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CLINICAL STUDY

Effect of soothing-liver and nourishing-heart acupuncture on early selective serotonin reuptake inhibitor treatment onset for depressive disorder and related indicators of neuroimmunology: a randomized controlled clinical trial

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Abstract

OBJECTIVE: To observe the effect of soothing-liver and nourishing-heart acupuncture on selective serotonin reuptake inhibitor (SSRIs) treatment effect onset in patients with depressive disorder and related indicators of neuroimmunology.

METHODS: Overall, 126 patients with depressive disorder were randomly divided into a medicine and acupuncture-medicine group using a random number table. Patients were treated for 6 consecutive weeks. The two groups were evaluated by the Montgomery-Asberg Depression Rating Scale (MADRS) and Side Effects Rating Scale (SERS) to assess the effect of the soothing-liver and nourishing-heart acupuncture method on early onset of SSRI treatment effect. Changes in serum 5-hydroxytryptamine (5-HT) and inflammatory cytokines before and after treatment were recorded and compared between the medicine group and the acupuncture-medicine group.

RESULTS: The acupuncture-medicine group had significantly lower MADRS scores at weeks 1, 2, 4, and 6 after treatment compared with the medicine group ($P < 0.01$). The acupuncture group had significantly lower SERS scores at weeks 1, 2, 4, and 6 after treatment compared with the medicine group ($P < 0.01$). At 6 weeks after treatment, serum 5-HT in the acupuncture-medicine group was significantly higher compared with the medicine group ($P < 0.01$). Interleukin-6 (IL-6) in the acupuncture-medicine group was significantly lower than that in the medicine group ($P < 0.01$), whereas there was no significant difference in IL-1β between the groups ($P > 0.05$). Anti-inflammatory cytokines IL-4 and IL-10 were significantly higher in the acupuncture-medicine group compared with the medicine group ($P < 0.01$, $P < 0.05$, respectively).

CONCLUSION: The soothing-liver and nourish-

ing-heart acupuncture method can effectively accelerate the onset of SSRI effects when treating depressive disorder and can significantly reduce the adverse reactions of SSRIs. Moreover, acupuncture can enhance serum 5-HT and regulate the balance of pro-inflammatory cytokines and anti-inflammatory cytokines.

Key words: Acupuncture; Soothing-liver and nourishing-heart method; Early onset; Serotonin uptake inhibitors; Depressive disorder; Serotonin; Inflammatory cytokines; Randomized controlled trial

INTRODUCTION

Depressive disorders are a class of mental disease that have a high prevalence and recurrence rate. According to epidemiologic data, the prevalence of depressive disorder is 10%-20%, and the morbidity ratio of males to females is 1∶2.[1,2] The recurrence rate of depressive disorder is 21% in 1 year, and 75% in 10 years.[3] Depressive disorder has a high morbidity and relapse rate and severely affects mentality, social life, work, and study.[4] Although there are nonpharmacologic treatments for depressive disorder, such as psychotherapy and electroconvulsive therapy, medicine therapy is most commonly used and is convenient in the three phases of the disease: the acute phase, the consolidation period, and the maintenance period.[5] Selective serotonin re-uptake inhibitors (SSRIs) are the most widely used fist-line treatments for depressive disorder, and more than 50% of worldwide antidepressant prescriptions are SSRIs.[6,7] However, SSRIs require 4-6 weeks or even more before treatment effects are obvious.[8] This period can lead to many disadvantages during the treatment course depression, such as symptoms remitting slowly, reduction in treatment compliance, and increased suicide risk.[9] Therefore, accelerating the onset of SSRI effect is very important for depression treatment.[10] We aimed to perform a randomized clinical trial to study the effect of the soothing-liver and nourishing-heart acupuncture method on the onset of SSRI treatment effect for depression and explore the related neuroimmunology mechanism.

MATERIALS AND METHODS

Study design

The study was a randomized controlled clinical trial. Patients were randomized using a random number table. Patients were unaware of their group allocation. One hundred twenty-six outpatients were coded from number 1 to 126. Each coded patient number corresponded to a random number. Those patients with odd random numbers were allocated to the medicine group and those with even numbers were allocated to the acupuncture-medicine group. The study met the standards of medical ethics and was approved by the ethics committee of Seventh People's Hospital of Hangzhou. All patients signed an informed consent form.

Standards of inclusion

Patients were included if they: (a) met the diagnostic criteria for major depressive disorder or recurrent depressive disorder according to the International Statistical Classification of Diseases and Related Health Problem 10th Revision (ICD-10); (b) scored ≥ 12 points in the Montgomery-Asberg depression rating scale (MADRS); (c) were aged 18 to 60 years old; and (d) had not taken SSRIs within 4 weeks of study inclusion or stopped taking other antidepressants for more than 4 weeks.

Standards of exclusion

Patients were excluded if they: (a) had physical illnesses, organic brain diseases, or were dependent on medications or alcohol; (b) were pregnant or lactating; (c) had adverse or allergic reactions; or (d) had psychotic symptoms.

Standards of suspension

Patients were suspended from the study if they: (a) could not tolerate the acupuncture or SSRI treatment; (b) had serious adverse reactions during the study; (c) refused to be treated with acupuncture or SSRIs, or used other medicines or treatment during the study; (d) failed to visit; (e) willingly quit the study because of unexpected conditions; or (f) had poor obedience with incomplete data during the study.

Grouping and treatment

Overall, 126 patients with depressive disorder were randomly divided into the medicine group and the acupuncture-medicine group. Each group eventually had 60 patients, with 5 patients that dropped out of the study from the medicine group and 1 patient from the acupuncture-medicine group.

Medicine group: patients with depressive disorder were randomly treated with fluoxetine (Lilly Pharmaceutical Limited Company, Suzhou, China), paroxetine (GlaxoSmithKline Pharmaceutical Limited Company, Tianjin, China), citalopram (Lundbeck Pharmaceutical Limited Company, Xian, China), sertraline (Pfizer Pharmaceutical Limited Company, Dalian, China), or fluvoxamine (Abbott Pharmaceutical Limited Company, Chatillon Sur Chalaronne, France). The starting dose of fluoxetine, paroxetine, and citalopram was 20 mg/d, and dose adjustment was 20-60 mg/d. The starting dose of sertraline was 50 mg/d, and dose adjustment was 50-200 mg/d. The starting dose of fluvoxamine was 50 mg/d, and dose adjustment was 50- 300 mg/d. Medications were administered orally 1-2 times/d, and