

A Clinical Study on the Treatment of Insomnia with Incompatibility between Heart and Kidney by Embedding Beans in Ear Points and Huanglian Ejiao Decoction

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Zhang et al.: Clinical Study on the Treatment of Insomnia

We attempt to discuss the clinical efficacy of ear-point burial combined with Huanglian Ejiao Decoction in the treatment of insomnia due to incompatibility between heart and kidney. We selected 120 patients diagnosed with heart-kidney incompatibility insomnia from Yichun Hospital of traditional Chinese medicine terminal disease treatment center as participants. Then randomly divided them into observation group and control group (n=60). Control group adopted Huanglian Ejiao Decoction frying before going to bed. Observation group, after receiving the same therapy as control group, then combined with ear point burial. Compared both groups on clinical effectiveness, traditional Chinese medicine syndrome score, etc., After treatment of both groups, observation group possessed remarkably lower traditional Chinese medicine syndrome score than control group ($p<0.05$) and clinical efficiency of observation group (95 %) was remarkably higher than control group (85 %) ($p<0.05$). Ear point burial combined with Huanglian Ejiao Decoction can effectively improve the sleep of insomnia patients with incompatibility between heart and kidney, and improve the clinical efficacy.

Key words: Huanglian Ejiao Decoction, mental disorders, insomnia, clinical research

Bumei is insomnia, which is defined as difficulty falling asleep or maintaining sleep at night. Research shows that about 30 % of the population has sleep problems and the sleep quality of 10 % of them will cause daytime fatigue^[1]. We can classify insomnia in many methods. For example, it can be primary (a type of sleep disorder or latent mental disorder, alcohol or drug abuse) or secondary (accompanied by another disease). It can be divided into acute (onset time <1 mo) or chronic (onset time >1 mo) as well^[2]. Frequent insomnia have serious consequences, including increased risks of health problems, increased medical care costs, inability to work, decreased productivity and non-motorized vehicle accidents^[3]. If not treated in time, insomnia can cause excessive tiredness during the day, lack of concentration and attention, depression and a decline in quality of life. Long term use of sleeping pills will bring many other problems to people with insomnia^[4]. Studies have indicated that the auricle of the human body is rich in nerves, blood vessels and lymph. If beans are buried in auricular points to improve sleep, it can stimulate

relevant acupoints to function and then regulate the hormone balance and immune system function of the human body, thus it helps regulate the body's function and improve the body's tension^[5]. According to records, Huanglian Ejiao Decoction mainly treats Shao yin fever syndrome, mainly due to kidney yin deficiency in the lower, heart fire hyperactivity in the upper^[6]. The main symptoms are upset, insomnia, thirsty and yellow urine^[7]. Untreated insomnia usually does not worsen over time, seriously affecting the quality of life and requires effective and safe treatment or intervention. Therefore, we attempt to clarify the clinical effectiveness and safety of ear acupoint burial of beans and Huanglian Ejiao Decoction in the treatment of insomnia with incompatibility between heart and kidney and to provide a reliable support for the Traditional Chinese Medicine (TCM) treatment of insomnia. Let us check the following reports. It is a random test for this research. We selected 120 patients diagnosed with heart-kidney incompatibility insomnia from Yichun Hospital of TCM terminal

