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•Original research article•

A comparison study of Quetiapine and Risperidone's effectiveness and safety on treating alcohol-induced mental disorder

Bei LV, Haishui DUAN

Background: Compared with Risperidone, Quetiapine's effectiveness and safety on treating alcohol-induced mental disorder is still unclear.

Objective: To investigate the clinical effectiveness and safety of Quetiapine on treating alcohol-induced mental disorder.

Methods: One hundred and forty-eight patients with alcohol-induced mental disorder were divided into the experimental group (75 patients) and the control group (73 patients) by the treatments they received. The patients in the experimental group were treated with Quetiapine by taking it three times per day orally. The mean (sd) maintenance dose was 151.2(27.3) mg/d, and the treatment cycle was 6 weeks. Patients in the control group received Risperidone once per day orally with a mean (sd) maintenance dose being 2.3(0.9) mg/d, and the treatment cycle was 6 weeks as well. The PANSS scale was used to assess patients' before and after treatment. The researchers also observed any adverse reactions in both treatment strategies and evaluated the effectiveness and safety of both treatment strategies.

Results: The mean (sd) PANSS scale score of the experimental group after two weeks of treatment was 71.9 (10.2), which was clearly better than the mean (sd) score before treatment (82.6 [11.4]), and was significantly better than the control group's mean (sd) score after two weeks (76.5[12.8]). Also, the experimental group's scores after 4 weeks of treatment and 6 weeks of treatment were significantly better than the control group. The experimental group's efficacy rate (94.7%) was higher than the control group's (90.4%); the cure rate of the experimental group (33.3%) was higher than that of the control group (24.7%), and the difference was statistically significant. The rates of adverse reactions in the experimental and control groups were 13.3% and 19.2% respectively, and they were significantly different from each other.

Conclusion: Treating alcohol-induced mental disorder with Quetiapine is more effective than treating it with Risperidone. Quetiapine can improve patients' symptoms quickly, and lower the chance of adverse reactions. It is effective and safe.

Keywords: mental disorder, alcohol, Quetiapine, effectiveness

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1. Introduction

Psychoactive substances are referred to as the kinds of chemical substances that can affect people's emotion, daily behavior, state of consciousness, and result in abusing substances.[1] The symptoms of mental disorders caused by that mainly include hallucinations, delusions, emotional impulsiveness, paranoia and so on.[2] Previous studies suggest that the prognosis of psychoactive substance-induced mental disorders is normally quite poor. For psychoactive substance-induced mental disorders, psychotic symptoms almost always remain and social functioning can be impaired

Elderly Mental Health Department, Chongqing San Xia Central Hospital Pinghu Brunch, Sichuan Province

*correspondence: Haishui Duan, Mailing address: female mental health department, No. 826 Beishan Avenue, Wanzhou District, Chongqing, China. Postcode:404100. E-mail: fvhbjiofgjh@sina.com

if substance abuse is severe. Alcohol-induced mental disorder is a clinically common disorder induced by abusing psychoactive substances; taking medicine is the first choice of treating this kind of disorder, and large doses of B vitamins combining with small doses of antipsychotics are mostly used in clinical settings currently.[3] Several studies have shown that treating mental disorders induced by psychoactive substances with Quetiapine and Risperidone can achieve good effectiveness, and both drugs can control hallucinations and delusions effectively. However, little research has been done to compare these two drugs. The present study found that treating alcohol-induced mental disorder with Quetiapine is effective with a lower chance of adverse reactions.

