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CLINICAL STUDY

Efficacy of Zhenjingdingzhi decoction in treating insomnia with *Qi*-deficiency of heart and gallbladder: a randomized, double-blind, controlled trial

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Abstract

OBJECTIVE: To evaluate the clinical efficacy of Zhenjingdingzhi decoction in treating insomnia with *Qi*-deficiency of heart and gallbladder.

METHODS: We conducted a double-blind, randomized, controlled trial involving 100 patients with insomnia of *Qi*-deficiency of heart and gallbladder. Patients were randomly divided into the treatment group (n = 50) and the control group (n = 50) according to a random number table. The treatment group was given Zhenjingdingzhi decoction, while the control group was treated with Suanzaoren decoction. the pharmacological treatment lasted for 8 weeks. The clinical efficacy was assessed by using Spiegel scale, Pittsburgh sleep quality index (PSQI) and Traditional Chinese Medicine (TCM) syndrome scores.

RESULTS: Comparing Spiegel scores between the two groups at 4 and 8 weeks, the differences in curative effect between the two groups were both significant (both $P < 0.05$). The total effective rate was 46% in the treatment group and 27.7% in the control group at 4 weeks, and 80% and 53.2% at 8 weeks, respectively; After 8 weeks, PSQI scores showed that the total effective rates differed significantly between the two groups ($P < 0.01$): 84% in the treatment group and 59.6% in the control group; In improving sleep quality and sleep duration, the curative effect of the treatment group was better than that of the control group ($P < 0.05$). TCM syndrome, especially insomnia and palpitation, was improved better in the treatment group after 8 weeks as compared to that in the control group ($P < 0.05$). The total effective rate of the two groups was 84% and 66%, respectively.

CONCLUSION: Zhenjingdingzhi decoction is effective and safe for the treatment of insomnia with *Qi*-deficiency of heart and gallbladder, especially for improving sleep quality and sleep duration.

Key words: Sleep initiation and maintenance disor-

ders; Shyness; Heart *Qi* deficiency; Zhenjingdingzhi decoction; Randomized controlled trial; Double-blind method

INTRODUCTION

Studies by the World Health Organization have shown that almost 30% people in the world suffer from insomnia.[1] Insomnia is recognized as one of the global public health issues which are not fully appreciated or well solved.[2] According to epidemiological studies, the incidence rate of insomnia in China is 10% to 20%.[3] In view of these facts, the late Professor Jianhua Hu, Shanghai famous specialist of Traditional Chinese Medicine (TCM), extracted Zhenjingdingzhi decoction to treat insomnia on basis of TCM theory, with reference to non-prescription medicine and literature, after decades of clinical trial and error. Zhenjingdingzhi decoction is modified from Ganmaidazao decoction, added Tiannanxing (*Rhizoma Arisaematis Erubescentis*), Shichangpu (*Rhizoma Acori Tatarinowii*), Zhenzhumu (*Concha Margaritifera Usta*), Yuanzhi (*Radix Palygalae*) and Danshen (*Radix Salviae Miltiorrhizae*). It has the effects of melting Phlegm, regulating *Qi*, supplementing *Qi* and nourishing heart to calm mind. In order to further verify the clinical efficacy of this decoction on insomnia, we observed and analyzed the therapeutic effect by comparing with Suanzaoren decoction[4,5] which is widely approved at home and abroad - to provide the basis for the clinical treatment of insomnia and further explore the new direction of treating sleep disorders in TCM.

MATERIALS AND METHODS

Diagnostic standards

Diagnostic standards of insomnia in Western Medicine are stipulated by Chinese Classification of Mental Disorders Third Edition (CCMD-3) (F51.0).[6] In reference to Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine Symptoms of Chinese Medicine,[7] standard for diagnosing in TCM defines main syndromes as difficulty in falling asleep, or waking up easily, or waking up frequently during the night with difficulty of returning to sleep, or keeping sleepless all night, and symptoms persisting for more than 4 weeks. Also we adopted accompanying symptoms as follows: dreaminess, vexation, dizziness and headaches, palpitation and amnesia, fatigue and lassitude, without other organic disease or inducement that violate sleep. The main syndromes of *Qi*-deficiency of heart and gallbladder type referring to Clinic Terminology of Traditional Chinese Medical Diagnosis and Treatment-Syndromes GB/T16751.2-1997,[8] includes palpitation and timidity, inability to fall asleep, festless sleep, and the secondary syndromes includes being susceptible to fright, shortness of breath and lassitude, lack of strength and spontaneous perspiration. And main feature of tongue and pulse diagnosis: whitish tongue and white fur, stringy-thready pulse.

Inclusion standards

Patients were included if they: (a) conformed to the above-mentioned diagnostic standards; (b) were 18-65 years old; (c) suffer from insomnia over 4 weeks. All patients volunteered for this trial and provided written informed consent. The study was approved by Medical Ethics Committee, Shanghai Longhua Hospital Affiliated to Shanghai University of TCM.

Exclusion standards

Patients were excluded if they: (a) did not conform the diagnostic standards of insomnia or *Qi*-deficiency of heart and gallbladder; (b) were < 18 years old or > 65 years old; (c) were pregnant or lactating; (d) had diabetes, psychiatric disorder or serious suicidal tendency.

Eliminating cases and standards of dropout

Patients were eliminated if they: (a) stopped the treatment halfway due to adverse reactions or non-efficacy reasons; (b) added other drugs; (c) provided incomplete data that couldn't be counted; (d) did not complete the therapy as planned; (e) did not conform to inclusion standards but were included by mistake.

Patients were considered dropouts of the study if they had poor compliance, serious adverse reactions, complications or special physiological changes that made them inappropriate to continue the trial during the therapy. When data were statistically analyzed, adverse reactions should be recorded in the statistics of adverse reaction and patients who had completed 1/2 of the therapy should be evaluated the efficacy.

Randomization, double-blind method

From October 2012 to September 2013, a cohort of 100 insomnia patients who visited Neurology Department of Longhua Hospital Affiliated to Shanghai University of TCM was recruited and divided randomly into two groups of 50 by their visiting sequence. The medicine of the two groups was uniformly decocted, packaged by the Department of Pharmaceutical Preparation of Longhua Hospital Affiliated to Shanghai University of TCM, Shanghai, China. According to a random number table, each study decoction was randomly numbered and indicated on the package. The researchers issued the study decoction on the basis of the subjects visiting sequence which was consistent with that on the decoction package. At the end of the trial, we entered the observation data into the established database. Primary unblinding was executed when the data was locked by the statistics professional. And A group and B group were established. Secondary unblinding was executed when the statistics was completed, and the treatment group and the control group were definite.