Journal of Human Reproduction and Endocrinology

ORIGINAL RESEARCH

Open Access

Improving Effects of Liver-Soothing and Menstruation-Regulating Acupuncture in Combination with Press-Tack Needling on Sex Hormone Levels and Sleep Quality of Patients with Perimenopausal Insomnia

Xiaoqin Huang [1,*], Su Shi [2]

1. Department of Gynaecology and Obstetrics, Huzhou Wuxing District Integrated Traditional Chinese and Western Medicine Hospital, 313099 Huzhou, Zhejiang, China
2. Acupuncture and Moxibustion Massage Department, Huzhou Wuxing District Integrated Traditional Chinese and Western Medicine Hospital, 313099 Huzhou, Zhejiang, China

Keywords

Perimenopausal insomnia
Liver-soothing and menstruation-regulating Acupuncture
Press-tack needling
Sex hormones
Sleep quality

* **Correspondence**

Xiaoqin Huang
Department of Gynaecology and Obstetrics, Huzhou Wuxing District Integrated Traditional Chinese and Western Medicine Hospital, 313099 Huzhou, Zhejiang, China
E-mail: 13819230000@163.com

Received: 2 June 2024
Revised: 19 July 2024
Accepted: 26 July 2024
Published: 2 August 2024

Journal of Human Reproduction and Endocrinology **2024; 1(1): 36-45.**

Abstract

Objective: This study aims to explore the improving effects of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling on sex hormone levels and sleep quality of patients with perimenopausal insomnia (PMI). **Methods**: 88 PMI patients, who were treated in our hospital and received the treatment of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling from April, 2022 to April, 2024 were included, and set as A group. During the same time, 83 PMI patients treated with liver-soothing and menstruation-regulating acupuncture were included as B group. The duration of treatment in the two groups was 30 days. The clinical efficacy of the two groups was compared. The data of sleep scores and levels of sex hormone indexes were collected from the two groups. **Results**: The clinical total effective rate in the A group was higher than that in the B group ($p < 0.05$). Compared to before treatment, PSQI, follicle-stimulating hormone (FSH) and luteinizing hormone (LH) levels were decreased in the two groups after treatment ($p < 0.05$), and these levels in the A group were lower than those in the B group ($p < 0.05$). Compared to before treatment, the E_2 level was increased in the two groups after treatment ($p < 0.05$), and its level in the A group was higher than that in the B group ($p < 0.05$). **Conclusions**: There is a significant efficacy of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling on the treatment of PMI patients. This combined therapy can alleviate the patients' clinical symptoms, improve their sleep quality and regulate sex hormone levels, suggesting its clinical application value.

1 Introduction

Most perimenopausal women struggle with insomnia, termed as perimenopausal insomnia (PMI), due to the weakening of the ovaries and hormonal changes in their bodies. The clinical symptoms of PMI are mainly manifested as anxiety, depression, and sleep disturbances and may affect the quality of life of patients in severe cases, and those with severe disease progression may even experience physical and mental disabilities [1-3]. The epidemiological evidence shows that the incidence of PMI ranges from 16% to 47% and its high incidence impairs the quality of life of patients [4]; therefore it is important to explore effective methods for treating PMI.

In recent years, traditional Chinese medicine (TCM) is favored by an increasing number of patients due to its good efficacy and low side effects, and has become one of the major clinical therapies [5,6]. In TCM, it is believed that PMI belongs to the disease of "insomnia" and is diagnosed as "the syndrome of liver and kidney insufficiency" based on syndrome differentiation. The patients with PMI experience qi depression in the liver caused by factors like family influence. The obstruction of qi movement in the body leads to accumulation of depression and transformation into fire, qi and blood exhaustion, and harassment of spirit, eventually resulting in PMI [7]. Huan Feng et al. have reported that auricular point seed burying combined with fire dragon pot moxibustion therapy is a effective method in treating perimenopausal women with insomnia [8].