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disease treatment center as participants. Then randomly divided them into observation group and control group (n=60). Inclusion criteria includes all patients met the diagnostic criteria for insomnia with heart-kidney incompatibility^[8] and there were no abnormalities in cranial imaging and laboratory examinations. The patients complained that it was difficult to fall asleep, easy to wake up after sleep or difficult to fall asleep after waking up for 21 d or more, especially not sleeping all night or even difficult to fall asleep all night. At the same time, it is accompanied by heart palpitation and upset, insomnia and dreaminess, dizziness, hot flashes, night sweats, general fatigue and other syndrome of heart kidney disharmony; in the past 15 d, no outside hospital treatment, no other Western medicine treatment, TCM treatment, acupuncture treatment, etc.; informed patients and family members of the relevant conditions and obtained informed consent and signed an informed consent form. Exclusion criteria includes patients with severe underlying diseases of other organs or mental disorders; secondary insomnia caused by other physical discomforts (such as bone pain, cough, trauma, surgery, etc.); pregnant or lactating women; suspicious or clear history of alcohol abuse, drug abuse or psychoactive drugs. Both groups had no statistical difference in basic data, such as gender, age and disease course and they had comparability as shown in Table 1. Control group contains Huanglian Ejiao decoction which is composed of *Coptis chinensis* (15 g), *Scutellaria baicalensis* (12 g), peony (12 g), chicken seed yellow (15 g) and Ejiao (15 g). Take 1 dose a day, decoct 400 ml of juice and take it twice at noon and 1 h before going to bed. Observation group after receiving the same therapy as control group, combined with ear acupoint embedding beans. The specific treatment methods are as embedding beans in ear points, dialectically select acupuncture points for local skin disinfection with 75 % alcohol, press cowherb seed ear plaster 3-5 times a day for 1-3 min at each acupoint, taking the local acid swelling tolerance as the degree; select acupoints based on body differentiation, select acupoints based on syndrome differentiation. Identify the time of onset, take the acupoint, pick the pressing needle and bury the needle; disinfect the local acupoints with 75 % alcohol, press with needle pressing paste, 3-5 times a day, 1-3 min for each acupoint, taking the local acid swelling tolerance as the degree. Keep the strength moderate during the operation, adjust the strength in time according to the patient's discomfort, avoid damaging the ear tissues and try to keep the ear points dry. 1 w treatment of both groups was considered as a course, after 15 d treatment,

evaluated the clinical efficacy of both groups. The specific clinical efficacy reference standards are as follows: Recovery is defined as the recovery of sleep symptoms, normal sleep time or sleep time is more than 6 h, after waking up, the spirit is good; significantly effective means sleep quality improves significantly, while sleep time at night is greater than 3 h; effective means sleep quality improves slightly, but sleep time is less than 3 h; invalid sleep quality has not improved, sleep time has not improved and even worsened.

Total clinical effective rate=(Recovery+Significantly effective+Effective)/Total number

Use Statistical Package for the Social Sciences (SPSS) 26.0 software to analyze all data. Express the count data as n % and tested by chi square test. Express measurement data conforming to normal distribution and homogeneity of variance as ($\bar{x}\pm s$). Use independent sample t test for comparison between groups. Use the paired t test to compare the same group before and after treatment. Use rank sum test for comparison between groups. $p<0.05$ was considered to possess statistical significance. 60 patients included in observation group, ages were from 41 to 72 y old and 30 females. 60 patients included in control group, ages were from 39 to 73 y old and 32 females as shown in Table 1. Both groups had no difference in TCM syndrome scores before treatment, so it possessed no statistical significance ($p>0.05$); after treatment, observation group possessed remarkably lower TCM syndrome scores than control group, it had statistical significance ($p<0.05$) as shown in Table 2. After 15 d treatment for both groups, the total clinical effective rate of observation group (93.3 %) was remarkably higher compared with control group (80 %). They were obviously different and it possessed statistical significance ($p<0.05$) as shown in Table 3. "Bumei" is called insomnia in Western medicine. There are many documents that record insomnia in the past dynasties. Insomnia was first recorded in "Nanjing", which expounds that the main pathogenesis of insomnia is weakness of Qi and blood, and the mechanism recorded in the "Huangdi Neijing" is that the yang does not enter the yin and the yin and yang are out of balance^[9]. Zhang Zhongjing believes that insomnia is mainly caused by insufficient liver blood, yin deficiency and excessive fire, and records that Huanglian Ejiao Decoction can be used to treat insomnia. "Jingyue Quanshu" states that the dialectical insomnia belongs to the heart-kidney incompatibility type, and the elderly patients are prone to it. The method of communicating the heart-kidney has obvious curative effect^[10]. Huanglian

