Evaluation of the effectiveness of auriculotherapy for insomnia

Luong Thi Ngoc Yen[1], Le Thi Thuy[2], Tran Van Dung[2], Doan Van Minh[3*]

(1) Binh My Nursing Home, Ho Chi Minh city

(2) Department of Traditional Medicine and Physical Therapy, Tan Phu District Hospital, Ho Chi Minh city

(3) Faculty of Traditional Medicine, University of Medicine and Pharmacy, Hue University

Abstract

Background: In modern life, Insomnia is a common problem that affects both health and living quality of people. Auriculotherapy, a traditional medicine – based approach is a therapeutic method in which specific points in auricles are stimulated to achieve specific therapeutic purposes. It is also a safe and simple procedure for treating insomnia. **Objectives:** To evaluate the effects of auriculotherapy on treating insomnia at Department of Traditional Medicine and Physical Therapy, Tan Phu District Hospital, Ho Chi Minh city. **Methods:** Includes 64 patients were treated with auriculotherapy, according to the research methodology, clinical trial, assess the results before and after treatment. **Results:** For Pittsburgh Sleep Quality Index (PSQI) total score, an average initial score 15.77 ± 1.88, decreased to 7.77 ± 2.48, the difference was statistically significant ($p<0.05$). The difference between low PSQI score and high PSQI score was associated with age (younger age) and disease duration ($p<0.05$). **Conclusions:** Auriculotherapy help improve sleep quality (sleep latency, sleep duration, sleep efficiency, sleep disturbance and PSQI score), the difference was statistically significant ($p<0.05$).

Keywords: *Insomnia, auriculotherapy.*

1. INTRODUCTION:

Sleep is a basic phenomenon of life, sleep is an essential and humans spend their one-third of life span in sleeping [1, 2]. However, there are around 10% - 30% of population suffering from chronic worldwide [3]. In Vietnam, insomnia is also very common. According to Bui Quang Huy (2019), about 30 - 45% of adults had insomnia on 1 year [2]. Insomnia treatment is a combination of a team including internal medicine, psychologists, traditional medicine, society, religion,... [4, 5]. Auriculotherapy is a health care modality whereby the external surface of the ear, or auricle, is stimulated to alleviate pathological conditions in other parts of the body. Ear seeds used for auriculotherapy can be made from many materials. The most common ones are made from Vaccaria seeds or Wang Bu Liu Xing (WBLX). Treatment with auriculotherapy helps patients not have to go to medical falcilities everyday, with less pain and side effects. This research was carried out with the following research objectives:

(1) To survey the clinical characteristics of insomnia patients at the Department of Traditional Medicine and Physical Therapy, Tan Phu District Hospital, Ho Chi Minh city.

(2) To evaluate the effectiveness of insomnia treatment using auriculotherapy for insomnia patients at the Department of Traditional Medicine and Physical Therapy, Tan Phu District Hospital, Ho Chi Minh city.

2. MATERIALS AND METHODS

2.1. Research subjects

Patients diagnosed with insomnia on the basis of medical diseases treated who came for examination and treatment at the Department of traditional medicine and physical therapy

2.1.1. Inclusion criteria: Patients were diagnosed with insomnia according to Diagnostic and statistical manual of mental disorders (DSM-5-TR) standards, with the following criteria: the patients complained about the quantity or quality of sleep; Insomnia occured at least 3 nights/weeks; Insomnia occured at least 3 months; affects social activities [6]; Age≥18; PSQI>5; Patients voluntarily participated in the study.

2.2.2. Exclusion criteria: Patients didn't participate in the study; non-compliance with the treatment; had a history or were currently suffering from mental health; used sedatives before and during the research process; Pregnant and lactating women; The patients were too old and weak;

PSQI ≤ 5; Insomnia due to illness; causes of insomnia due to alcohol, addictive subtances and caffein.

2.2. Research methods

2.2.1. Study design: The study was conducted according to the clinical intervention research

**Corresponding Author: Doan Van Minh. Email: dvminh@huemed-univ.edu.vn*

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method, comparing before and after treatment.