As a therapy of TCM, acupuncture has been proved to be effective in the treatment of PMI, relieving patients' sleep disorders, with satisfactory short- and medium-term effects as well as a high safety profile [9,10]. In addition, the previous study has shown that Bushen Anshen acupuncture effectively improved the subjective and objective sleep quality in PMI patients of kidney-yin deficiency [11]. Meanwhile, *FU Qing-zhu Gynecology* suggests that the pathological lesions in women are closely related to the liver, puts forward the idea that the smoothing and replenish of the liver qi is conducive to the internal and external well-being of the body, and advocates the treatment method of liver-soothing and menstruation-regulating. Based on this idea, the acupuncture for soothing the liver and regulating menstruation has been widely applied in the clinical treatment of perimenopause-related symptoms [12]. In addition, press-tack needling is a special acupuncture treatment, and it is performed by inserting press needles into the skin and leaving them under the skin at the acupoints for a longer period of time, during which these acupoints are stimulated by regular massage to mediate the patient's bodily functions. Evidence has shown that press-tack needle acupuncture can be an adjunctive treatment for PMI and enhance sex hormones in patients with favorable outcomes [13]. Therefore, the present study aims to further investigate the clinical application value of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling in the treatment of PMI, in order to improve the sleep quality and regulate sex hormone levels of patients as well as provide a reference basis for clinical practice.

2 Methods

2.1 Participants

88 PMI patients, who were treated in our hospital and received the treatment of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling from April, 2022 to April, 2024, were included and set as A group. During the same time, 83 PMI patients treated with liver-soothing and menstruation-regulating acupuncture were included as B group. This study was approved by the Ethics Committee of our hospital, and all the enrollees signed the written informed consent.

Inclusion criteria: (1) Insomnia meets the diagnostic criteria in the Chinese Guidelines for the Diagnosis and Treatment of insomnia in adults (2017 edition) [14].

(2) Perimenopause meets the diagnostic criteria in the Chinese Guidelines on Menopause Management and Menopause Hormone Therapy (2018 edition) [15]. (3) TCM syndrome type meets the diagnostic criteria in the Standards for Diagnosis and Efficacy of TCM Syndrome. Primary symptoms: insomnia, dreaminess, dysphoric fever and sweating, as well as anxiety and irritability. Secondary symptoms: soreness and weakness of waist and knees, chest tightness and palpitations, dizziness and tinnitus, as well as forgetfulness and fatigue, etc. [16]. (4) Patients aged 41 to 60 years who have clear consciousness and are able to receive acupuncture treatment. (5) Pittsburgh sleep quality index (PSQI) > 7 points. (6) Patients have not received other related treatments such as hormone replacement before enrollment.

Exclusion criteria: (1) Insomnia caused by other factors. (2) History of sex hormone administration within 6 months. (3) Patients with other systemic serious diseases or malignant tumors. (4) Patients with mental disorders and poor treatment adherence. (5) Patients with other neurological disorders. (6) Pregnancy or currently lactating.

2.2 Therapeutic interventions

2.2.1 B group

All patients in both groups were orally administrated with 2 mg estazolam (Manufacturer: Xinchang Pharmaceutical Factory of Zhejiang Medicine CO., Ltd., National Medical Products Administration Approval No.: H33020353) at bedtime. The patients in the B group were given the treatment of liver-soothing and menstruation-regulating acupuncture. Specifically, the patient was asked to lie supine and close his eyes to relax mind and body. Yongquan (KI1), Shenting (GV24), Baihui (GV20), Neiguan (PC6), Zhongwan (CV12), Yintang (GV29), Taichong (LR3), and Sanyinjiao (SP6) acupoints were selected and subjected to routine disinfection. After that, sterilized traditional acupuncture needles were inserted into the skin in a flat manner and embedded at the selected acupoints for 30 min. During the retention period, the needles were rotationally manipulated once every 10 min. After the needles were withdrawn, the sparrow-pecking moxibustion was performed on Yongquan acupoint for 10-15 min using lighted moxa sticks once a day. The treatment lasted for 30 days.

