EFFICACY OF AURICULAR ACUPRESSURE USING SEMEN VACCARIAE (WANG BU LIU XING) SEEDS ON ACUPOINTS OF NADA PROTOCOL IN TREATING PRIMARY INSOMNIA: A PILOT STUDY

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This pilot study first aimed to evaluate the safety and efficacy of this twenty-day auricular acupressure using Semen Vaccariae (Wang Bu Liu Xing) in improving the sleeping conditions of primary insomnia patients. The secondary aim was to evaluate the improvement of some other self-reported symptoms caused by insomnia. A clinical prospective pre–post study was designed, enrolling 60 primary insomnia patients. Each patient was administered the auricular acupressure on five acupoints of NADA protocol of both ears by applying the Vaccariae seeds and was instructed to gently press 1 minute/acupoint each time, four times a day for twenty consecutive days. After 20 days, the mean total sleep time increased significantly from 3.8 ± 1.0 to 5.4 ± 1.0 (hours) (p<0.05). The mean ISI score decreased from 19.3 ± 5.4 at D0 to 9.5 ± 4.7 (points). The sleep efficiency increased significantly from 52.7 ± 13.9 to 80.7 ± 10.0 (%) (p<0.05). The number of patients suffering from self-reported insomnia-related symptoms (including fatigue, decreased concentration, anxiety, decreased memory, dizziness) decreased significantly compared to those at baseline (p<0.05). Auricular acupressure using Semen Vaccariae ear seeds followed the NADA protocol showed both safety and potential efficacy in improving sleep quality and other insomnia-related symptoms.

Keywords: Insomnia, Wang Bu Liu Xing, National Acupuncture Detoxification Association, NADA, Auricular acupressure.

I. INTRODUCTION

Primary insomnia is a common disease associated with psychogenic factors, affecting millions of people worldwide.[1] Insomnia is a subjective complaint, which varies from individual to individual, often involves difficulties falling asleep, poor sleep quality and quantity, waking undesirably early or during the night and complaints of resultants such as daytime fatigue or sleepiness, decreased concentration, dizziness...[1] Insomnia is often more common in females, older adults, and people with comorbidities of medical or mental illnesses.[1,2] A cross-sectional study on randomly selected Sweden participants showed 32.1% experienced difficulty initiating or maintaining sleep, and poor ability to restore sleep at least four nights per week; 75% reported daytime symptoms.[3] Around one fourth to one third of Americans and approximately 30 - 45% of Vietnamese adults experience insomnia symptoms at some point in a year.[2,4,5] The high prevalence of insomnia results in impaired function, increases risks of medical and psychiatric morbidity and mortality for the patients, and increases healthcare costs.[5,6] According to recent guidelines, cognitive behavioral therapy is recommended as the first-line treatment for chronic insomnia in adults of any age, pharmacological intervention

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can be offered if cognitive behavioral therapy for insomnia is not sufficiently effective or not available.[7,8] In Traditional medicine, insomnia (Shi Mian) is mainly caused by the disturbance of the Mind, or the dysfunction of the Heart, or the disharmony between yin (sleep) and yang (awakening), or the irregular circulation of defensive Qi. Based on the etiologies of Shi Mian, each insomnia patient can be prescribed with the suitable traditional remedies or acupuncture, acupressure and massage...[9,10]

The map of the auricular microsystem has been described as an inverted fetus, therefore auricular acupoints have long been used to treat effectively many systemic conditions. In comparison with auricular acupuncture, auricular acupressure seems likely to be more cost-effective, time-saving, easier to be accepted by patients and have fewer risk of adverse events of acupuncture (bleeding, infection...) as it is a non-invasive procedure. Since the 1970s, The National Acupuncture Detoxification Association (NADA) of America has developed an auricular acupuncture protocol including 5 points: Shen Men, Sympathetic A, Kidney, Liver, and Lower Lung, which was initially used to be an adjunctive therapy in substance abuse treatment. From then, this protocol was applied as a comprehensive care model. It showed potential efficacy in treating insomnia, trauma, substance misuse/abuse, and other related behavioral and mental health disorders worldwide.[11,12] However, to the best of our knowledge, there is no research conducted in Viet Nam to evaluated the therapeutic efficacy of auricular acupressure using Wang Bu Liu Xing (WBLX) ear seeds following NADA protocol in improving sleep for patients with insomnia. As such, the current pilot study was conducted with two aims:

1. Evaluating the safety and improving sleep efficiency of WBLX ear seeds acupressure followed NADA protocol in treating primary insomnia.

