Curative effect of acupuncture and moxibustion on insomnia: a randomized clinical trial

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Abstract

OBJECTIVE: To observe the effect of acupuncture and moxibustion on insomnia and explore its mechanism.

METHODS: One hundred and twenty patients were randomly divided into an experiment group and a control group. Sixty patients in the experiment group were treated once a day with acupuncture at Baihui (GV 20), Sishencong (EX-HN 1), Shenmai (BL 62), and Zhaohai (KI 6) and with moxibustion at Baihui (GV 20) and Sishencong (EX-HN 1). Sixty patients in the control group were acupunctured once a day at Shenmen (HT 7), Neiguan (PC 6), and Sanyinjiao (SP 6). The Pittsburgh Sleep Quality Index (PSQI) was used to compare sleep improvement between the two groups.

RESULTS: The total effective rate was 87.7% in the experiment group and 76.3% in the control group. The PSQI scores and the total score were lower after treatment than before treatment in both groups. However, the reduction in the experiment group was greater than that in the control group in sleeping quality, time to fall asleep, sleeping disorder, and daytime function (P<0.05).

CONCLUSION: Acupuncture and moxibustion at Baihui (GV 20), Sishencong (EX-HN 1), Shenmai (BL 62), and Zhaohai (KI 6) significantly improved insomnia symptoms in the experiment group compared with the control group.

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Key words: Acupuncture; Sleep initiation and maintenance disorders; Treatment outcome; Randomized clinical trials

INTRODUCTION

Insomnia, a common sleeping disorder, manifests as an insufficiency of sleep time and a decline in sleep quality. Therefore, insomnia greatly influences the life, study, and work of patients. Prolonged use of sleeping pills can bring about drug dependence and hypofunction. We have used acupuncture and moxibustion to treat insomnia without adverse reactions. Therefore, we sought to perform a randomized clinical trial to further explore the effect of acupuncture and moxibustion on insomnia.

MATERIALS AND METHODS

Patient data

One hundred and twenty outpatients of the Department of Acupuncture and Moxibustion in the Third Affiliated Hospital of Henan College of Traditional Chinese Medicine from January 2010 to December
2011 were randomly divided into an experiment group and a control group. Among the 60 patients in the experiment group, there were 23 males and 37 females aged (39 ± 13) years with Pittsburgh Sleep Quality Index (PSQI) scores of 18 ± 4. Among the 60 patients in the control group, there were 26 males and 34 females aged (40 ± 13) years with PSQI scores of 17 ± 4. There was no statistical difference (P > 0.05) in sex, age, or PSQI score between the two groups.

**Research design**

This study was a single-blind randomized controlled trial. Individuals were randomized by a computer-generated allocation list. The patients and registrar did not know to which group the patient had been allocated. This study met the standards of medical ethics and was approved by the ethics committee of the Third Affiliated Hospital of Henan College of Traditional Chinese Medicine. All patients signed an informed consent form.

**Standard of diagnosis**

We adopted the insomnia-diagnosing standard from the third edition of the Chinese Classification of Mental Diseases (CCMD-3) and the sleep-detecting method published by the World Health Organization (WHO). Sleeping efficiency was determined with the formula (sleeping efficiency = actual time asleep/time from going to bed to getting up × 100%). All patients conformed to the insomnia diagnosis standard in the CCMD-3 and their illness course exceeded half a year. Patients with insomnia caused by somatic or mental diseases or by prolonged use of tranquilizers or other drugs were excluded.

**Standard of inclusion**

Patients were included if they: (a) conformed to the standard for diagnosing insomnia, (b) were 18-65 years old, (c) had no insomnia caused by substantive damage to internal organs, (d) had not taken Chinese medicines (including Chinese patent drugs and decoctions for nourishing the heart to calm the mind) or Western Medicine (including bromide, Librum, or diazepam) to treat insomnia in the past week, or if they took these drugs for 5 days but stopped taking them for more than 7 days, and (e) signed an informed consent form.

