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COMPARISON OF THE EFFICACY OF MANUAL ACUPUNCTURE VERSUS MANUAL ACUPUNCTURE COMBINED WITH LOW-LEVEL INTRAVASCULAR LASER THERAPY IN THE TREATMENT OF NON-ORGANIC INSOMNIA AT THE DEPARTMENT OF TRADITIONAL MEDICINE, THONG NHAT HOSPITAL

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ABSTRACT: The rate of insomnia is increasing day by day in life, and finding effective non-pharmacological treatment methods for insomnia is very necessary. Low-level intravascular laser therapy is a new method in the treatment of sleep disorders that needs to be exploited and evaluated for therapeutic effectiveness. To determine the efficacy of treating non-organic insomnia with low-level intravascular laser therapy combined with manual acupuncture compared to manual acupuncture alone in patients with non-organic insomnia. 60 patients diagnosed with non-organic insomnia at the Department of Traditional Medicine - Thong Nhat Hospital from February 2024 to July 2024. Patients were randomly divided into 2 groups. The intervention group (n=30) was treated with low-level intravascular laser therapy combined with manual acupuncture and the control group (n=30) was treated with conventional manual acupuncture. Treatment efficacy was evaluated based on the PSQI (The Pittsburgh Sleep Quality Index) scale and the number of awakenings before treatment, after 5 and 10 days of treatment. After 10 days of treatment, the group using manual acupuncture combined with low-level intravascular laser therapy showed a significant and notable reduction in PSQI scores compared to the group using only manual acupuncture, from 17.2 points to 13.33 points, a total of 3.87 points, changing the sleep disorder level from moderate to mild. The average sleep onset time decreased from 101.67 minutes to 41 minutes, corresponding to a score reduction from 2.63 points to 1.43 points. Average sleep hours per night increased from 3.23 hours to 5.27 hours, corresponding to a score reduction from 2.9 points to 2.1 points. Average sleep efficiency increased from 40.59% to 59.91%, corresponding to a score reduction from 2.87 points to 2.5 points. For sleep quality, it decreased from 2.9 points to 1.87 points. Average daytime dysfunction decreased from 1.77 points to 1.1 points. Number of awakenings decreased from 2.70 points to 1.77 points. These improvements were statistically significantly different from the group using only manual acupuncture. The combined method of manual acupuncture with low-level intravascular laser therapy is more effective than using manual acupuncture alone in treating non-organic ins**omnia.**

Keywords: non-organic insomnia; manual acupuncture; low-level intravascular laser therapy

1. INTRODUCTION

The rate of insomnia has been and is increasingly rising and becoming alarming in today's life [1]. Various different studies have shown that the rate of chronic insomnia accounts for up to 50%-60%, commonly found in elderly people, women, those with diseases and mental illness . Prolonged insomnia leads to lack of strength, loss of concentration, memory reduction, and decreased work productivity . The trend of combining physical therapy methods and Traditional Vietnamese Medicine (TVM) is increasingly being applied flexibly and widely in clinical treatment. Among these, acupuncture is a relatively safe TVM method that has been used for a very long time, and there are many studies proving its effectiveness in treating insomnia [7-9]. The group of acupoints Neiguan (Inner Pass), Shenmen (Spirit Gate), and Sanyinjiao (Three Yin Intersection) is a classic group of spirit-calming acupoints that has been used extensively in clinical insomnia treatment. Author Đoàn Văn Minh has studied this group of acupoints on patients with non-organic insomnia, comparing before and after treatment, showing that sleep duration and sleep efficiency improved significantly . Low-level intravascular laser therapy is a form of treatment by introducing a laser source inside the blood vessel to directly shine laser light on blood cells and other blood components, which has the effect of improving blood flow and regulating body functions, and has also been studied and proven to have therapeutic effects on insomnia . However, there are not many studies clearly proving the effectiveness of this combination, so the question is raised: "Is the method of manual acupuncture combined with low-level intravascular laser therapy more effective than manual acupuncture alone on patients with non-organic insomnia?" From this, we set out the research objectives as:

1. Compare the changes in PSQI scale components before and after intervention.

2. Compare the differences in PSQI scores between the two study groups.

3. Compare the effect of reducing the number of awakenings between the two study groups.

2. STUDY SUBJECTS AND METHODS

2.1. Study design:

Randomized controlled clinical trial.

2.2. Location and time of study:

From February 2024 to July 2024 at the Department of Traditional Medicine, Thong Nhat Hospital.

