The Needle-Rolling Therapy for Treatment of Non-organic Chronic Insomnia in 90 Cases

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Objective: To evaluate the therapeutic effects of needle-rolling therapy for chronic insomnia. Methods: In the present multi-central randomly controlled clinical study, 180 cases of chronic insomnia were randomly divided into the following two groups, a treatment group (90 cases) treated by the needle-rolling therapy and a control group (90 cases) treated with clonopin. The treatment course for both the two groups was 4 weeks. The therapeutic effects were evaluated based on improvement of the TCM symptoms and the Pittsburgh's sleep-quality index (PSQI). Results: After treatment, there were significant differences between the two groups in the effective rate (P<0.05), and in the total score of PSQI and in the scores of the 4 sub-items, i.e. sleep-quality, sleep-efficiency, hypnotic and daytime function (P<0.05). Although there was no significant difference between the two groups in the effective rate after a 3-month follow-up period, significant differences still existed in the 3 sub-items of sleep-efficiency, hypnotic, and daytime function of the PSQI (P<0.05). Conclusion: As compared with hypnotics of the second generation, the needle-rolling therapy may show better therapeutic effects for chronic insomnia patients.

Key words: insomnia; acup-mox therapy; needling method; needle-rolling

Insomnia is a chief complaint for poor or unsatisfactory sleep, which includes difficulty in falling asleep, repeated or long time awakening, early awakening, insufficient sleep time; and its affection on the daytime functions, such as alertness, energy, cognition function, behavior and emotion. Insomnia is a disorder with the highest morbidity in dyssomnia.1 It is suggested in an article about the evaluation on random control test (RCT) for acupuncture treatment of insomnia that acupuncture may be effective for treatment of insomnia (P<0.0001).2 However, it needs more evidences. The authors have applied the needle-rolling therapy in clinical treatment of insomnia for many years. Based on the large-sample multi-central random control researches with related quantitative evaluations, this study is aimed at providing the best clinical evidences for the therapeutic effects of needle-rolling therapy in treating insomnia, so as to popularize this therapy in clinic.

CLINICAL MATERIALS

General data

In this research, the multi-central random and positive drug parallel control tests were conducted from April 2003 to March 2005, with three medical units joining in, 180 cases up to the research criteria were enrolled in the research (90 cases in the needle-rolling therapy group, and 90 cases in the control group). With the help of PEMS3.0 statistical analysis software developed by the Huaxi College of Public Health of Sichuan University, the random
An arrangement for the 180 subjects was produced, i.e. the treatment distribution of the listed serial case number from 001–180 to the three corresponding experimental centers. The number of the experimental centre was designed randomly: number 1 being the College of Acupuncture-Moxibustion and Chinese Tuina of Chengdu University of Traditional Chinese Medicine, number 2 being the Special Hospital of Acupuncture and Moxibustion of Sichuan Provincial Academy of Traditional Chinese Medicine, and number 3 being the Department of Acupuncture of Huaxi Hospital of Sichuan University.

Before treatment, the comparisons of the statistical base-lines suggested that there were no significant differences between the two groups in the indexes of sex, age frequency distribution, the mean duration of illness and its frequency distribution, the mean time for falling asleep and its frequency distribution, the mean time of actual sleep, and the total score of Pittsburg’s sleep-quality index (PSQI) ($P > 0.05$).

The diagnostic criteria
The western medical diagnosis was made according to the diagnostic criteria for non-organic insomnia (primary insomnia). The TCM diagnosis was made based on the diagnostic criteria for insomnia. The criteria for enrollment

1) Cases with insomnia up to the western diagnostic criteria for non-organic insomnia and the TCM diagnostic criteria for ‘insomnia’, characterized by difficulty in falling asleep, easy awakening, unsound sleep, dreamy sleep, early awakening or difficulty to fall asleep again after awakening, daytime sleepiness, lassitude, distractibility, and decreased memory; and the patients having the superior idea of extremely caring about the sleep result. 2) The sleep latent period >30 min., 3 times/per week. 3) The total score of PSQI >7.4) The age range was 16–75 years. And 5) The patients agreeing to sign the aware letter of consent.