**Standard of exclusion**

Patients were excluded if they: (a) did not conform to the standards of diagnosis and inclusion, (b) had accepted other treatments possibly influencing the indexes of effects used in this study, (c) had serious cardio-cerebral blood vessel, liver, kidney, hematopoietic system, or mental diseases, (d) were pregnant or lactating female patients, and (e) had other factors necessarily excluded.

**Standard of rejection**

Patients were removed from the study if they: (a) violated the therapeutic plan in manipulation, (b) suspended two treatments in the therapeutic period, or (c) used other methods to help insomnia symptoms.

**Standard of dropout**

Patients were considered dropouts of the study if they: (a) failed to visit, (b) willingly quit the therapeutic process or could not persist in treatment because of unexpected conditions, or (c) had poor obedience with incomplete data during the clinical trial.

**Standard of suspension**

Patients who could not tolerate the treatment or had serious adverse reactions during treatment suspended the clinical trial. Patients who refused to be treated or continued to use drugs or other treatments during the therapeutic period were also suspended.

**Needles**

Dispensable Hanyi needles, 0.30 mm in diameter and 25 mm or 40 mm in length, were used for acupuncture (produced by Tianjin Huahong Medical Material Limited Company, batch number 101201, Tianjin, China).

**Taking acupoints**

Acupoints were taken in the two groups in reference to Acupuncture and Moxibustion, TCM teaching material for higher education. Acupoints in the experiment group were: Baihui (GV 20), Sishencong (EX-HN 1), Shenmai (BL 62), and Zhaohai (KI 6). Xinshu (BL 15) and Pishu (BL 20) were added for deficiency of both heart and spleen. Xinshu (BL 15) and Danshu (BL 19) were added for Qi deficiency of both heart and gallbladder. Xingjian (LR 2) and Taichong (LR 3) were added for fire-syndrome caused by stagnation of liver-Qi. Taixi (KI 3) and Taichong (LR 3) were added for hyperactivity of fire because of Yin deficiency.

Acupoints in the control group were: Shenmen (HT 7), Neiguan (PC 6), and Sanyinjiao (SP 6). Adjunct acupoints were the same as in the experiment group.

**Manipulation**

Patients in the experiment group lay in the dorsal position. After the skin was routinely sterilized, needles were inserted into Baihui (GV 20) and Sishencong (EX-HN 1) 0.8 cm deep. After the needleling sensation, the uniform reinforcing-reducing method was performed. Needles were inserted into Shenmai (BL 62) and Zhaohai (KI 6) 0.5 cm deep. After the needleling sensation, the reinforcing method was performed at Zhaohai (KI 6) and reducing method at Shenmai (BL 62) and adjunct acupoints. After acupuncture, a doctor held a moxa roll (produced by Nanyang Wolong Hanyi Mugwort Floss Factory, Nanyang, China) with one end ignited to perform moxibustion at Baihui (GV 20) and Sishencong (EX-HN 1) for 40 min. During its retention, the needle was manipulated once ev-
ory 10 min. The treatment was carried out once in the afternoon every day for 15 days as a course of treatment. Patients in the control group lay in the dorsal position. After the skin was routinely sterilized, needles were inserted into Shenmen (HT 7) 0.5 cun deep, Neiguan (PC 6) 0.8 cun deep, and Sanyinjiao (SP 6) 1.0 cun deep. After the needle sensation, the uniform reinforcing-reducing method was performed. The reducing method was practiced at adjunct acupoints. During its retention, the needle was manipulated once every 10 min. The treatment was carried out once in the afternoon every day for 15 days as a course of treatment.

Measurements
We adopted the scale for evaluating PSQIs, including: sleep quality, time to fall asleep, sleeping time, sleeping efficiency, daytime functions, and total score. Specially assigned persons were in charge of enquiring about illness condition and making a record before, 1 week, and 2 weeks after treatment and a record of patients who were clinically cured 7 days after the end of treatment.