2. Methods

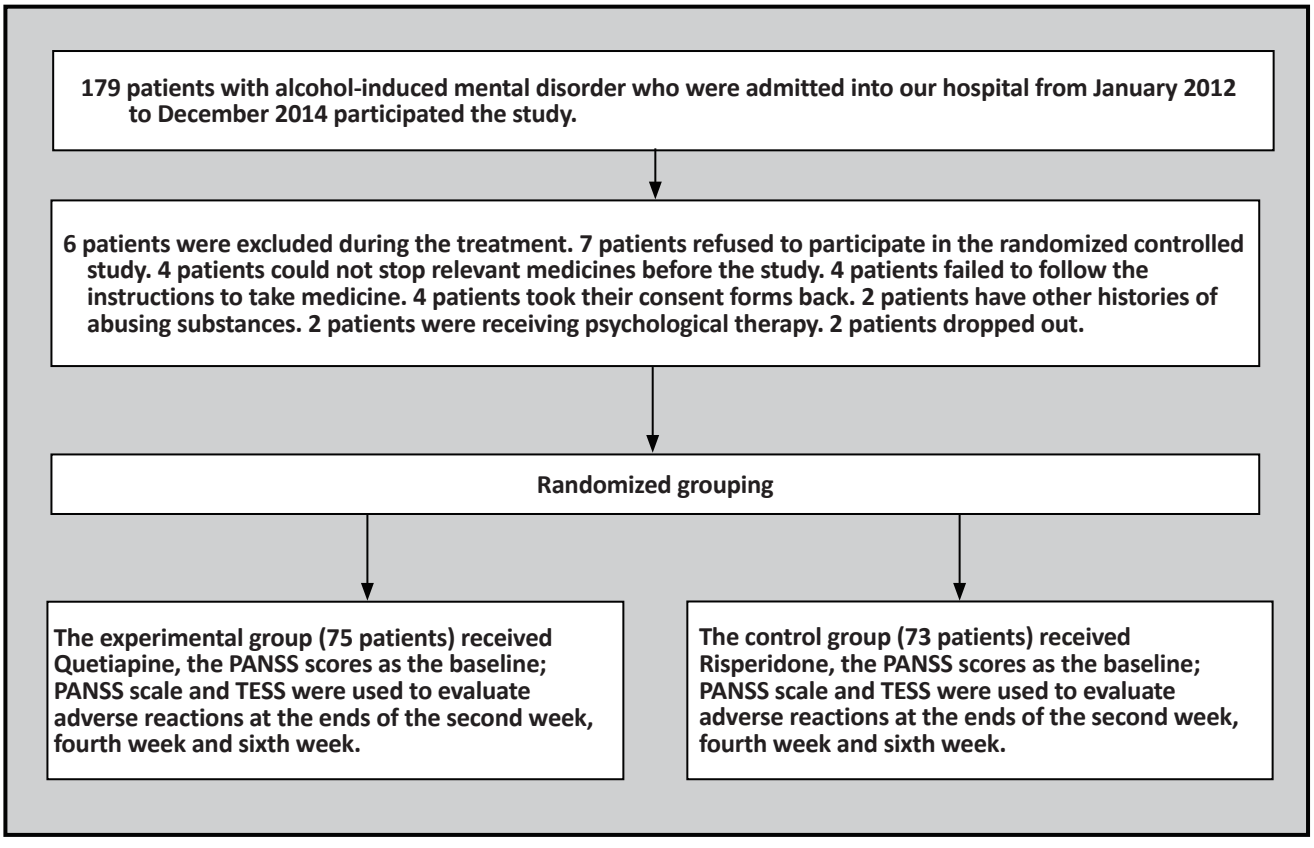
2.1 Study design

The present study adopted a randomized, open and controlled design. It is an analysis of clinical cases.

2.2 Sample selection

The process used to recruit participants is presented in Figure 1. All participants were patients with alcohol-induced mental disorder who were admitted to our hospital from January 2012 to December 2014. In order to compare the differences between treating patients with Quetiapine and Risperidone, possible confounding factors needed to be eliminated. Therefore, the present study only recruited patients whose main medicine was Quetiapine or Risperidone. One hundred and seventy-nine patients who were below 60 were recruited initially, then 31 patients were excluded due to a variety of reasons (i.e. 6 patients were excluded during the treatment. 7 patients declined to participate in the randomized controlled study. 4 patients could not stop relevant medicines before the study. 4 patients failed to adhere to medication regiment. Four patients later withdrew consent. 2 patients had a history of abusing other substances. 2 patients were receiving psychological therapy. 2 patients dropped out.). 148 patients were randomly divided into two groups. There were 75 patients in the experimental group with an age range of 33 to 57. The mean (sd) age was 40.1 (6.3), and the mean (sd) years of abusing alcohol was 11.7 (7.1). The mean (sd) course of disease was 23.1 (6.5) months. The control group had 73 patients with an age range from 31 to 58. The mean (sd) age was 39.8 (6.0) years and the mean (sd) years of abusing alcohol was 12.1 (6.8). The mean (sd) course of disease was 22.7 (6.3) months. The ages and histories of abusing alcohol of both groups were not significantly different. This study design was approved by the ethics committee of

Figure 1. Flowchart of the study



the Chongqing San Xia Central Hospital. The participants and their family provided written consent to participate in this study.

