differences of TESS average score between two groups in 2, 4, and 8 weeks after post treatment were all reached statistical significance ($p < .01$). The results of TESS showed that the degree of adverse effects of palipredone sustained release tablet were slightly, which means that this particular antipsychotic would be easily acceptable by patients and suggests that effects of palipredone sustained release tablet have more advantages associated with the prolonged treatment period. The efficacy of palipredone in this present study was similar to the result by Liu et al. (2004) who studied olanzapine in the treatment of schizophrenia in outpatient. However, the efficacy of palipredone was lower than the efficacy of palipredone in the schizophrenia treatment conducted by Kane et al. (2007) and the efficacy of risperidone combining with quetiapine conducted by Tao et al. (2005). This indicated that there is a slight difference between the hospitalization treatment and outpatient treatment.

3.3. Side effects

The TESS scores of two groups are presented in Table 2. The comparison of side effects (adverse reactions) between the two groups is shown in Table 3.

Table 3. Comparison of ADR between the two groups.

Groups	Sample Size	Dry Mouth	Blurred Vision	Thrill	Myotonia	Akathisia	Weight Increase	ECG Change	Constipation	Headache
Observation	106	10	8	5	4	4	4	4	4	4
Control	102	16	14	8	7	6	9	8	8	7

In Table 3, the pre and 3 times post-treatment evaluation results of blood analysis, hepatic function, renal function were not obviously abnormal ($p > .05$). The ECG results of observation group indicated that 3 patients had sinus tachycardia, 1 patient had Q-T interval prolongation whereas the ECG results of control group indicated that 8 patients had changes in their ECG. Among these 8 patients, 5 patients had sinus tachycardia, 3 patients showed changes in T wave, 2 patients had atrioventricular block, and 2 patients had partly changes in their s-t segment.

3.4. Dosage of palipredone sustained release tablet

In the observation group, 33 patients (33.1%) took 3mg/d, 58 patients (54.7%) used 6mg/d, and 15 patients (14.2%) medicated 9mg/d. When evaluating both efficacy and side effects, we suggested that either 3mg/d or 6mg/d dosage of palipredone sustained release tablet was more suitable for the outpatients with satisfactory efficacy.

4. DISCUSSION

The main adverse effects of paliperidone sustained release tablet were dry mouth, blurred vision, thrill, myotonia, akathisia, weight increase, ECG changes, constipation, and headache. The incidence of these adverse reactions increased with the increased dose of medication and mainly occurred in 1-4 weeks. After 4 weeks, these adverse reactions became less severe; and the degree and frequency of paliperidone were less than those of risperidone, and less than those of the observation results in TESS (Liu et al., 2004; Sun & Zhou 2007; Tao et al., 2005). The results of this study supported the conclusion.

Since paliperidone sustained release tablet has the advantage of satisfactory efficacy, lower incidence of adverse reactions with a slight degree, and taking medicine once a day, it can improve patients' compliance and is suitable for schizophrenia patients in the outpatient setting to acquire a better clinical effect. Thus, currently it is a better medication in the treatment of schizophrenia in outpatient.

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