



Efficacy of Auricular Point Pressing Beans Combined with Modified Suanzaoren Decoction in Treating Post-Stroke Insomnia

Jin Huang, Yu Liu

Xiangyang Hospital of Traditional Chinese Medicine (Xiangyang Research Institute of Traditional Chinese Medicine), Xiangyang 441000, Hubei, China

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Abstract

Objective: To analyze the effect of auricular point pressing with beans combined with modified Suanzaoren Decoction in treating post-stroke insomnia. **Methods:** A total of 80 patients with post-stroke insomnia admitted to our hospital from December 2019 to December 2021 were included in this study by convenience sampling and randomly divided into two groups with equal numbers of cases using a digital random table. Both groups of patients received modified Suanzaoren Decoction treatment, while patients in the observation group also received auricular point pressing with beans treatment on this basis. Both groups of patients underwent biochemical tests before medication and at the end of the treatment course. The serum tumor necrosis factor-alpha levels of the two groups of patients before medication and at the end of the treatment course were compared. The Pittsburgh Sleep Quality Index was used to assess the sleep quality of patients before medication and at the end of the treatment course, and the scores of the two groups were compared. The efficacy of the two groups of patients was evaluated according to the “Guiding Principles for Clinical Research on New Traditional Chinese Medicines” and the total effective rates of the two groups were compared. **Results:** Before medication, there was a minor difference in serum tumor necrosis factor-alpha (TNF- α) levels between the two groups of patients ($p > 0.05$). At the end of the treatment course, the serum TNF- α level in the observation group had increased compared to the pre-medication level, significantly higher than that in the control group ($p < 0.05$). Before medication, the Pittsburgh Sleep Quality Index (PSQI) showed a minor difference between the two groups ($p > 0.05$). At the end of the treatment course, the PSQI in the observation group had decreased compared to the pre-medication level, significantly lower than the assessment results in the control group ($p < 0.05$). The total effective rate of treatment in the observation group was higher than that in the control group, showing a statistically significant difference ($p < 0.05$). **Conclusion:** The combination of auricular point pressing therapy with modified Suanzaoren Decoction demonstrates a definite therapeutic effect in treating post-stroke insomnia, more effectively improving patients' serum TNF- α levels and sleep quality, and is worthy of application.

Keywords

Post-stroke insomnia; Suanzaoren decoction; Auricular point pressing therapy; Tumor necrosis factor; Sleep quality; Therapeutic effect

1. Introduction

Cerebral stroke is a cerebrovascular disease caused by various factors that lead to a disturbance in the brain's blood supply, resulting in ischemic and hypoxic necrosis of brain tissue. Cerebral stroke has a high incidence rate in China, particularly among the elderly population. With the development of intravenous thrombolysis therapy and other emergency treatment techniques, the mortality rate from cerebral stroke has significantly decreased^[1]. However, stroke patients are prone to sequelae, with insomnia being a common one. This complication not only affects the recovery of neurological function and daily life in stroke patients but may even increase their risk of recurrence. In recent years, traditional Chinese medicine has played a significant role in the treatment of stroke and its complications. Suanzaoren Decoction has the effect of nourishing blood and tranquilizing the mind, while auricular point pressing with bean is a common external treatment method in traditional Chinese medicine^[2,3]. To analyze the efficacy of auricular point pressing with bean combined with modified Suanzaoren Decoction in treating post-stroke insomnia, a comparative analysis was conducted on 80 patients with post-stroke insomnia admitted to our hospital. The research process and results are reported as follows.

2. Materials and methods

2.1. Baseline data

A total of 80 patients with insomnia after stroke admitted to our hospital from December 2019 to December 2021 were included in this study using convenience sampling. They were randomly divided into two groups with an equal number of cases in each group using a digital randomization table. In the observation group, there were 25 male and 15 female patients; the youngest patient was 51 years old and the oldest was 75 years old, with an average age of (68.30 ± 4.11) years; the disease duration ranged from 1 to 3 months, with an average of (1.20 ± 0.43) months. In the control group, there were 23 male and 17 female patients; the youngest patient was 50 years old and the oldest was 78 years old, with an average age of (67.62 ± 4.08) years; the disease duration ranged from 1 to 3 months, with an average of (1.40 ± 0.45) months. The baseline data of the two groups showed minimal

differences ($p > 0.05$), allowing for a comparative study.