Ejiao Decoction was first recorded in “Treatise on Febrile Diseases”. The prescription contains 5 kinds of medicines: *Coptis*, *Radix Scutellariae*, Ejiao, Egg yolk and *Radix Paeoniae Alba*. It has the functions of nourishing yin, reducing fire and calming nerves. It is mainly used to treat body fluid loss, upset and difficult to sleep as the main symptomatic diseases and treat the syndrome of heart kidney disharmony^[11]. Insomnia is a serious public health problem. The incidence of insomnia increases with age and the incidence of women is twice that of men. The main symptoms of insomnia are difficulty falling asleep (sleep narcolepsy insomnia), difficulty maintaining sleep (sleep maintenance insomnia) or being unable to fall asleep after waking up early in the morning^[12]. According to the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and the 3rd edition of the International Classification of Sleep Disorders (ICSD-3)^[13,14], dissatisfaction with sleep time or quality must occur at least three nights a week within 3 mo to be diagnosed as chronic insomnia^[15]. In addition, patients diagnosed with insomnia symptoms have enough sleep time in time, but they still have sleep problems and cause at least one related daytime effect^[16]. The various causes of insomnia can be divided into susceptible factors, predisposing factors and persistent factors. Predisposing factors, such as maladaptive coping strategies, excessive cognitive emotional awakening and older age, make individuals more prone to sleep problems. At the same time, increased life pressure, irregular sleep habits and poor sleep hygiene will also increase the incidence of insomnia^[17]. If the patient’s sleep is disturbed repeatedly for a long time, it will lead to a vicious circle of chronic diseases^[18]. Insomnia

has traditionally been regarded as a type of symptom of another disease, rather than a discrete disease^[19]. Insomnia has traditionally been regarded as a symptom of another disease, rather than a discrete disease. It is well known that insomnia can increase the risk of depression and coronary heart disease. In addition to causing psychological distress, insomnia can also cause cognitive and psychomotor disorders, irritability and decreased work efficiency the next day and has been proven to reduce the quality of life and shorten life^[20]. This study also has limitations. First of all, we did not study the best dose composition of Huanglian Ejiao Decoction and the best important composition and dose of addition and subtraction in the treatment of insomnia. In the future, we will study the most suitable addition and subtraction of Huanglian Ejiao Decoction, which can play the same role without adverse side effects. Secondly, our research mainly focuses on the short-term effect of embedding beans in ear points combined with Huanglian Ejiao Decoction on insomnia syndrome of heart kidney disharmony. It is necessary to conduct a long term study on the recurrence of insomnia after a few weeks. In summary, this study found that TCM symptoms scores of ear point embedding beans combined with Huanglian Ejiao Decoction in the treatment of insomnia with heart kidney disharmony was remarkably lower than control group ($p < 0.05$) and clinical efficiency of observation group (95 %) was remarkably higher than control group (85 %) ($p < 0.05$). Therefore, embedding beans in ear points combined with Huanglian Ejiao Decoction can effectively improve the sleep of patients with insomnia of heart kidney disharmony type and improve the clinical curative effect; it is worth popularizing in clinic.

TABLE 1: BASELINE DATA OF BOTH GROUPS

	Observation group (n=60)	Control group (n=60)	t/ χ^2	p
Age	52.41±16.14	51.85±17.54	0.3	0.8
Gender (female)	30 (50 %)	32 (53.3 %)	0.1	0.9
Complications				
Hypertension	8 (13.3 %)	10 (16.67 %)	0.2	0.7
Coronary heart disease	11 (18.33 %)	9 (15.0 %)	0.4	0.5
Diabetes	7 (11.67 %)	8 (13.3 %)	0.4	0.6

TABLE 2: COMPARISON OF THE CURATIVE EFFECT OF TCM SYNDROMES BETWEEN BOTH GROUPS OF PATIENTS BEFORE AND AFTER TREATMENT

	Observation group	Control group	t	p
Before treatment	24.34±1.57	25.62±1.69	0.45	0.58
After treatment	2.45±1.04	7.51±1.34	4.79	0.001

Note: TCM: Traditional Chinese Medicine

TABLE 3: COMPARISON OF CLINICAL EFFICACY BETWEEN BOTH GROUPS

	Recovery	Significantly effective	Effective	Invalid	Total effective rate
Observation group	25 (41.6 %)	18 (30 %)	13 (21.67 %)	4 (6.7 %)	56 (93.3 %)
Control group	20 (33.3 %)	14 (23.3 %)	14 (23.33 %)	12 (20 %)	49 (80.0 %)
χ^2			6.64		
p			0.001		

Conflict of interests:

The authors declared no conflict of interests.

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