2.2.2 A group

Patients in the A group were subjected to press-tack needle acupuncture on the basis of treatment in the B group. Press-tack needles were selected according to the patient's body parts. When the patient was asked to be in an appropriate position, the selected acupoints were subjected to routine disinfection. The sterilized needles were pressed and adhered directly onto the acupoints as described in the B group. After insertion of the needles, the peel-off papers were removed and the needles were fixed with adhesive tape. The patients were required to press these acupoints 4 times a day for 2 min each time, and to press on them 1 more time before sleeping. Besides, after the first pressing, the sparrow-pecking moxibustion was performed on Yongquan acupoint for 10-15 min using lighted moxa sticks once a day. The treatment lasted for 30 days.

2.3 Research indicators

(1) Clinical efficacy: The clinical efficacy between the two groups after treatment was compared. Cured: The patient’s sleep returned to normal and the accompanying symptoms disappeared, with a PSQI reductive rate ≥ 75%. Significantly effective: The patient ’ s sleep time was increased and the accompanying symptoms were relieved, with a 50% ≤ PSQI reductive rate < 75%. Effective: The sleep time and accompanying symptoms of the patient were improved, with a 25% ≤ PSQI reductive rate < 50%. Ineffective: There was no change in symptoms, and a PSQI reductive rate was less than 25%. Cured, significantly effective, and effective results together

were considered as the total effective. PSQI reductive rate = (before treatment scores - post-treatment scores)/before treatment scores × 100% [16].

(2) Sex hormone indexes: The sex hormone indexes between the two groups before treatment and after 30 days of treatment were compared. Before and after treatment, 4 mL venous blood was sampled from each group in the morning and subjected to centrifugation to obtain the supernatant. Enzyme linked immunosorbent assay was used to detect levels of follicle-stimulating hormone (FSH), luteinizing hormone (LH) and estradiol (E_2) strictly following the operating instructions of kits, which were separately provided by Shanghai Chemtron Biotech Co., Ltd., Runhe Biomedical Technology (Shantou) Co., Ltd., and Guangxi Lan Yu Biotechnology Co. Ltd.

(3) Sleep scores: The sleep scores between the two group before treatment and after 30 days of treatment were compared. PSQI was used to assess the patients' sleep quality. The PSQI consists of 18 self-assessment items and they were divided into 7 sections. Each section was scored on a scale of 0-3 points, and the cumulative points were the total PSQI scores. The total scores ranged from 0-21 points, with higher scores indicating worse sleep quality [17].

2.4 Statistical analysis

SPSS 20.0 software was utilized for statistical analysis. Enumeration data were represented as cases (%), and the X^2 test was used for comparison between two groups. Ordinal data were analyzed using the rank sum test. Measurement data were analyzed using the Kruskal-Wallis test and reported using mean ± standard deviation for normally distributed data. Comparison between two groups was performed by independent samples *t*-test. Comparison in the same group at different time points was conducted by paired samples *t*-test. Differences were taken to be statistically significant if bilateral p values < 0.05.

3 Results

3.1 Comparison of clinical efficacy between the two groups

There was no significant difference in the general data between the two groups (p > 0.05), which was comparable, as shown in Table 1. The clinical total effective rate in the A group was higher than that in the B group (p < 0.05), as shown in Table 2.

3.2 Comparison of sex hormones between the two groups before and after treatment

Before treatment, there were no significant difference in the levels of FSH, LH and E_2 between the two groups (p > 0.05). After treatment, FSH and LH levels were reduced in the two groups compared to those before treatment (p < 0.05), and FSH and LH levels in the A group were lower than those in the B group (p < 0.05). After treatment, the E_2 level was increased in the two groups compared to that before treatment (p < 0.05), and the E_2 level in the A group was higher than that in the B group (p < 0.05), as shown in Table 3.

Table 1 Comparison of general information between the two groups.