2.1.1. Inclusion criteria

- (1) Diagnosed with stroke through imaging examination;
- (2) Meeting the relevant diagnostic criteria in the "Guidelines for the Diagnosis and Treatment of Insomnia in Chinese Adults";
- (3) Absence of other diseases affecting treatment prognosis;
- (4) Ability to communicate normally and good compliance;
- (5) Signed informed consent form.

2.1.2. Exclusion criteria

- (1) Mental disorders or cognitive impairment;
- (2) Allergy to the medications used in this study;
- (3) Patients who have recently taken antidepressants or other medications that may affect the efficacy;
- (4) Presence of other serious organic lesions;
- (5) Incomplete clinical data.

2.2. Methods

Both groups of patients received modified Suanzaoren Decoction treatment, with the following formula: *Caulis Polygoni Multiflori* 25 grams, *Rhizoma Anemarrhenae* 20 grams, *Ziziphi Spinosae Semen* 25 grams, *Rhizoma Chuanxiong* 20 grams, *Poria* 20 grams, *Radix Glycyrrhizae Preparata* 15 grams, *Os Draconis* (calcined) 25 grams, and *Concha Ostreae* (calcined) 25 grams. For patients with night sweats, an additional 20 grams of *Concha Ostreae* (calcined), 12 grams of *Fructus Tritici Levis*, and 8 grams of *Fructus Schisandrae* were added; for those who woke up easily, 20 grams of *Dens Draconis* and 10 grams of *Radix Ginseng* were added; for those whose anxiety affected their sleep, 8 grams of *Fructus Gardeniae* and 6 grams of *Rhizoma Coptidis* were added; and for those with excessive phlegm, 20 grams each of *Pericarpium Citri Reticulatae*, *Rhizoma Pinelliae*, and *Bambusae Concretio Silicea* (Note: "Gallbladder Heart" may be a misinterpretation or a specific term in TCM; please verify its accuracy) were added. One dose per day was decocted in water to obtain 300 milliliters of juice, which was taken twice daily for two consecutive months^[4,5].

On this basis, patients in the observation group

received auricular point pressing therapy with beans. Auricular points corresponding to Shenmen, Sympathetic, Heart and Spleen, etc., were selected. After confirming the sensitive areas of the auricular points with a probe, routine disinfection was performed using alcohol. Vascular forceps were used to attach Vaccaria seeds patches to the sensitive auricular points, and patients were instructed to appropriately massage these sensitive auricular areas for about 1–2 minutes each time, at least three times a day^[6,7].

2.3. Evaluation methods

Both groups of patients underwent biochemical tests before medication and at the end of the treatment course. The serum tumor necrosis factor-alpha (TNF- α) levels of the two groups were compared before medication and at the end of the treatment course. The biochemical tests for both groups were performed by the same laboratory physician, using an automatic biochemical analyzer and enzyme-linked immunosorbent assay kits to complete the corresponding tests.

The Pittsburgh Sleep Quality Index (PSQI) was employed to evaluate the sleep quality of patients before medication and at the end of the treatment course. Patients were asked to truthfully complete the questionnaire based on their sleep conditions over the past month, which included 19 self-assessment items and 5 negatively-worded items. Each item was scored on a scale of 0 to 3, and the cumulative scores of all factors constituted the total score for this assessment, with a maximum possible score of 21. The score was negatively correlated with sleep quality, and the scores of the two groups were compared.

The efficacy in the two groups of patients was determined according to the “Guidelines for Clinical Research on New Traditional Chinese Medicines”. Patients whose insomnia symptoms completely disappeared after treatment were considered cured, those whose insomnia symptoms significantly improved after treatment were considered effective, and those who did not meet the above criteria after treatment were considered ineffective. The total effective rate of treatment was the sum of the cure rate and the effective rate, and the total effective rates of the two groups were compared.

2.4. Statistical methods

The data of the two groups of patients were organized using Excel spreadsheets and statistically analyzed using the SPSS 16.0 software package. Measurement data were expressed as (mean \pm standard deviation) and analyzed using the t-test. Count data were expressed as the number of cases and analyzed using the chi-square (χ^2) test. A p -value less than 0.05 indicated a significant difference between the results of the two groups, with statistical significance.

3. Results

3.1. Comparison of serum tumor necrosis factor alpha level between the two groups

Before medication, there was a minimal difference in serum tumor necrosis factor alpha levels between the two groups of patients ($p > 0.05$). At the end of the treatment course, the serum tumor necrosis factor alpha level in the observation group increased compared to before medication and was significantly higher than that in the control group ($p < 0.05$), as shown in **Table 1**.