The criteria for exclusion
1) Secondary insomnia caused by somatic or mental diseases. 2) Dyssomnia caused by disorders of the nervous system. 3) Women in the pregnancy or breast feeding period. 4) Insomnia due to psychoactive drug abuse or dependence. And 5) The patients with local skin ulcer or sores.

METHODS

Methods of treatment
For the treatment group: 1) The needle-rolling apparatus was used (illustration omitted). 2) The areas stimulated: The 1st and the 2nd lines of the Bladder Channel and the Governor Channel on the back were the main area to be stimulated. 3) The operation: The patient was asked to be in a prone position. The operator used the needle-rolling instrument, 1) rolling along the 1st line of the Bladder Channel from Feishu (BL 13) to Shenshu (BL 23); 2) rolling along the 2nd line of the Bladder Channel from Dazhu (BL 11) to Zhishi (BL 52); and 3) rolling along the Governor Channel from Mingmen (GV 4) to Dazhui (GV 14). The needle-rolling was applied in a quite slow speed about 10 times, with the rolling force kept to make the patient feel comfortable and the skin turn red (a sign of smooth flow of qi and blood in the channel). Each of the needle-rolling treatments lasted 15–20 min.

Owing to ethical factor and the effectiveness of anti-insomnia drugs, insomnia patients tend to have big physical and psychological drug dependence. If the needle-rolling therapy could not show effects in a short period of time, the patient might receive other treating methods. Therefore, patients were told before the experiment to try their best to avoid using drugs. If the insomnia was unbearable, the patient should contact with the researcher in time, and the researcher could decide, based on his own judgment, whether to permit the patient to take 2 mg of clonazopan (the smallest dosage of the drug used).

For the control group: The patients in this group were given 4–6 mg of clonazopan daily to be taken before bedtime.
The patients in the two groups received treatment in the same environment. The treatment group received the needle-rolling therapy once daily in the daytime, each time lasting 15–20 min, 5 times a week with an interval on Saturday and Sunday. The control group was treated with the oral medication every night before bedtime. For the two groups, evaluations were done after a 4-week treatment course, and with a follow-up survey conducted for 3 months.

**The observation indexes**

1) The effective rate for improvement in dyssomnia (after a 4-week treatment with a follow-survey for 3 months), which was evaluated based on the criteria for therapeutic effects of ‘insomnia’ in *The TCM Criteria for Diagnosis and Therapeutic Effects* issued by The State Administration of TCM in 1994, combined with the evaluation criteria for therapeutic effects on insomnia formulated by WHO. 2) PSQI evaluation (after a 4-week treatment with a follow-up survey for 3 months). And 3) Detailed records for the side effects of the needle-rolling therapy, such as infection, injury, and unbearable pain or discomfort.

**The statistical method**

Statistical calculations were done by using the medical statistical software PEMS3.1 edition developed by the Statistics Teaching Section of Huaxi Hospital. The *t* test was applied for measurement data in accord with normal distribution (0.05 taken as the level for the intergroup homogeneity test of variance; Satterth waite method applied for the corrected *t* test on non-homogenous variance). Wilcoxon rank test or Wilcoxon symbol rank test was applied for measurement data not in accord with normal distribution. The available data were analyzed and evaluated by non-parameter *Ridit*. One-side test was generally used for hypothesis testing, giving the statistical quantity of test and its corresponding *P* value, with *P*≤0.05 being considered significant difference.

**RESULTS**

In this series, 180 cases were enrolled, and all of them completed the 4-week treatment. 179 cases were involved in the 3-month follow-up survey, among which 90 cases were from the treatment group, and 89 cases from the control group.