2.3. Study subjects

Patients aged 18-80 years old, regardless of gender, diagnosed with non-organic insomnia according to DSM V TR criteria, treated at the Department of Traditional Medicine - Thong Nhat Hospital. Not currently using antidepressants, psychiatric drugs, sleeping pills, glucocorticoids, antihistamines. Voluntarily agreed to participate in the study.

2.4. Sample size, sampling method

60 patients were randomly divided into 2 groups, 30 patients in each group. According to the formula:

$$n_1 \geq \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \left(\sigma_1^2 + \frac{\sigma_2^2}{r}\right)}{(\mu_1 - \mu_2)^2}$$

$$n_2 = n_1 \times r$$

α: type 1 error

β: type 2 error

μ_1, μ_2 are the means of group 1 and group 2 respectively

σ_1, σ_2 are the standard deviations of group 1 and group 2 respectively

r: the sample ratio in the 2 groups

Based on the mean values from Chyi Lo's study (2013), we used the means of each component in the PSQI scale to select the most feasible sample size for this study.

Type 1 and type 2 errors were 0.05 and 0.2 respectively

The means and standard deviations of sleep quality in the 2 groups were:

Group 1 (control group): 1.31 ± 0.75 Group 2 (intervention group): 0.80 ± 0.56

Intervention group: 10 sessions of manual acupuncture combined with low-level intravascular laser therapy over 2 consecutive weeks (excluding Saturdays and Sundays).

Control group: 10 sessions of manual acupuncture over 2 consecutive weeks (excluding Saturdays and Sundays).

2.5. Randomization and blinding

An independent statistician created a randomization table for 60 patients in each group with equal probability of selection. Randomization was organized in a 1:1 ratio by drawing lots. Patients who drew number 1 participated in the control group. Conversely, patients marked with number 2 participated in the intervention comparison group.

2.6. Study content

Control group: manual acupuncture treatment regimen once/day, duration 20 minutes, acupoint formula: Neiguan, Shenmen, Sanyinjiao on both sides. Acupuncture technique: balanced tonifying and reducing, needle depth 0.5-1 cun, creating the sensation of de qi by manual manipulation, re-manipulating after 10 minutes. Acupuncture needles: needles with diameter 0.3mm, length 2.5cm.

Intervention group: Using 22G intravenous cannula (Harsoria brand, made in India) to puncture through the skin into the venous lumen, withdraw the stylet and quickly thread the laser optical fiber needle (Guilin brand, China) into the cannula so that the laser needle tip is positioned inside the venous lumen. Machine parameters to be adjusted as follows: wavelength 632.8nm, energy intensity 1.28 W/cm^2, total energy 9.00 J, power: 5 mW, duration 30 minutes. After withdrawing the laser needle, let the patient rest for 10 minutes and perform manual acupuncture as in the control group.

2.7. Data collection

Research staff not participating in the randomization process will collect baseline variables (Age, Gender, TVM body constitution, Occupation, Marriage, Disease duration), outcome variables: average sleep onset time, average sleep hours, average sleep hours score, average sleep efficiency, average sleep efficiency score, average sleep quality score, average daytime dysfunction score, average PSQI score, average PSQI score reduction, average number of awakenings score before treatment, after 5 and 10 days of treatment.

2.8. Data processing

Collected data were processed using Stata 13 biostatistical software.

2.9. Ethics

All patients voluntarily participated in the study. The study only aimed to evaluate the therapeutic effectiveness for patients. All patient information was kept confidential and only served research purposes. The proposal was approved by the Biomedical Research Ethics Council of Thong Nhat Hospital.

3. RESULTS

3.1. Characteristics of study participants

In Table 1, study participants were all over 60 years old, with more women than men. No manual laborers participated in the study, most were retirees. 93.3% of study participants were married. The average disease duration of all patients participating in the study was 14.4 months. 23.3% of patients had Heart-Spleen dual deficiency constitution, 25.0% had Heart yin deficiency, 18.3% had Liver qi stagnation with fire, and Heart-Kidney non-interaction accounted for 33.3%.