3.2. Comparison of Pittsburgh sleep quality index assessment results between the two groups

Before medication, there was a minimal difference in the Pittsburgh Sleep Quality Index between the two groups of patients ($p > 0.05$). At the end of the treatment course, the Pittsburgh Sleep Quality Index in the observation group decreased compared to before medication and was significantly lower than that in the control group ($p < 0.05$), as shown in **Table 2**.

3.3. Comparison of clinical efficacy between the two groups

The total effective rate of treatment in the observation group was higher than that in the control group, with a statistically significant difference ($p < 0.05$), as shown in **Table 3**.

4. Discussion

Insomnia is a common complication of stroke. Data indicates that the incidence of insomnia during the acute

Table 1. Serum tumor necrosis factor alpha level before and after treatment in both groups (ng/L)

Group	Before treatment	After treatment	t-value (Within-group)	p-value (Within-group)
Observation group	98.32 ± 9.26	229.61 ± 10.12	60.534	< 0.05
Control group	99.27 ± 9.23	196.20 ± 12.05	40.388	< 0.05
t-value (Between-group)	0.460	13.428		
p-value (Between-group)	> 0.05	< 0.05		

Table 2. Pittsburgh sleep quality index assessment results before and after treatment in both groups

Group	Before treatment	After treatment	t-value (Within-group)	p-value (Within-group)
Observation group	16.72 ± 2.19	10.06 ± 2.07	13.978	< 0.05
Control group	16.95 ± 2.15	13.11 ± 2.03	8.213	< 0.05
t-value (Between-group)	0.474	6.653		
p-value (Between-group)	> 0.05	< 0.05		

Table 3. Total effective rate of treatment in both groups

Group	Before treatment	After treatment	t-value (Within-group)	p-value (Within-group)
Observation group	16.72 ± 2.19	10.06 ± 2.07	13.978	< 0.05
Control group	16.95 ± 2.15	13.11 ± 2.03	8.213	< 0.05
χ ² value (Between-group)	0.474	6.653		
p-value (Between-group)	> 0.05	< 0.05		

phase of stroke approaches 70%, with the rate remaining close to 50% after 18 months. The causes of insomnia following a stroke are complex and may be related to the location of the injury and the severity of the condition in stroke patients [8]. The nuclei that regulate sleep, including the locus coeruleus and hypothalamus, can be damaged in stroke patients, leading to the interruption of relevant conduction pathways. This disruption can prevent the initiation of sleep or disrupt the sleep-wake rhythm. Additionally, stroke patients often face a prolonged recovery period, during which many experience prolonged limb weakness and other sequelae. The financial strain caused by long-term treatment can impose significant psychological burdens on patients, leading to anxiety and other emotions that severely affect their sleep [9]. Insomnia after stroke not only affects the neurological recovery and daily life of stroke patients but may also increase their risk of recurrence. Therefore, it is particularly important to strengthen the treatment of this

complication.

Stroke falls under the category of “apoplexy” in traditional Chinese medicine (TCM), while insomnia is classified as “insomnia disorder”. There are numerous records regarding both conditions in TCM literature. TCM views apoplexy primarily through the lenses of external wind theory and internal wind theory, attributing the onset of apoplexy to liver Yang hyperactivity and internal wind agitation. External wind, heart fire, Qi counterflow, and blood stasis are considered closely related to the occurrence of apoplexy [10]. There is no explicit record of “insomnia after stroke” in traditional Chinese medical literature. However, stroke patients often suffer from insomnia due to disrupted Qi and blood circulation, phlegm and blood stasis, blocked meridians, and hyperactivity of liver Yang, which disturb the mind. Insomnia, in turn, does not deplete Yin essence, leading to a decline in Qi and blood in patients, thus creating a vicious cycle with stroke. Therefore, the treatment