Standard for evaluating curative effect
In reference to the standard for evaluating curative effects on insomnia in the Principle for Directing Clinical Research into New Chinese Drugs published by the Health Ministry, cured insomnia includes sleeping time returning to normal, sleeping time at night exceeding 6 h, or patients feeling rested after sound sleep. An obvious effect means that sleep is clearly improved, sleeping time increases by more than 3 h, and sleep becomes sounder. Effectiveness means that symptoms are alleviated and sleeping time increases by less than 3 h. Ineffectiveness means that insomnia is unimproved or aggravated and the patient drops out.

Statistical analyses
Because the acupuncture and moxibustion practitioner cannot be double-blinded in clinical experiments, the single-blind method is used. Specially assigned persons are independently in charge of manipulation, recording illness condition, and statistic analysis. SPSS 13.0 software (produced by SPSS China Software Shanghai Limited Company, Shanghai, China) was used to process data. Measurement data are expressed as mean value ± standard difference ( x ± s). A t-test of paired data was used for comparison before and after treatment in the same group. A t-test of two independent samples was used for comparison between two groups. A χ² test was used to compare enumeration data. P<0.05 is regarded as a statistical difference.

RESULTS
Comparison of clinical curative effects between the two groups
Among the 60 patients in the experiment group, three dropped out (two were patients with poor obedience and one failed to visit), leaving a qualification rate of 95%. The treatment in the experiment group resulted in cure in 27 patients, an obvious effect in 11 patients, effectiveness in 12 patients, and ineffectiveness in seven patients. The total effective rate was 87.7%. Among the 60 patients in the control group, one dropped out (failed to visit), a qualification rate of 98.3%. The treatment in the control group resulted in cure in 22 patients, an obvious effect in 13 patients, effectiveness in 10 patients, and ineffectiveness in 14 patients. The total effective rate was 76.3%. A χ² test showed that the total effective rate in the experiment group was much higher than that in the control group (P<0.01) (Table 1).

There was a statistical difference (texp=3.12, tcon=3.22, P<0.01) in the total PSQI score before and after treatment in the two groups. Both therapeutic methods had curative effects on insomnia. There was a statistical difference (t=2.89, P<0.01) in the total PSQI score after treatment between the two groups. The improvement of the total PSQI score in the experiment group was greater than that in the control group. The difference of total PSQI score before and after treatment in the experiment group was better than that in the control group (Table 2). There was a statistical difference (P<0.05) in the score of the various PSQIs before and after treatment in the two groups. Both therapeutic methods had curative effects on insomnia. There was a statistical difference (P<0.01) in the score of sleep quality, time to fall asleep, sleep disorder, and daytime function after treatment between the two groups. There was no statistical difference (P>0.05) in the sleeping time and sleeping efficiency scores, indicating that the curative effect in the experiment group was better than that in the control group in sleeping quality, time to fall asleep, sleep disorder, and daytime function. Comparison of differences in the score of various PSQIs before and after treatment between the two groups showed that the improve-

Table 1: Comparison of curative effects on insomnia in patients between two groups (n)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Cure</th>
<th>Obvious effect</th>
<th>Effectiveness</th>
<th>Ineffectiveness</th>
<th>Total effective rate (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>59</td>
<td>22</td>
<td>13</td>
<td>10</td>
<td>14</td>
<td>76.3</td>
<td>0.000</td>
</tr>
<tr>
<td>Experiment</td>
<td>57</td>
<td>27</td>
<td>11</td>
<td>12</td>
<td>7</td>
<td>87.7</td>
<td></td>
</tr>
</tbody>
</table>

Notes: experiment group were treated once a day with acupuncture at Baihui (GV 20), Sishencong (EX-HN1), Shenmai (BL 62), and Zhaohai (KI 6) and with moxibustion at Baihui (GV 20) and Sishencong (EX-HN1); control group were acupunctured once a day at Shenmen (HT 7), Neiguan (PC 6), and Sanyinjiao (SP 6). The efficiency of two groups were 76.3%, 87.7%; the Experimental group was significantly higher than that in control group (P<0.01).
DISCUSSION