Group		A group (n = 88)	B group (n = 83)	X^2/t	p
	Age (years)	49.52 ± 5.68	50.49 ± 6.31	-1.058	0.292
	Disease course (months)	11.97 ± 6.14	12.86 ± 5.75	-0.977	0.330
Sleep condition (cases)	Falling asleep and waking up easily	50	45	1.293	0.527
	Dreaminess at night or waking up earlier	27	31		
	Sleepless all night	11	7		
TCM syndrome (cases)	Qi stagnation due to liver depression	19	30	4.478	0.214
	Yin deficiency in liver and kidney	17	14		
	Dual deficiency of the heart and spleen	31	23		
	Qi deficiency in heart and gallbladder	21	16		

Table 2 Comparison of clinical efficacy between the two groups [cases (%)].

Group	Cases	Cured	Significantly effective	Effective	Ineffective	Total effective rate
A group	88	11 (12.50)	39 (44.32)	28 (31.82)	10 (11.36)	78 (88.64)
B group	83	3 (3.61)	21 (25.30)	36 (43.37)	23 (27.71)	60 (72.29)
X^2						15.960
p						0.001

Table 3 Comparison of sex hormones between the two groups before and after treatment (mean ± standard deviation).

Group	Cases	FSH (mIU/mL)		LH (mIU/mL)		E_2 (pg/mL)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
A group	88	61.39 ± 4.02	41.73 ± 3.55 *	27.38 ± 3.29	21.04 ± 1.82 *	18.11 ± 2.34	25.43 ± 2.81 *
B group	83	62.17 ± 5.64	54.68 ± 4.20 *	28.16 ± 3.75	24.65 ± 1.47 *	17.92 ± 1.76	22.50 ± 1.72 *
t		-1.046	-21.819	-1.448	-14.218	0.597	8.165
p		0.297	0.000	0.149	0.000	0.551	0.000

Note: compared to before treatment, * $p < 0.05$.

3.3 Comparison of sleep quality between the two groups before and after treatment

Before treatment, there were no significant difference in PSQI scores between the two groups ($p > 0.05$). Compared to before treatment, PSQI scores were decreased in the two groups after treatment ($p < 0.05$), and the scores in the A group were lower than those in the B group ($p < 0.05$), as shown in Table 4.

3.4 Comparison of treatment adherence and patients' satisfaction between the two groups

There was no significant difference in treatment adherence between the two groups ($p > 0.05$). The satisfaction of patients in A group was higher than that in group B, and there was no significant difference ($p > 0.05$), as shown in Table 5 and Table 6.

3.5 Comparison of adverse effects between the two groups

No itchy skin rashes were found at the acupuncture sites of patients in the two groups.

Table 4 Comparison of sleep quality between the groups before and after treatment (mean ± standard deviation, points).

Observational indicators		A group (n = 88)	B group (n = 83)	*t*	*p*
Sleep quality	Before treatment	2.53 ± 0.41	2.61 ± 0.58	-1.046	0.297
	After treatment	0.75 ± 0.24 *	1.39 ± 0.60 *	-9.253	0.000
Time of falling asleep	Before treatment	2.48 ± 0.63	2.42 ± 1.07	0.450	0.653
	After treatment	0.87 ± 0.52 *	1.13 ± 0.51 *	-3.298	0.001
Sleep time	Before treatment	2.74 ± 0.69	2.72 ± 0.64	0.196	0.845
	After treatment	0.90 ± 0.47 *	1.25 ± 0.98 *	-3.004	0.003
Sleep efficiency	Before treatment	2.62 ± 0.35	2.59 ± 0.42	0.509	0.612
	After treatment	0.76 ± 0.28 *	1.03 ± 0.57 *	-3.966	0.000
Sleep disorders	Before treatment	2.41 ± 0.34	2.38 ± 0.50	0.461	0.645
	After treatment	0.68 ± 0.27 *	0.89 ± 0.46 *	-3.665	0.000
Hypnotic drugs	Before treatment	2.62 ± 0.87	2.57 ± 1.08	0.334	0.739
	After treatment	0.82 ± 0.33 *	1.10 ± 0.62 *	-3.716	0.000
Daytime dysfunction	Before treatment	2.36 ± 0.84	2.32 ± 0.91	0.299	0.765
	After treatment	0.78 ± 0.29 *	1.21 ± 0.76 *	-4.941	0.000
Total scores	Before treatment	18.36 ± 3.57	17.86 ± 3.20	0.962	0.337
	After treatment	5.59 ± 1.24 *	7.92 ± 1.64 *	-10.517	0.000