Inclusion criteria: (a)Patients met the criteria of psychoactive substance-induced mental disorder in Chinese classification and diagnostic criteria of mental disease, the third version (CCMD-3),[4] and there was exact evidence indicating the substance was alcohol; (b)The patients' scores on the Positive and Negative Syndrome Scale (PANSS) were equal to or above 60;[5] (c) Patients' physical examination and testing results were normal, and there was no relevant drug contraindications; (d) patients were between the ages of 18 and 60, (e) legal guardians provided written informed consent. **Exclusion criteria:** (a)The patients who had severe medical conditions and could not tolerate relevant drugs were excluded; (b)The patients who had a history of abusing other substances or were in lactation or pregnant were excluded; (c) patients who were diagnosed with schizophrenia, bipolar disorder or other mental disorders were excluded; (d)patients who were allergic to Quetiapine or Risperidone were excluded; (e) patients whose legal guardians refused to have them participate were excluded; (f)patients who had to receive electrical stimulation therapies or psychological therapies or other therapies that might compromise the results of the present study were excluded.

Drop-out criteria: (a) patients who became intolerant of the drugs or suffered from worse symptoms could drop out; (b) patients who refused to participate, lost contact or had other unexpected situations could drop out; (c) patients who did not take medicine according to the instructions could drop out.

2.3 Medicine

Quetiapine, product name: Qi Wei, dose: 100mg, Hunan Dong Ting Pharmaceutical Co., Ltd, China, approved number: H2000466.

Risperidone, product name: Wei Si Tong, dose: 1mg per tablet, Xian Yang Sen Pharmaceutical Co., Ltd, China, approved number: H20010309.

2.4 Grouping and treatment

The present study is a 6-week randomized, double-blind, controlled clinical study. One hundred and forty-eight patients were divided into the experimental group (i.e. receiving Quetiapine, 75 cases) and the control group (i.e. receiving Risperidone, 73 cases) with randomized number generated by a computer. In order to be clean, all patients stopped taking any relevant medicine a week before the study, and they also stopped drinking alcohol, smoking and using other substances that might have an effect on their prognoses. The patients in the experimental group took Quetiapine orally. In the first week of the treatment, the dose was increased gradually. In other words, on the first and second days, they took 25 mg three times per day, and then the dose was increased by 25 mg every two days. On the seventh day, the dose was 75 mg three times per day. In the second week of the treatment, the dose was adjusted within 100-300 mg every day, depending on patients' symptoms and tolerance of the medicine, and the mean (sd) dose was 151.2 (27.3) mg. The course of treatment was 6 weeks. The patients in the control group took Risperidone orally, starting with 1 mg/d. The dose was increased to 4 mg/d gradually, and was adjusted according to the symptoms and tolerance of the medicine. The highest dose was 6 mg/d, and the mean (sd) dose was 2.3 (0.9) mg/d. The course of treatment was also 6 weeks. During the treatment course, all patients did not take other antipsychotics at the same time. For the ones who showed severe insomnia they were treated with Zolpidem. If the patients had tremor and delirium responses during the treatment, they were injected with 100 mg B_1 vitamin, 0.5 mg B_{12} vitamin with the supportive treatment of 1 mg Clonazepam intravenous infusion and adding Potassium.