**The criteria for therapeutic effects**

1) Clinically cured: The sleep turned normal, with a 75% rise in sleep-efficiency and disappearance of the main clinical symptoms. Improved: The sleep time prolonged, with a 25%–74% rise in sleep-efficiency and improvement of the accompanying symptoms. Failed: The sleep was not improved, with a <25% rise in sleep-efficiency and no obvious improvement in the accompanying symptoms.

2) PSQI evaluation: 7 items were involved in the evaluation, namely, sleep-quality, falling-asleep time, sleep time, sleep-efficiency, sleep-disturbance, hypnotic, and daytime function. Each item was scored 0–3. The accumulated score of the 7 items constituted the total score of PSQI (0–21), the higher the score, the poorer the sleep quality.

**The therapeutic effects after 4-week treatment**

The *Ridit* test suggested significant differences between the two groups in the therapeutic effects (*P*<0.05) (Table 1).

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Cured</th>
<th>Improved</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>90</td>
<td>18</td>
<td>56</td>
<td>16</td>
</tr>
<tr>
<td>Control</td>
<td>90</td>
<td>10</td>
<td>44</td>
<td>36</td>
</tr>
<tr>
<td>Total</td>
<td>180</td>
<td>28</td>
<td>100</td>
<td>52</td>
</tr>
</tbody>
</table>

**The therapeutic effects in a 3-month follow-up survey**

The *Ridit* test suggested no significant differences between the two groups in the long-term therapeutic effects (*P*>0.05) (Table 2).
Table 2. The intergroup comparison of therapeutic effects in a 3-month follow-up survey.

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Cured</th>
<th>Improved</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>90</td>
<td>5</td>
<td>31</td>
<td>54</td>
</tr>
<tr>
<td>Control</td>
<td>89</td>
<td>2</td>
<td>25</td>
<td>62</td>
</tr>
<tr>
<td>Total</td>
<td>179</td>
<td>7</td>
<td>56</td>
<td>116</td>
</tr>
</tbody>
</table>

Comparison of PSQI before and after treatment and in a 3-month follow-up survey

As shown in Table 3, intragroup comparisons of the two groups showed that there were significant differences in all the indexes \((P<0.05)\) except the falling-asleep time before treatment as compared with that 3 months later \((P>0.05)\). It is indicated that an active treatment is beneficial to the improvement of sleep condition for insomnia patients \((P<0.05)\).

The intergroup comparisons showed that the treatment group is superior to the control group in improving the sleep quality, sleep efficiency, hypnotics and daytime function, and in the total score after the 4-month treatment. Moreover, the intergroup comparisons of the indexes 3 months later showed that the treatment group still has the superiority in the long-term therapeutic effects for the sleep efficiency, hypnotic and daytime function.

Table 3. Comparison of PSQI before and after treatment and 3 months later (\(X \pm S\))

<table>
<thead>
<tr>
<th>Group</th>
<th>Time</th>
<th>Sl.-quality</th>
<th>Fallasl. time</th>
<th>Sl.-time</th>
<th>Sl.-efficiency</th>
<th>Sl.-disturbance</th>
<th>Hypnotic</th>
<th>Daytime function</th>
<th>Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Before treatment</td>
<td>2.62±0.81</td>
<td>2.81±0.54</td>
<td>2.08±0.93</td>
<td>2.23±0.96</td>
<td>1.52±0.60</td>
<td>2.67±0.86</td>
<td>2.73±0.47</td>
<td>16.67±2.78</td>
</tr>
<tr>
<td></td>
<td>4-week treatment</td>
<td>0.90±0.95</td>
<td>2.37±0.91</td>
<td>0.99±0.76</td>
<td>0.86±1.00</td>
<td>1.03±0.35</td>
<td>2.63±0.89</td>
<td>1.44±0.62</td>
<td>10.22±2.93</td>
</tr>
<tr>
<td></td>
<td>3-month follow-up</td>
<td>1.52±0.69</td>
<td>2.63±0.71</td>
<td>1.24±0.79</td>
<td>0.80±0.93</td>
<td>1.18±0.52</td>
<td>1.15±0.99</td>
<td>1.33±0.49</td>
<td>9.88±2.62</td>
</tr>
<tr>
<td>Control</td>
<td>Before treatment</td>
<td>2.42±0.98</td>
<td>2.79±0.61</td>
<td>1.90±0.89</td>
<td>2.17±1.01</td>
<td>1.44±0.62</td>
<td>2.68±0.73</td>
<td>2.68±0.56</td>
<td>15.98±3.16</td>
</tr>
<tr>
<td></td>
<td>4-week treatment</td>
<td>1.18±0.79</td>
<td>2.49±0.92</td>
<td>1.04±0.73</td>
<td>1.44±1.09</td>
<td>1.12±0.45</td>
<td>2.87±0.56</td>
<td>1.74±0.62</td>
<td>11.89±3.27</td>
</tr>
<tr>
<td></td>
<td>3-month follow-up</td>
<td>1.52±0.72</td>
<td>2.69±0.69</td>
<td>1.21±0.77</td>
<td>1.72±1.08</td>
<td>1.27±0.47</td>
<td>1.94±1.06</td>
<td>1.91±0.51</td>
<td>12.28±3.47</td>
</tr>
</tbody>
</table>