2. Evaluating the efficiency in improving other self-reported symptoms caused by insomnia, including fatigue, decreased concentration, anxiety, decreased memory, and dizziness.

II. MATERIALS AND METHODS

1. Study materials

The NADA protocol used in this study includes five acupoints: Shen Men, Sympathetic, Kidney, Liver, and Lower Lung.[11–13]

Shen Men is located in the triangular fossa, superior and central to the tip of the triangular fossa (not at the tip), between the junction of the superior crus and the inferior crus of the antihelix.

Sympathetic is located at the junction of the more vertically rising internal helix and the more horizontal inferior crus (covered by the brim of the helix root above it).

Kidney is located at the superior concha and superior to the Stomach point (hidden by the overhanging ledge of the inferior crus).

Liver is located at the peripheral concha ridge and concha wall, peripheral to the Stomach point.

Lower Lung is located at the lower region of the inferior concha.

WBLX ear seeds were 2 mm hard globular beads with adhesive plaster (0.5 cm x 0.5 cm) manufactured by Feng Shui Xing Shui Medical Device Commercial Limited Company, China. The acupoint detector device used in this study was manufactured by Komatsu Medical Device Research Institute, Nanjing, China (Patent number: ZL 98227652.4).

2. Participants

Inclusion criteria

Participants meeting all the following criteria were enrolled in this study: age ≥ 18 years, regardless of gender, primary insomnia diagnosed according to ICD 10 – CM: F51.01 and DSM-5;[14] total score of Insomnia Severity Index (ISI) ≥ 8 points;[15] using no other treatments during the study participation.

Exclusion criteria

Patients with any of the following conditions were excluded: secondary or comorbid insomnia; comorbidities of other mental disorders according to the DSM-5; piercing of the ear or having scar tissue at any place of NADA points; history of previous treatment by acupuncture or auricular acupuncture in 1 month before the study.

3. Methods

Study design

This present study was a prospective interventional pilot pre-post study. Participants were primary insomnia patients selected from the Outpatient Acupuncture Clinic, Hanoi General Hospital of Traditional Medicine, Hanoi, Vietnam, from March 2020 to October 2020. Eligible patients were enrolled and treated with auricular pressure using NADA protocol for twenty consecutive days. The convenience sampling method was used to recruit 60 eligible patients.

Study protocol

The efficacy of the study procedure was evaluated by comparing data collected at baseline (D0: pre-study), after ten days (D10), and after twenty days of auricular acupressure (D20: post-study). The primary outcomes were the safety of the procedure and an increase in total sleep time, sleep efficiency (self-reported by sleep diary), and a decrease in ISI score. The secondary outcomes were reductions in the proportion of patients suffering from other self-reported symptoms (fatigue, decreased concentration, anxiety, memory loss, and dizziness).

After being fully examined at the baseline, patients received WBLX seeds on five bilateral ear acupoints following the NADA protocol: Shen Men (TF2), Sympathetic A (IH 4), Kidney (SC 6), Liver (CR 2), and Lower Lung (IC 2). Each point was sterilized with 70% ethyl alcohol before an adhesive plaster was attached with one seed of Semen Vaccariae. Patients were instructed to gently press the seeds with appropriate strength until a slight aching or soreness was felt on the acupoints, maintaining the force for 1 minute each time, four times a day for 20 consecutive days. The patients were recommended to divide their waking time into four sections during the day and each time of acupressure was performed in each section, but the exact time would not be chosen too strictly to prevent them from causing anxiety. The ear seed patches were changed once every five days or when the plaster detached.

Study evaluations

The safety of the procedure was evaluated by monitoring the adverse events that occurred during the study. If the patients experienced severe adverse events, appropriate medical treatment was administered without delay.

The severity and improvement of insomnia were evaluated using ISI.[16] ISI questionnaire consists of 7 self-report questions evaluating insomnia's nature, severity, and impact using a 5-point Likert scale (0 = no problem; 1 = mild, 2 = moderate, 3 = severe, 4 = very severe problem). The total ISI scores at baseline and D10, D20 were interpreted following the ISI Guidelines for Scoring/Interpretation: no clinically significant insomnia (0 – 7); subthreshold insomnia (8 – 14); clinically moderate insomnia (15 – 21); clinically severe insomnia (22 – 28).