2.5 Outcome measures and effectiveness

Two professional clinicians examined the same patients at the end of the second, fourth and sixth week, and scored them independently. Pearson product-moment correlation indicated that the consistency between two raters was good. Scores of PANSS indicated the effectiveness of the treatments on patients. The patients' blood, urine, liver function, kidney function, blood sugar and ECG were examined regularly, and adverse reactions were documented during the treatment. Treatment Emergent Symptom Scale was employed to evaluate the effectiveness and adverse reactions, and the results were documented.[6]

The methods of rating effectiveness can be referred to the method adopted by Sun and colleagues,[7] and the effectiveness is classified as cured, improved markedly, improved and ineffective. Cured: the reduction rate of PANSS score >= 75%; improved markedly: the reduction rate of PANSS score is between 50% and 74%; improved: the reduction rate of PANSS score is between 25% and 49%; ineffective: the reduction rate of PANSS score < 25%; the total effectiveness = (cured + improved markedly + improved)/n × 100%; the cure rate = (cured/n × 100%). The reduction rate of PANSS score (%) = (the total score before treatment – the total score after treatment)/the total score before treatment × 100%.

2.6 Statistical analysis

SPSS 17.0 software was used to analyze the data. Continuous data were presented as the mean (standard deviation) ($\bar{x}$ **(sd)**), and independent sample t-tests were employed. Discreet data were presented as relative number of constituent ratios (%), and c^2 tests were employed. The present study used repeated

measures analysis of variance to evaluate the changes of two groups' PANSS scores after 6 weeks of treatment. Significance level was set at $p<0.05$.

3. Results

3.1 Demographic and clinical information

There were 75 patients in the experimental group (63 males, 12 females). The age range was 18-67, and the mean (sd) age was 32.8 (17.8) years. The mean (sd) years of consuming alcohol was 18.3 (3.9). The course of disease ranged from 3 months to 16 years, and the mean (sd) course was 2.9 (4.5) years. Their mean (sd) PANSS score was 82.62 (11.47) after they were admitted into the hospital. There were 73 patients in the control group (66 males, 7 females). The age range was 18-70, and the mean (sd) age was 37.9 (16.8). The mean (sd) years of consuming alcohol was 16.4 (4.2). The course of disease ranged from 4.5 months to 13 years, and the mean (sd) course of disease was 5.8 (1.8) years. The mean (sd) PANSS score was 81.21 (18.16). There were no significant differences between the two groups' gender, course of disease and PANSS scores ($p>0.05$), so they were comparable clinically.

3.2 Comparing PANSS scores of before and after treatment

After two weeks of treatment, patients in both groups had improved, and their PANSS scores were lower than those before being admitted to the hospital. Moreover, the reduction of PANSS score in the experimental group was more obvious than that in the control group. The differences in the scores of positive symptoms, negative symptoms and total scores between the two groups were significant. After six weeks of treatment, the experimental group's patients' scores in all items of PANSS were lower than those in the control group, and both groups' scores were better than those before treatment (all $p<0.05$). Furthermore, the scores after the second week, the forth week and the sixth week were all lower than the baseline score, and the experimental group's PANSS scores were still lower than the control group's PANSS scores. The differences were all statistically significant (Table 1).

3.3 Comparing effectiveness before and after treatment

After six weeks of treatment, patients in both groups had clear improvements. The total effectiveness rate of

Table 1. The comparisons of both groups' PANSS scores before and after treatment ($\bar{x}$ (sd), points)

Group	Item	Baseline	Second week	Fourth week	Sixth week	$F_{time}(p)$	$F_{group}(p)$	$F_{time.group}(p)$
Control group (n=73)	Positive symptoms	25.1(4.7)	22.4 (7.2)	17.6 (5. 4)	12.2 (7.7)	7.53 (0.038)	---	---
	Negative symptoms	21.9(5.9)	20.5 (4.8)	15.0 (3.2)	11.9 (6.5)	11.98 (0.041)	---	---
	Psychopathology	35.8(7.9)	33.8 (11.5)	30.1 (9.8)	21.8 (2.9)	21.18 (0.040)	---	---
	Total score	81.2 (18.6)	76.5 (12.8)	61.8 (12.3)	45.6 (9.9)	40.72 (0.014)	---	---
Experimental group (n=75)	Positive symptoms	24.5(7.4)	20.2 (4.8)	14.7 (5.9)	10.2 (3.2)	31.12 (0.024)	23.84 (0.042)*	52.98 (0.019)*
	Negative symptoms	21.3(6.8)	18.3 (6.1)	13.4 (6.0)	8.9 (6.2)	24.52 (0.040)	33.91 (0.029)*	40.91 (0.033)*
	Psychopathology	36.3(4.6)	32.1 (8.2)	26.8 (10.2)	19.6 (4.8)	41.67 (0.021)	35.90 (0.042)*	50.76 (0.023)*
	Total score	82.6 (11.4)	71.9 (10.2)	54.4 (11.0)	39.7 (6.9)	61.98 (0.002)	34.84 (0.012)*	63.98 (0.003)*