Note: compared to before treatment, * $p < 0.05$.

Table 5 Comparison of treatment adherence between the two groups [cases (%)].

Group	Cases	Positive cooperation	Passive cooperation	Negative cooperation	Cooperation
A group	88	35 (39.77)	49 (55.68)	4 (4.55)	84 (95.45)
B group	83	40 (48.19)	35 (42.17)	8 (9.64)	75 (90.36)
X^2			3.857		
p			0.145		

Table 6 Comparison of patients' satisfaction between the two groups [cases (%)].

Group	Cases	Highly satisfactory	Basically satisfactory	Unsatisfactory
A group	88	45 (51.14)	39 (44.32)	4 (4.55)
B group	83	36 (43.37)	41 (49.40)	6 (7.23)
X^2			1.121	
p			0.571	

4 Discussion

To improve the clinical efficacy of patients with PMI, this study explored the effect of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling on the treatment of PMI patients. The results demonstrated that this combined therapy might have a good efficacy in treating PMI patients.

Women who enter the perimenopausal period may experience insufficient or disordered secretion of sex

hormones due to the deterioration of ovarian function and hypothalamic-pituitary function, and thus develop sleep disorders [18]. Based on the above mechanism, the present study analyzed following three indicators to assess sex hormone levels. FSH, LH and E_2 are all specific biomarkers of menopausal women. During the perimenopausal period, the levels of FSH and LH are increased and the level of E_2 is decreased, thereby manifesting a disturbance of sex hormone levels [19]. According to the results of our study, combination of liver-soothing and menstruation-regulating acupuncture with press-tack needling played an effectively regulatory role in sex hormone levels, and was more effective than liver-soothing and menstruation-regulating acupuncture alone. By stimulating the meridians and collaterals as well as zang-fu organs at acupoints, liver-soothing and menstruation-regulating acupuncture can help to "sooth the liver" and "regulate menstruation", and thereby regulate sex hormone levels [20,21]. Taichong acupoint belongs to the liver channel of foot reverting yin. Baihui acupoint is also known as Sanyan Wuhui acupoint, a confluence points of multiple meridians, and the stimulation of Baihui, Taichong and Shenting acupoints can sooth the liver, down-regulate qi and regulate qi movement, which plays a role in tranquilizing spirit to calm mind, thereby stabilizing the ovarian function [20,21]. Sanyinjiao acupoint belongs to the spleen meridian, and needling at this acupoint can regulate the functions of the body's endocrine and reproductive systems and improve the immunity to alleviate insomnia. Yongquan acupoint is the starting point of meridian qi in the kidney channel, and it is considered as a wood acupoint in the five-element theory [20,21]. This acupoint can act on the kidney channel to promote the kidney qi to rise in the heart and coordinate the heart and kidney. Acupuncture on Yongquan acupoint can play a role in directing fire back to its origin and regulating yin and yang, thus regulating sex hormone levels and treating many diseases in perimenopause [20,21]. Additionally, the activation of intracerebral dopamine system by acupuncture regulates the physiological function of the hypothalamus-pituitary-ovarian axis and thus improves the microenvironment of endocrine and ovarian in the human body, leading to benign changes in the hormonal levels of FSH and LH [22]. In addition to the above foundations, press-tack needling is characterized by "superficial needling" and "shallow needling", and is a subcutaneous needle-embedding therapy, which can regulate the functions of the meridians and collaterals as well as zang-fu organs by stimulating the twelve cutaneous regions. The retention of press-tack needles in the skin plays a continuous role through sustainable acupressure, and is more conducive to regulating sex hormone levels and easily accepted by patients due to the small size of the needles, safety and free of pain [23]. The study of Xingmiao Quan et al. has confirmed that press-tack needling can effectively improve clinical symptoms of PMI patients as well as regulate their sex hormone levels [24]. In light of this, combination of liver-soothing and menstruation-regulating acupuncture with press-tack needling can effectively regulate sex hormone levels in treating PMI patients, and thus obtains a better efficacy than liver-soothing and menstruation-regulating acupuncture alone.