Table 1. Basic characteristics of the study population

		Total (n=60)	Control group (n=30)	Intervention group (n=30)
Age (years)		62.1	61.23	62.97
Gender	Male	25 (41.7%)	14 (23.3%)	11 (18.3%)
	Female	35 (58.3%)	16 (26.7%)	19 (31.7%)
TVM body constitution (n (%))	Heart-Spleen dual deficiency	14 (23.3%)	7 (11.7%)	7 (11.7%)
	Heart yin deficiency	15 (25.0%)	7 (11.7%)	8 (13.3%)
	Liver qi stagnation with fire	11 (18.3%)	5 (8.3%)	6 (10.0%)
	Heart-Kidney non-interaction	20 (33.3%)	11 (18.3%)	9 (15.0%)
Occupation (n(%))	Manual labor	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Mental work	16 (26.7%)	7 (11.7%)	9 (15.0%)
	Retired	44 (73.3%)	23 (38.3%)	21 (35.0%)
Marriage (n (%))	Have family	56 (93.3%)	30 (50.0%)	26 (43.3%)
	Single	4 (6.7%)	0 (0.0%)	4 (6.7%)
Disease duration (months)		14.4	14.8	14.1

3.2. Comparison of changes in PSQI scale components before and after intervention

Table 2. Average sleep onset time per night of the two groups at each time point

	Control group (N=30)			Intervention group (n=30)		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
Average sleep onset (minutes)	110.00	91.00	95.67	101.67	68.67	41.00
Average sleep onset (points)	2.67	2.50	2.50	2.63	2.07	1.43
Average sleep hours (hours)	3.03	3.17	2.87	3.23	4.03	5.27
Average sleep hours score (points)	2.97	3.00	2.93	2.90	2.73	2.10
Average sleep efficiency (%)	39.59	42.54	37.55	40.59	49.99	59.91
Average sleep efficiency score (points)	2.93	2.90	3.00	2.87	2.80	2.50
Average sleep quality score (points)	2.97	2.83	2.67	2.90	2.50	1.87
Average daytime dysfunction score (points)	1.93	1.73	1.60	1.77	1.53	1.10
Average PSQI score (points)	17.60	16.97	16.73	17.20	15.57	13.33
Average PSQI score reduction (points)		0.63	0.87		1.33	3.87
Average number of awakenings score (points)	2.73	1.73	2.60	2.70	2.10	1.77

T0: immediately after intervention, T1: after 5 days, T2: after 10 days

3.2.1. Comparison of average sleep onset time per night between the two groups

The average sleep onset time per night for the control group after 5 days was 110.00 minutes, after 10 days was 91.00 minutes and 95.67 minutes. The group using intravascular laser decreased from 101.67 minutes to 68.67 minutes and 41.00 minutes. The score for evaluating average sleep onset time per night in the control group after 5 days was 2.67, after 10 days was 2.5 and 2.5. In the group using intravascular laser, it decreased from 2.63 to 2.07 and 1.43 points.

3.2.2. Comparison of average sleep efficiency between the two groups

The average sleep duration per night in the control group was 3.17 hours after 5 days and 2.87 hours after 10 days. In the group treated with intravascular laser therapy, sleep duration increased from 3.23 hours to 4.03 hours after 5 days and 5.27 hours after 10 days. In terms of symptom scores, the control group showed no improvement after 5 days, increasing slightly from 2.97 to 3.00 points, and decreasing slightly to 2.93 points after 10 days. In contrast, the group treated with intravascular laser therapy showed a decrease from 2.90 points to 2.73 after 5 days, and further decreased to 2.10 points after 10 days.

3.2.3. Comparison of average sleep quality scores between the two groups

The average sleep efficiency of the control group after 5 days of treatment increased from 39.59% to 42.54%, after 10 days was 37.55%. The group using intravascular laser after 5 days of treatment increased from 40.59% to 49.99%, after 10 days increased to 59.91%. The average sleep efficiency score of the control group after 5 days changed from 2.93 points to 2.90 points, after 10 days increased to 3.00 points. The group using intravascular laser after 5 days decreased from 2.87 points to 2.80 points, after 10 days of treatment decreased to 2.50 points.

3.2.4. Comparison of average daytime dysfunction scores between the two groups at each time point

The average sleep quality score in the control group decreased from 2.97 points to 2.83 points after 5 days of treatment, and further decreased to 2.67 points after 10 days. In the group treated with intravascular laser therapy, the average sleep quality score decreased from 2.90 points to 2.50 points after 5 days, and to 1.87 points after 10 days

3.2.5. Comparison of Average Daytime Dysfunction Scores Between Two Groups Over Time

The average sleep quality score in the control group decreased from 2.97 points to 2.83 points after 5 days of treatment, and further decreased to 2.67 points after 10 days. In the group treated with intravascular laser therapy, the average sleep quality score decreased from 2.90 points to 2.50 points after 5 days, and to 1.87 points after 10 day**s**

3.3. Comparison of differences in PSQI scores between the two groups

The control group after 5 days of treatment decreased 0.63 PSQI points, after 10 days decreased a total of 0.87 points. The group using intravascular laser, after 5 days decreased 1.33 PSQI points, after 10 days decreased a total of 3.87 points. The PSQI score of the control group after 5 days of treatment decreased from 17.60 points to 16.97 points, after 10 days of treatment was 16.73 points. The PSQI score of the group using intravascular laser decreased from 17.20 points after 5 days of treatment to 15.57 points, after 10 days of treatment was 13.33 points.