Note: Intragroup comparison, \(*P<0.05\); intergroup comparison, \(\Delta P<0.05\).

Safety analysis

The needle-rolling therapy with no needle inserted causes no infections and infectious diseases. So, the safety analysis for the present study is based on the accounts of both the doctors and patients and according to the observations. In this research, no patient reported abnormal reactions and no doctor sent reports for severe incidents.

DISCUSSION

The epidemiological survey of insomnia has shown that at present in China, the morbidity of insomnia has reached to 10%–20%. Chronic insomnia can cause a series of damages to the human body, including decrease in attention, judgment, memory and daily life ability. It can also increase the danger of mental depression. Persistent insomnia can often make people dejected and impatient, which are a dangerous factor and the premonitory for mental disturbance, seriously affecting people’s life, work and health.\(^6\)

Although insomnia is a sleep disturbance in the night, it affects the two physiological functions of sleep and awakening. Its treatment should be focused on giving double-phase regulation to the whole cycle of insomnia–awakening.\(^7\) At present, the commonly-used drugs in clinic for insomnia are sedative-hypnotics and antianxieties, the action of which is to make the patient fall asleep quicker, with obviously
prolonged rapid eye movement (REM) sleep time, during which the patient is not easily to awake. However, 95% of the patients have got, in various degrees, shortened slow-wave sleep and quick eye movement sleep, drug dependence, withdrawal symptoms, and even the phenomenon of ‘drug-drunk’. For this, searching for new method of treatment has become the key point in clinical treatment.

The needle-rolling therapy was created by the late acupuncture expert of Sichuan Province, Prof. YU Zhong-quan (余仲权). The authors think, the therapeutic effect obtained from the needle-rolling therapy for chronic insomnia lies in that the large-area gentle stimulation is given on the channels and collaterals where the ‘five zang’s Shu-Mu points’ locate, which has the action of strengthening functions of the zang-fu organs. And, through the channels and collaterals, this stimulation will enter the brain, so as to regulate yin, yang, qi, and blood to treat insomnia. Modern neuroanatomy has proved that there are posterior ramuses of the spinal nerve distributing on both side of the spine, and at the deep layer there distribute the sympathetic trunk, sympathetic paravertebral ganglia, and gray and white ramus communicans connecting to the spinal nerves. Therefore, the large-area stimulation by the needle-rolling therapy is likely to effectively adjust the disturbed function of the vegetative nerves and the microcirculatory system on the body surface, and activate the regulatory nerves of the corresponding internal organs. And through the regulatory functions of the nerves and body fluid, the influence may show on the release of chemical mediators of the peripheral nerve and central nerve, such as dopamine, noradrenalin, acetylcholine, somatotropin and corticotrophin-releasing factor, thus yielding the therapeutic effects.

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