2.2.2. Place and time: Patients diagnosed with insomnia on the basis of medical diseases treated who came for examination and treatment at the Department of traditional medicine and physical therapy from October 2022 until April 2023.

2.2.3. Sample size: The study selected a convenience sample of 60 patients, with an estimated dropout rate of 10%, so the sample is 66 patients. There were 64 patients who met the criteria consistent with the disease selection criteria, agreed to participate in the study and complied with the research process.

2.2.4. Research materials: Acupoints group included Shenmen (TF4), Subcortex (AT4), Occiput (AT3), Heart (CO15), Spleen (CO13), Kidneys (CO10) [7]. Vaccaria seeds (Wang Bu Liu Xing) Ear Dou Patch from Feng Fan branch - China were inserted at six points in D0 and D8. They were left in place for 5 days during each treatment session. Auriculotherapy intervention lasted 5 days per week. Take the therapy on right ear in the first week and on left ear in the second week. 30 minutes – 1 hours before bedtime, the patients used their fingers to apply pressure to acupoints, 1 minute each acupoint. The intervention datas were collected from day 0 (D0), day 5 (D5), day 10 (D10), day 15 (D15).

2.2.5. Data collection tools: PSQI test includes 19 items which are grouped into 7 components, including (1) sleep duration, (2) sleep disturbance, (3) sleep latency, (4) daytime dysfuntion due to sleepiness, (5) sleep efficiency, (6) overall sleep quality and (7) sleep medication use. Evaluating each element in the PSQI scale divided into levels: No disorder (0 point=Good result), mild disorder (1 point=Fair result), disturbed moderate disorder (2 points=Average outcome), Severe disorder (3 points=Poor outcome). The seven component scores are then summed to obtain a global PSQI score, which ranges from 0 to 21. Higher score indicates poorer sleep quality, with a

score greater than 5 suggesting significant sleep difficulties [8].

2.2.6. Statistical analysis: All statistical analyses were performed, using SPSS 20.0. Considering the comparison of each group before and after the intervention, Wilcoxon signed-rank test was used for quantitative variables and Chi-square test for qualitative variables.

2.2.7. Ethical issue: This study was conducted after being approved by the Ethics Committee of Hue University of Medicine. All patient's information was kept confidential and anonymous. The inform consent was waived due to the retrospective nature of the study.

3. RESULTS

3.1. Baseline Characteristics of Participants

Study of 64 insomnia patients using auriculotherapy with characteristics following: Regarding gender, the majority of women was 68.7%, the ratio of women to men = 2.2; Regarding age, the average age of patients in the study was 57.25 ± 12.92 years old, the age group from 50 to <70 years old accounted for the highest proportion of 60.9%. Regarding occupation, 56.3% of patients in the study were elderly - retirement group. Regarding disease duration, the average disease duration of patients was 2.46 ± 2.16 years, the highest proportion of patients with a disease duration 1-3 years accounted for 64.1%.

The four common Traditional Chinese Medicine (TCM) diagnosed among 64 subjects with insomnia disorder were dual deficiency of the heart-spleen, yin deficiency with effulgent fire depressed, liver qi transforming into fire, and non-interaction between the heart and kidney [9], with prevalence 43.8%, 35.9%, 10.9%, and 9.4%, respectively.

3.2. Primary Outcomes

Table 1. Outcome Measures for sleep latency

Sleep latency	D0		D5		D10		D15		P
	n	%	n	%	n	%	n	%	
≤ 30 minutes	21	32.8	32	50	47	73.4	53	82.8	pN0-N5=0.01; pN0-N10, pN0-N15< 0.001
>30 minutes	43	67.2	32	50	17	26.6	11	17.2	

Sleep latency gradually improved after treatment corresponding to the proportion of patients with sleep latency over 30 minutes, the difference was statistically significant (p_{N0-N10}, p_{N0-N15}<0.001).

Table 2. Outcome Measures for sleep duration

Sleep duration	D0		D5		D10		D15		P
	n	%	n	%	n	%	n	%	
< 6 hours/night	64	100	64	100	58	90.6	32	50	pN0-N10, pN0-N15 < 0.05
≥ 6 hours/night	0	0	0	0	6	9,4	32	50	
Average sleep duration (hours)	4.13 ± 0.57		4.66 ± 0.53		5.18 ± 0.55		5.68 ± 0.64		p N0/N5/N10/N15 <0.05

Sleep duration classification improved over 10 and 15 days of treatment, the patients' average sleep duration increased, the difference was statistically significant (p<0.05).