In this study, we regulated defensive Qi and invigorated brain marrow using acupuncture and moxibustion to treat insomnia. Compared with conventional methods, this method can improve sleep quality by adjusting the brain’s sleep function, improving symptoms of dreaminess, dizziness, headache, heavy head and poor memory, and promoting the periodicity from light to deep sleep. Traditional Chinese Medicine hypothesizes that there is a close relationship between sleep and wakefulness and defensive Qi movement in the body with the alternation of day and night and the balance of Yin and Yang heel vessels. Ling Shu that, “defensive Qi moves in the Yang during the day, and Yin during the night, as Yin corresponds to night, dominating sleep ... people fall asleep when Yang Qi ends but Yin Qi is grand, and vice versa ... Yin and Yang converge with each other in the Yin and Yang heel vessels, Yang joins Yin, Yin leaves Yang. As Yang reaches its limit, the eyes open, and vice versa.” That is, only when there is a balance of the Yin heel vessel and Yang heel vessel can people gain regular sleep. Consequently, regulation of the heel vessels and balance of Yin and Yang can treat insomnia. Shenmai (BL 62) and Zhaohai (KI 6) are both in the Eight Influential Points. Zhaohai (KI 6) is a point on the kidney meridian of foot shaoyin, which links with the Yin heel vessel. Acupuncture should use the reinforcing method. Shenmai (BL 62) is a point on the bladder meridian of foot taiyang, which links with the Yang heel vessel. Shenmai should be stimulated with the reducing method. These two points can reinforce Yin and reducing Yang, possibly improving sleep. The governor vessel is also closely related to the brain. As stated in Su Wen, the governor vessel goes “up to [the] forehead, reach [es] the top of [the] head, [the] collateral brain.” Baihui (GV 20) is located in the middle of the top of the head, which is at the intersection of the governor vessel, the meridian of foot taiyang, hand shaoyang, foot shaoyang, and foot jueyin. Ling Shu says that the “brain is the sea of marrow, which conveys up to the cover, down to Fengfu (GV 16).” The cover in this context means Baihui (GV 20), which has extensive contact with all parts of the body. Sishencong (EX-HN 1), located 1 cun anterior, posteri-
or and lateral to Baihui (GV 20), has two anterior and posterior points that are both on the governor vessel, and two lateral points that adjoin the bladder meridian, which is collateral to the kidney. The meridian Qi communicates with the primary spirit, calming the nerves and improving intelligence, reinforcing the brain and regulating the mind. Therefore, it can promote sleep, uplift the spirit, and strengthen memory.

5-HT, located at the head end of the raphe nucleus, plays an important part in the maintenance of slow-wave-sleep. The bodies of the 5-HT nerve cells are mainly concentrated at the raphe nuclei. Therefore, reducing the potency of 5-HT could advance sleep. Studies have shown that moxibustion can protect the hippocampal neurons of chronic stress rats, significantly improving the content of brain-derived neurotrophic factor. It can also significantly increase cerebral cortex 5-serotonin levels and its metabolite 5-hydroxyindoleacetic acid in presenium rats, and participate in the signal transduction of the neurotrophic factor in the brain. Therefore, moxibustion can resist insomnia, improve awakening, and ensure normal functioning in daytime.

REFERENCES
9 He ZK. Application of acupuncture at Baihui (GV 20) to treating diseases in brain. Zhong Yi Yao Dao Bao 2010; 16 (9): 116-117.
14 Zhang HZ, Jia CS, She YF. Clinical observations on treatment of obstinate insomnia with acupuncture mainly at Zhaoxai (KI 6) and Shenmai (BL 62). Sichuang Zhong Yi 2003; 21(6): 75-76.