Change of ISI score = Total ISI score after treatment – total ISI score before treatment. The changes were classified as Significant improvement if the ISI score changed > 8 points; moderate improvement if the ISI score changed from 7 to 8 points, slight improvement if the ISI score changed from 1 to 6 points, unimproved if the ISI score showed no change.

The total sleep time and efficiency were assessed according to the sleep diary of the patients.[17] Total sleep time was counted by hours. Sleep efficiency = (Total time asleep/ Total time in bed) x 100%.[17]

4. Statistical data analysis

Study results are shown as mean ± standard deviation (SD) or frequencies when appropriate. Comparisons were conducted between D0, D10, D20. For normally distributed variables, means were compared using paired t-tests (two-tailed), and nonparametric variables were analyzed using Pearson Chi-square X^2 tests or Fisher exact tests. P values < 0.05 were considered to present statistically significant changes. Statistical analyses were performed with STATA software, version 11.0.

III. RESULTS

Table 1. Baseline characteristics of the patients (n = 60)

Characteristic	Value
Age (years, mean ± SD)	46.9 ± 18.0
Sex, n (%)	
Female	43 (71.7%)
Male	17 (28.3%)
Marital status, n (%)	
Single	6 (10.0%)
Married	52 (86.7%)
Separated	2 (3.3%)
Insomnia duration (%)	
Less than 1 month	None
1 to less than 6 months	20.0%
6 to less than 12 months	6.7%
12 to less than 5 years	40.0%
5 years or longer	33.3%
ISI (mean score ± SD)	19.3 ± 5.4
Total sleep time (hours, mean score ± SD)	3.8 ± 1.0
Sleep deficiency (%, mean score ± SD)	52.7 ± 13.9
Self-reported symptoms caused by insomnia, n (%)	
Fatigue	50 (83.3%)
Decreased concentration	46 (76.7%)

Characteristic	Value
Anxiety	42 (70.0%)
Decreased memory	50 (83.3%)
Dizziness	44 (73.3%)

The mean age of the patients was 46.9 ± 18.0 years. Most were female (71.7%) and married (86.7%) at the time of the study. The insomnia duration ranged from 1 month to more than 5years.

*** Safety and adverse events during the study:**

Among 60 patients enrolled, 93.3% reported no abnormal eventduring the study. Only one patient (accounted for 1.7%) had minor bleeding at one acupoint's position which was self-controlled without medical treatment. Three patients (5.0%) reported minor itchiness at the site of the ear seeds, but no medical treatment was needed.

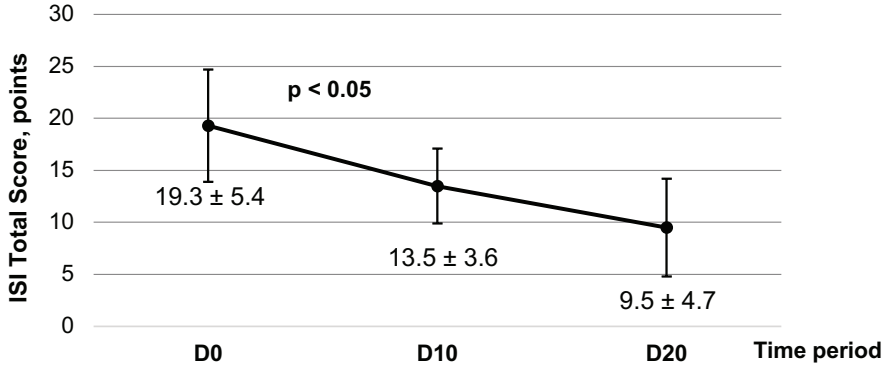

Figure 1. Change of ISI total score by study periods (n = 60)

Figure 1 illustrates the significant change of the total ISI score before and after the WBLX auricular acupressure (p < 0.05) with a substantial decrease from 19.3 ± 5.4 (points) at D0 to 9.5 ± 4.7 (points) at D20.