Insomnia can further lead to endocrine and immune system diseases in PMI patients, and eventually results in a variety of diseases, affecting patients' physical and mental health and quality of life [5]. In this study, we assessed the sleep quality of PMI patients using PSQI. According to the results, combination of liver-soothing and menstruation-regulating acupuncture with press-tack needling effectively improved sleep quality of PMI patients, and obtained a better efficacy than liver-soothing and menstruation-regulating acupuncture alone. Through the stimulation of acupoints, liver-soothing and menstruation-regulating

acupuncture plays a role in tranquilizing spirit to promote sleep. Neiguan acupoint belongs to the pericardium meridian, and needling this acupoint is beneficial to sleep by calming the heart and tranquilizing spirt. Yintang acupoint belongs to the governor vessel and is an essential acupoint for unblocking the brain and tranquilizing spirit [25,26]. Zhongwan acupoint belongs to the conception vessel and is an alarm point of the stomach, and needling both Yintang and Zhongwan acupoints can has an effect of regulating the governor and conception vessel as well as mediating yin and yang, which thereby improves the patients' sleep disorders [25,26]. Meanwhile, nerve endings and blood vessels are clustered at acupoints, and the stimulation of acupoints using acupuncture can activate genes in sleep-associated cytokine pathways, regulate neurotransmitter transmission in the brain, and simultaneously reduce the catecholamine level, thereby improving sleep [27]. The combined application of press-tack needling can sustainably stimulate the acupoints, which enhance the effect of liver-soothing and menstruation-regulating acupuncture, thereby improving the patient's sleep quality. The study of Wenwen Zhu et al. has proven that different acupuncture therapies have different efficacy and the combination therapy has better outcomes [28]. Besides, a study has confirmed that acupuncture has a good safety profile in the treatment of patients with PMI [29]. Therefore, liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling in treating patients with PMI can effectively improve the patients' sleep disorders and enhance their sleep quality, with a good safety profile.

There are still some limitations in this study. PMI patients are frequently accompanied by depression and anxiety. The related rating scales were not collected in this study for assessing efficacy. In the future, we need to conduct in-depth studies to refine the results and provide stronger evidence supporting the application of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling in treating PMI patients.

In summary, there is a significant efficacy of liver-soothing and menstruation-regulating acupuncture in combination with press-tack needling on the treatment of PMI patients, and this therapy can alleviate the patients' clinical symptoms, improve their sleep quality and regulate sex hormone levels, which has clinical application value.

Acknowledgements

We appreciate the efforts and cooperation of all research staff and patients involving this study. The design, management, analysis, and reporting of the study are entirely independent of Pharmaceutical Co., Ltd.

Conflicts of Interest

The author declares no conflicts of interests.

Author Contributions

X.H. and S.S. conceptualized the trial, and participated in creating the study design and the statistical analysis plan. S.S. made the first draft of the manuscript. All authors reviewed and revised the manuscript critically for important intellectual content, reviewed the final manuscript as submitted, read and approved the final manuscript.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of our hospital, and all the enrollees signed the written informed consent.

Funding

This research received no external funding.

Availability of Data and Materials

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding authors.

Supplementary Materials

Not applicable.

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