Table 3. Outcome Measures for sleep efficiency

Sleep efficiency	D0		D5		D10		D15		P
	n	%	n	%	n	%	n	%	
< 75%	64	100	61	95.3	44	68.8	24	37.5	pN0-N5, pN0-N10, pN0-N15 < 0.05
≥ 75%	0	0	3	4.7	20	31.2	40	62.5	
Average sleep efficiency (%)	56.06 ± 8.02		63.2 ± 7.24		70.33 ± 7.71		77.04 ± 8.51		p N0/N5/N10/ N15<0.05

The proportion of patients with sleep efficiency ≥ 75% and the average sleep efficiency gradually increased after treatment, the difference in sleep efficiency before and after treatment was statistically significant (p<0.05).

Table 4. Outcome Measures for sleep disturbance

Sleep disturbance	D0		D5		D10		D15		P
	n	%	n	%	n	%	n	%	
0-1 time/night	16	25	17	26.6	37	57.8	54	84.4	pN0-N10, pN0-N15<0.05
>1 time/night	48	75	47	73.4	27	42.2	10	15.6	
Average sleep disturbance (times)	1.98 ± 0.75		1.94 ± 0.73		1.44 ± 0.77		0.88 ± 0.81		p N0/N5/N10/N15 <0.05

There was an improvement in the classification of sleep disturbance in D10 and D15, the difference in sleep efficiency before and after treatment was statistically significant (p<0.05).

Table 5. Outcome Measures for PSQI score

	D0	D5	D10	D15	P
PSQI score (points)	15.77 ± 1.88	13.88 ± 2.15	10.02 ± 2.30	7.77 ± 2.48	pN0-N5, pN0-N10, pN0-N15<0.05

The average PSQI score gradually decreased after treatment. Post-treatment, the average PSQI score is 15.77 ± 1.88 (points), reduced to 7.77 ± 2.48 (points) in D15 (p<0.05).

Table 6. Outcome measures for other factors

Characteristic		Improvement in PSQI score n (%)			p
		<50% (n=26)	≥50% (n=38)	Total (n=64)	
Age	18 - <50	4 (25%)	12 (75%)	16 (100%)	<0.05
	50 - <70	15 (38.5%)	24 (61.5%)	39 (100%)	
	≥ 70	7 (77.8%)	2 (22.2%)	9 (100%)	
Time of illness	<1 year	1 (14.3%)	6 (85.7%)	7 (100%)	<0.05
	1 - 3 years	14 (34.1%)	27 (65.9%)	41 (100%)	
	>3 years	11 (68.8%)	5 (31.2%)	16 (100%)	

Occupation	Mental work	2 (10%)	18 (90%)	20 (100%)	<0.05
	Manual labor	3 (37.5%)	5 (62.5%)	8 (100%)	
	Retirement	21 (58.3%)	15 (41.7%)	36 (100%)	

Evaluating PSQI score improvement on a number of factors: Regarding age, the highest rate of improvement is the 18 - <50 years old group; Regarding disease duration, the group with disease severity <1 year had the highest PSQI score improvement; Regarding occupational characteristics, the group of elderly-retired patients had an improvement level lower than other groups. The difference before and after treatment was statistically significant (p<0.05).

4. DISSCUSION

General characteristics of the study object

Classifying patients according to traditional medicine disease type, 43.8% of patients had heart and spleen damage - with the highest percentage. The results of our study were similar to Le Thi Tuong Van's (2016) study, the highest rate of patients with bipolar heart-spleen deficiency is 46.7% [10]. And it was also consistent with the observations of many other researchers that insomnia mainly encounters two forms of heart and spleen deficiency, heart and kidney insufficiency, and research was only conducted on these common diseases [11].

The treatment effectiveness of atrial pressure method

Our study evaluated the effect of improving sleep quality through the PSQI (Pittsburgh Sleep Quality Index) scale at four-time D_0, D_5, D_{10}, D_{15}. To further clarify the effects of the method, we conducted analysis on each stage, sleep characteristics, or improvement in score PSQI.