3.4. Comparison of the effect of reducing the number of awakenings between the two groups

After 5 days of treatment, the average number of awakenings score in the control group decreased from 2.73 to 1.73 points, after 10 days was 2.60 points. After 5 days of treatment, the average number of awakenings score in the group using intravascular laser decreased from 2.70 points to 2.10 points, and after 10 days was 1.77 points.

4. DISCUSSION

4.1. Changes in PSQI scale components before - after intervention and between the 2 groups

Both study groups showed significant improvement in reducing sleep onset time. The control group decreased from 110 minutes to 95.67 minutes, corresponding to a score reduction from 2.67 to 2.5. The intervention group (using low-level intravascular laser) had stronger improvement, decreasing from 101.67 minutes to 41 minutes, corresponding to a score reduction from 2.63 to 1.43. The results of the laser group were almost equivalent to previous research, showing this method is more effective than the control group. The results are nearly equivalent to the study by Đoàn Văn Minh .

Regarding average sleep hours per night, both study groups showed improvement

in reducing sleep onset time. For the control group, the change in average sleep hours per night from day 0 to days 5 and 10 were 3.03 hours, 3.17 hours, 2.87 hours respectively, corresponding to point changes of 2.97 points, 3.0 points, 2.93 points. In the intervention group, there was significantly better improvement at 3.23 hours, 4.03 hours, 5.27 hours respectively, corresponding to score reductions of 2.9 points, 2.73 points, 2.1 points. The average sleep hours per night at baseline (T0) for both study groups was generally similar to Đoàn Văn Minh's study at about 3 hours .

The study showed that both intervention and control groups had improvements in sleep efficiency; however, the intervention group combining manual acupuncture and low-level intravascular laser achieved higher maximum efficiency, up to 59.91% compared to 37.55% in the control group. Although lower than Đoàn Văn Minh's previous study , the significant improvement in sleep efficiency in the intervention group still showed considerable effectiveness of this combined method.

The intervention group combining manual acupuncture and low-level intravascular laser had significant improvement in sleep quality, with PSQI scores decreasing from 2.9 points to 1.87 points. Although not achieving the same effectiveness as Huo ZJ's previous study, the level of improvement was still equivalent, possibly due to differences in study subjects and baseline variables . Overall, this intervention method still showed significant effectiveness in improving sleep quality.

Research results showed the intervention group had significant improvement in daytime dysfunction, with scores decreasing from 1.77 to 1.1 points, while the control group only decreased from 1.93 to 1.6 points. This was consistent with Huo ZJ's study, showing that the combined intervention method achieved better effectiveness than single treatment. Improvement in nighttime sleep quality was directly related to improving daytime function, achieving similar effectiveness to previous research .

4.2. Differences in PSQI scores between the 2 study groups

The PSQI score in the intervention group had significant improvement, decreasing from 17.2 to 13.33 points, equivalent to changing the sleep disorder level from moderate to mild. While the control group only improved by 0.87 points, the sleep disorder level remained moderate. This result even surpassed Hou ZJ's previous study . This shows that the combined method of manual acupuncture and low-level laser therapy has great potential in treating non-organic sleep disorders.

4.3. Comparison of the effect of reducing the number of awakenings between the two study groups

After 5 and 10 days of treatment, the intervention group using manual acupuncture combined with low-level laser had significant improvement in average number of awakenings, from 2.70 to 1.77 points. Meanwhile, the group using only traditional manual acupuncture did not have the expected improvement. This result was consistent with previous studies by Xuan Yin and Wu JH, showing that the combined method of manual acupuncture and low-level laser is more effective than traditional acupuncture, especially in improving nighttime awakenings .

5. CONCLUSION

The combined method of manual acupuncture with low-level intravascular laser therapy is more effective than using manual acupuncture alone in treating non-organic insomnia.

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