* $F_{time}(p)$: the results of repeated measure ANOVAs within the experimental and control groups;
$F_{group}(p)$ and $F_{time.group}(p)$: the between group factor results and between group x time factor results of the repeated measure ANOVAs which were used to compare the changes of the scores of all items over time between the experimental and control groups.

the experimental group was 94.7%, which was higher than that of the control group (90.4%). The cure rate of the experimental group was also higher than that of the control group (24.7%). These two comparisons were both statistically significant (χ2=3.14, *p*=0.035) (Table 2).

3.4 Evaluation of safety

After six weeks of treatment, there were no abnormal results in either groups regular examinations and testing, and there were no patients who dropped out of the treatment. There were 10 patients (13.3%) who showed adverse reactions in the experimental group. The adverse reactions mainly included loss of appetite and insomnia. There were 14 patients (19.2%) who showed adverse reactions in the control group, and the main symptoms were sleepiness, insomnia, and extrapyramidal reaction. After these 24 patients in both groups were treated, their symptoms were improved and none of them stopped the treatment due to the adverse reactions. Compared to the control group, the experimental group clearly had fewer cases with adverse reactions, and this difference was significant ($\chi 2 = 6.073$, $p = 0.041$) (Table 3).

4. Discussion

4.1 Main findings

Alcohol-induced mental disorder is a clinically common mental disorder, and its morbidity is increasing. The

Figure 2. Total PANSS scores comparison between two groups

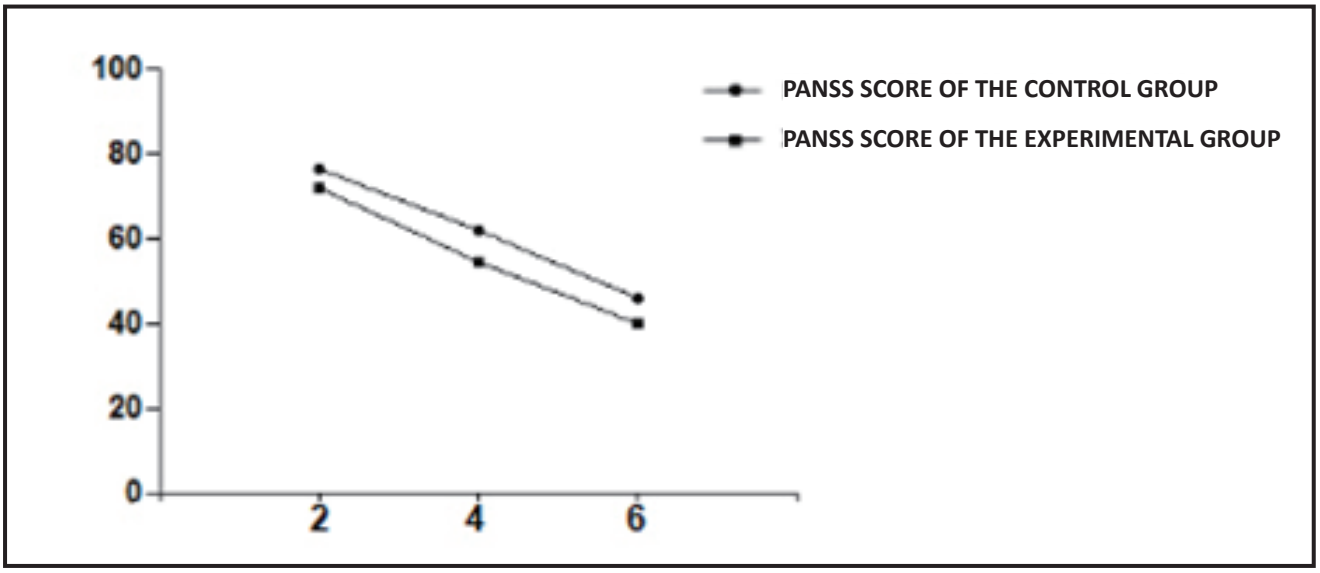


Table 2 The comparisons of the effectiveness of two groups before and after treatment