of insomnia after stroke should primarily focus on regulating the Yin and Yang of the viscera, calming the mind, and replenishing Qi^[11]. In the Suanzaoren Decoction, Poria helps to stabilize essence and calm the mind, Anemarrhena nourishes Yin, moistens dryness, clears heat, and purges fire, Suanzaoren (*Ziziphi Spinosae Semen*) replenishes Qi, nourishes blood, and calms the heart and mind, *Ligusticum chuanxiong* dispels wind, relieves pain, promotes blood circulation, and regulates Qi, *Polygonum multiflorum* calms the mind, nourishes the spirit, dispels wind, and unblocks the meridians, calcined oyster shell heavily sedates and calms the mind, calcined dragon bone subdues liver Yang and tranquilizes the mind, and licorice harmonizes all the ingredients^[12]. Modern research has confirmed that *Ziziphi Spinosae Semen*, a key herb in the Suanzaoren Decoction, exhibits various pharmacological effects. The hydrolyzed substance of jujuboside A can penetrate the blood-brain barrier and form hydrogen bonds with γ -aminobutyric acid receptors, thereby prolonging total sleep time^[13]. The flavonoid components in *Ziziphi Spinosae Semen* can synergize with the central inhibitory effects of sodium pentobarbital. Animal experiments have demonstrated that these components can counteract the excitation induced by amphetamine in mice, exhibiting good anti-anxiety and sleep-inducing effects. Furthermore, animal experiments have confirmed that the volatile oils contained in *Ziziphi Spinosae Semen* can inhibit cerebral activity in animals, demonstrating a significant central sedative effect^[14]. Thus, applying the Suanzaoren Decoction to the treatment of patients with insomnia after stroke yields favorable sleep-promoting effects.

Traditional Chinese medicine holds that each of the five internal organs and six viscera in the human body has its corresponding representative area on the auricle. By precisely attaching medicinal beans to auricular points with adhesive tape, stimulating sensations such as sourness and fullness are induced at these points, which can regulate the corresponding visceral functions, balance Yin and Yang, and regulate Qi and blood. Therefore, this study applied auricular point sticking therapy to the treatment of patients with insomnia after stroke. Selecting corresponding acupoint points such as Shenmen, Jiaogan, and Xinpi for treatment can have a calming and soothing effect on the mind and regulate Qi and blood. Combined

with Suanzaoren Decoction, it can enhance therapeutic efficacy^[15]. The Pittsburgh Sleep Quality Index (PSQI) was used to evaluate the sleep quality of the two groups of patients before and after treatment. This scale has been proven to have good reliability and validity. The results showed that there was little difference in the PSQI scores between the two groups before medication ($p > 0.05$). At the end of the treatment course, the PSQI score of the observation group decreased compared to that before medication and was significantly lower than that of the control group ($p < 0.05$). In terms of overall therapeutic efficacy, the total effective rate in the observation group was 95.00%, higher than the 75.00% in the control group. Based on the above results, the combined application of Suanzaoren Decoction and auricular point sticking therapy in the treatment of patients with insomnia after stroke has better therapeutic efficacy and can significantly improve patients' sleep quality. It is noteworthy that the use of auricular point pressing therapy with beans is contraindicated in patients with heart disease or auricular skin lesions. This external traditional Chinese medicine therapy can be employed once the patient's lesions have healed. During the treatment period, it is also essential to enhance health education for patients, improving their understanding of auricular point pressing therapy with beans and their compliance with the treatment to ensure its efficacy.

Tumor necrosis factor (TNF) is a pro-inflammatory cytokine produced by macrophages and also a cytokine that can damage neurons. The expression of TNF- α in normal brain tissue is almost rhythmic, with the highest levels occurring during deep sleep. A study on Parkinson's disease patients with sleep disorders found that plasma TNF- α concentrations were associated with sleep disturbances and other non-motor symptoms in Parkinson's disease patients. TNF- α and other inflammatory mediators can activate a series of downstream signaling pathways in the brain, thereby prolonging the duration of non-rapid eye movement sleep. These inflammatory mediators can also alter neuroendocrine activity, prompting the release of neurotransmitters that cause brain excitation, leading to symptoms such as sleep disturbances and memory decline in patients. The increase in TNF- α is due to its release from activated glial cells in the substantia nigra of

the central nervous system. The high expression of this inflammatory mediator at night can promote sleep to a certain extent; otherwise, it can cause sleep disturbances^[16]. Based on this, both the observation group and the control group patients in this study underwent biochemical tests before and after medication administration. The serum tumor necrosis factor-alpha (TNF- α) levels of the two groups of patients before and after treatment were statistically analyzed and compared. There was a minor difference in the serum TNF- α levels between the two groups of patients before medication ($P > 0.05$). At the end of the treatment course, the serum TNF- α level in the observation group patients had increased compared to that

before medication and was significantly higher than the test results of the control group patients ($p < 0.05$). This result indicates that the treatment of post-stroke insomnia patients with auricular point pressing combined with Suanzaoren Decoction can improve patients' sleep quality by regulating their TNF- α levels.

In conclusion, the combined treatment of auricular point pressing and modified Suanzaoren Decoction has a definite therapeutic effect on post-stroke insomnia, effectively elevating patients' serum TNF- α levels and improving their sleep quality, and is thus worthy of application.

Disclosure statement

The author declares no conflict of interest.

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