About sleep latency, pre-treatment, patients took more than 30 mins to fall asleep, taking highest rate of 67.2%, this rate decreased to 17.2% after 15 days of treatment, the difference is statistically significant with p<0.05. The time it took for the patient to fall asleep was also known as awake time, latent sleep time... This stage was heavily influenced by psychological factors (anxiety, thinking, etc.), use of stimulants (coffee, alcohol, beer,…), irregular sleep, condition (noise, temperature,…), chronic pain… Normally patients had proactively eliminate all factors that can be changed such as environment condition, stimulants, sleep time, painkillers, etc. … when there were no results, they went for examination and treatment. Patients in the study were instructed to apply semen vaccariae 1 minute each acupoint, 30 minutes - 1 hour before bedtime. In addition to the stimulation of auriculotherapy causing changes in the nerves system, the patient also applied pressure to acupoints that would help distract the patient's attention, reducing anxiety and thinking, contributing to improve sleep latency [2, 3].

The patient's average sleep time was 4.13 ± 0.57 (hours), gradually increasing after treatment. After 15 days, this value is 5.68 ± 0.64 (hours), the difference between D0 and D15 was statistically significant (p<0.05). The average sleep time after 15 days of patients in our study was higher than the results of Le Thi Tuong Van (2016) [10], Nguyen Truong Nam (2020), Nguyen Van Tam (2019) [12, 13]. The difference may be because before treatment the average sleep time in our study was higher than the one in these studies. Sleep time classification had also been improved, similar to the result of study of Duong Thi Phuong Thao (2018) [14].

The proportion of patients with sleep efficiency ≥75% and the average sleep efficiency of patients gradually increased after treatment, the significant improvement was statistically with p<0.05. Our research results are consistent with many authors': Nguyen Truong Nam (2020); Duong Thi Phuong Thao (2018); Le Thi Tuong Van (2016) [10, 12, 14]. The improvement in patients' hours of sleep per night in the general studies and in our study generally led to a good improvement in sleep efficiency.

The patient's average sleep disturbance gradually decreased after treatment, statistically significant difference was with p<0.05. The sleep–wake cycle is controlled by the hypothalamic neurons, on old brains, these cells have ability to self-excite, leading to activation and stimulation wakefulness, this may explain the higher number of sleep disturbance in elderly patients than in younger patients. Auriculotherapy affects on acupoints in addition to the effect on the five organs according to traditional medicine theory it appears that stimulation of the hypothalamus also affects the hypothalamus of the brain, then the patient's symptoms of waking up during the night are improved [2, 3].

PSQI scores gradually decreased after treatment, the difference was statistically significant (p<0.05). Stimulation of the pinna area of the tympanic membrane has a positive impact on the brain's connection network (cortical and subcortical brain

structures) and the limbic system, increasing the secretion of some hormones such as endorphin, enkephalin, and melatonin to help reduce pain, fatigue, enhance immunity; Balancing the activities of the sympathetic and parasympathetic nervous system has a vasodilating effect on internal organs, helping to improve circulation, thereby making positive changes to sleep such as reducing sleep time and increasing sleep latency. sleeping duration, etc [1, 2, 3].

Insomnia is closely related to the aging process and decli ne in cognitive function [2]. The younger the patient's age, the higher the rate of PSQI score improvement above 50%. Patients with disease duration <1 year had a higher PSQI score improvement rate than other groups, statistically significant difference was with p<0.05. There were differences in the recovery levels of different occupational groups. The least improvement in the elderly-retirement group was also related to brain degeneration in this group.

5. CONCLUSION

The most common TCM diagnoses among subjects with insomnia disorder was dual deficiency of the heart-spleen. Auriculotherapy with our acupoints group (Shenmen (TF4), Subcortex (AT4), Occiput (AT3), Heart (CO15), Spleen (CO13), Kidneys (CO10)) helped improve sleep quality (sleep latency, sleep duration, sleep efficiency, sleep disturbance and PSQI score), the difference was statistically significant (p<0.05).

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