Group	Cured (%)	Improved markedly (%)	Improved (%)	Ineffective (%)	Total effectiveness (%)
Experimental group (n=75)	25(33.3)*	36(48.0)	10(13.3)	4(5.3)	71(94.7)
Control group (n=73)	18(24.7)	29(39.7)	19(26.0)	7(9.6)	66(90.4)

*Within all comparisons of items between two groups, there was a significant difference between the cure rate, χ^2=3.14, *p*=0.035

Table 3 The comparisons of the adverse reaction rate between two groups

Group	n	Loss of appetite	Sleepness	Dry mouth	Insomnia	Tremor	Comsti-pation	Weight gain	Relentlessness	Blurred vision	Adverse reaction rate(%)
Experimental group	75	2	1	1	2	1	1	1	0	1	13.3
Control group	73	1	2	1	2	2	1	2	2	1	19.2

present study has shown that compared to Risperidone, Quetiapine has better effectiveness on treating patients with this disorder. Quetiapine can lower patients' scores on the positive symptoms scale, negative symptoms scale, psychopathology scale and the total scores within a short period of time, and improve patients' clinical symptoms. The comparisons between these two groups were significantly different. After six weeks of treatment, the cure rate (33.3%) and the total effectiveness rate (94.7%) of the experimental group were higher than those of the control group (24.7%, 90.4%), so the prognoses were satisfying. The rate of the adverse reactions caused by the Quetiapine treatment (13.3%) was lower than that of the control group (19.2%), and this difference was statistically significant. Moreover, the scores after the second week, the fourth week and the sixth week were lower than the baseline score, and the experimental group's PANSS scores were lower than those of the control group. The differences of all items between two groups were statistically significant.

Psychoactive substances can lead to the strengthening effect of the dopamine midbrain limbic system. Previous studies have shown that almost all psychoactive substances including alcohol, amphetamines, and opioid drugs can make the dopamine level outside the cells higher than the normal level. Boutros and colleagues have found that when the psychoactive substance-induced mental disorders last more than six weeks, the mental symptoms are no longer related to the severity of abusing substances simply, but probably related to the pathological changes inside the brain.[8] Alcohol is a kind of neural characteristic friendly substance that can induce an anesthetic effect; consuming alcohol over the long term can lead to alcohol abuse, alcohol dependence, alcohol poisoning and withdraw symptoms, these consequences could severely impair patients' physical, mental and social functioning. [9] Currently, the main treatment for alcohol-induced mental disorder is medication, and atypical antipsychotic drugs can alleviate this kind of mental disorder effectively.[10] Besides the mental disorder, alcohol also affects patients' physical health, such as extrapyramidal system impairment and so forth; therefore, both treatment effectiveness and drugs'safety should be considered.[11] If during the treatment, patients with alcohol-induced mental disorder show tremor, delirium and other symptoms that jeopardize their lives, we need to prevent them from dying with corresponding treatments.

Risperidone is a derivative of benzene, and it is a selective single amine antagonist;it is one of the antipsychotic drugs that are used commonly in China, and it has relatively good effectiveness for treating psychoactive substance-induced mental disorder.[12] But Risperidone's blocking effect on D2 receptors is relatively strong, and it can lead to extrapyramidal system symptoms such as dysmyotonia, tremor, delirium, and relentlessness during treatment. Furthermore, Risperidone and its metabolism can block the D2 receptors on the hypothalamic-funnel pathway, which can lead to hyperprolactinemia.[13] Patients may stop taking medication due to the adverse reactions listed above, which leads to poor treatment effectiveness and relapse. Quetiapine is a kind of atypical antipsychotic drug that has become popular recently, and it has interaction with plenty neurotransmitter receptors. It is the antagonist of multiple neurotransmitter receptors in the neural system. Previous studies have shown that it plays its role by blocking 5-HT and DA receptors, and this can improve patients' positive symptoms effectively,[14,15] which can help alleviate patients' clinical symptoms. In the meantime, studies have also found that Quetiapine can stimulate dopamine's activity that is in a low excited state, therefore they suggest that it is effective on treating the unseen symptoms and cognition functioning impairment caused by alcohol.[16] Quetiapine's affinity to the 5-HT receptor is clearly higher than that to DA receptor, so it has less effect on other body parts while it is treating the mental disorder. Therefore, it has less side effects and a higher clinical adaptability, which extends its clinical application range.[17]

4.2 Limitations

The present study is a control study with a single center and a relatively small sample size, and the treatment the participants received before they were admitted into the hospital was not considered. Therefore, in order to verify the findings of the present study, the sample size should be expanded and the study design should be stricter. In this study, we increased the dose gradually so that the impairments caused by the medication would be reduced. In the meantime, we also gave the patients a period of time to adjust to the drugs. We were able to evaluate the responses of patients with mental disorder to Quetiapine and Risperidone after six weeks of treatment, but we still need more time to explore the safety and the effectiveness of drugs and their effectiveness on preventing mental disorders from relapsing. During the treatment, clinicians evaluated the adverse reactions in every clinical interview, but no standardized assessment tools were used to quantify the severity of complications. Hence, some adverse reactions which were not very severe were overlooked.

4.3 Implications

Even though the present study has a relatively small sample size and a short duration of observation, the clinical results of two groups of patients have still provided amble evidence that supports the following statement: the effect of Quetiapine on treating mental disorder induced by alcohol is better than that of Risperidone, and it can improve the symptoms quickly; moreover, the chance of causing adverse reactions is low, which suggests that it is safe.

Funding

None.

Conflict of interest

The authors declared no conflict of interest related to this manuscript.

Informed consent

All participants and their legal guardians provided signed informed consent to participate this study.

Ethics approval

The study was approved by the Ethics Committee of Chongqing San Xia Central Hospital Pinghu Branch.

Author contributions

Bei Lv took the responsibility to write the article, and Haishui Duan was in charge of reviewing the content.

喹硫平与利培酮治疗酒精致精神障碍的疗效及安全性对照研究

吕贝，段海水

背景：与利培酮相比，喹硫平治疗酒精所致精神障碍的安全性及有效性尚不明确。

目标：探讨喹硫平治疗酒精所致精神障碍的临床疗效及安全性。

方法：将 148 例酒精所致精神障碍患者按治疗方式分为观察组 75 例和对照组 73 例，观察组给予喹硫平治疗，每日口服 3 次，平均维持剂量为 151.2(27.3) mg/d，治疗周期为 6 周；对照组予以利培酮口服治疗，每天口服 1 次，平均维持剂量为 2.3(0.9) mg/d，维持治疗 6 周。分别于治疗前、后用 PANSS 量表评分，评估患者预后情况，并观察两种疗法治疗过程中的不良反应，评价两种治疗方法的安全性和有效性。

结果：观察组患者治疗 2 周后 PANSS 量表评分为 71.9(10.2) 分，较治疗前 (82.6 (11.4)) 分明显好转，且优于对照组的 76.5(12.8)；治疗 4 周、6 周后各项评分均优于对照组，两组比较差异有统计学意义；观察组有效率 (94.7%) 优于对照组 (90.4%)；痊愈率 (33.3%) 明显高于对照组 (24.7%)，两组比较差异具有统计学意义；观察组和对照组患者出现不良反应的概率分别为 13.3%, 19.2%，两组比较差异具有统计学意义。

结论：喹硫平治疗酒精所致精神障碍的效果优于利培酮，其可快速改善患者症状，且不良反应发生的风险低，是安全有效的。

关键词：精神障碍；酒精；喹硫平；疗效

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Dr. Bei Lv graduated from Mudanjiang Medical School with a bachelor degree in July 2006. She has been working in the geriatric psychological health department in Chongqing San Xia Central Hospital since July 2006. She is currently the chief doctor on her unit. Her research interests include the treatment for mental disorders and the analysis of the effectiveness of relevant antipsychotic drugs.