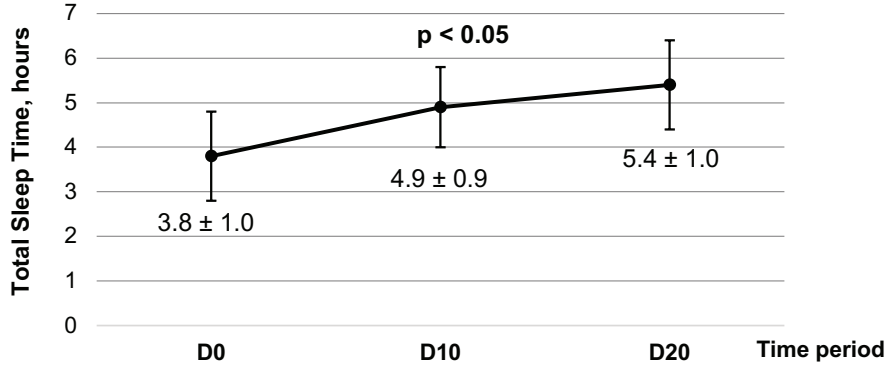

Figure 2. Change of total sleep time by study periods (n = 60)

Participants reported improved full sleep time**:** The mean sleeping duration at D0 was 3.8 ± 1.0 (hours), which was significantly increased to 5.4 ± 1.0 (hours) at D20 (p < 0.05).

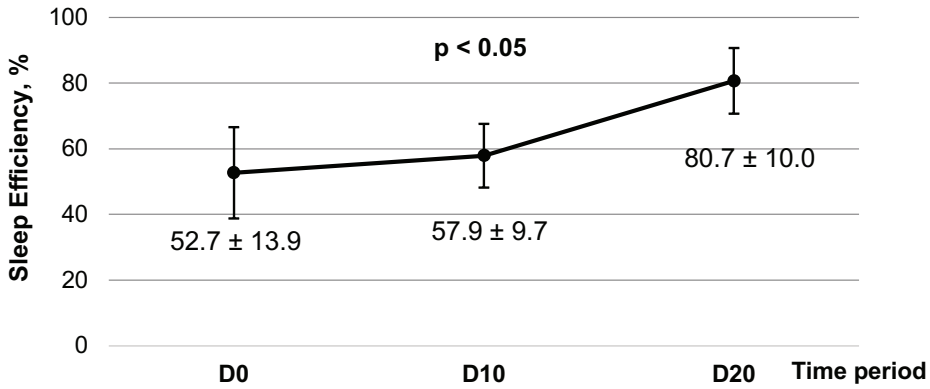

Figure 3. Change of sleep efficiency by study periods (n = 60)

Figure 3 shows a remarkable amelioration of sleep efficiency: Efficiency increased from 52.7 ± 13.9 (%) at baseline to 80.7 ± 10.0 (%) after twenty days of intervention.

Table 2. Changes in self-reported symptoms caused by insomnia by study periods (n = 60)

Symptoms	Time points								
	D0		D10		D20		p_{D0-D10}	$p_{D10-D20}$	p_{D0-D20}
	n	%	n	%	n	%			
Fatigue	50	83.3	44	73.3	24	40.0	> 0.05	< 0.05	< 0.05
Decreased concentration	46	76.7	32	53.3	12	20.0	< 0.05	< 0.05	< 0.05
Anxiety	42	70.0	18	30.0	10	16.7	< 0.05	< 0.05	< 0.05
Decreased memory	50	83.3	40	66.7	12	20.0	> 0.05	< 0.05	< 0.05
Dizziness	44	73.3	26	43.3	10	16.7	< 0.05	< 0.05	< 0.05

The improvements in self-reported symptoms caused by insomnia are shown in Table 2. All patients reported improvement in the five self-reported symptoms evaluated in this study. After ten days, 70% were free of anxiety, 46.7% experienced no decrease in concentration, and 56.7% had no dizziness ($p < 0.05$ compared to those at baseline). At the end of the study, the proportion of fatigue-free patients was 60%; no decrease in concentration and memory were reported in 80%; anxiety and dizziness were not sustained in 83.3% of the participants. These changes at the end of the treatment period were all statistically significant ($p < 0.05$).

IV. DISCUSSION

This pilot study was carried out on 60 eligible primary insomnia patients who met the inclusion and exclusion criteria for enrolling participants. After a twenty-session treatment period, no significant adverse effect was reported. Four cases with self-managed minor events required no specific medical treatment. The results from this study show that auricular acupressure using WBLX ear seeds on the acupoints of

NADA protocol was significantly effective in improving the sleep quality (through ISI score and sleep deficiency) and quantity (total sleep time) for treating primary insomnia in the study participants ($p < 0.05$). The subjective self-reported symptoms caused by insomnia (including fatigue, decreased concentration, anxiety, decreased memory, and dizziness) were also remarkably improved.

Insomnia is the most prevalent sleep problem affecting millions of patients regardless of sex, gender, or region. In our pilot study, all the participants had a history of insomnia for at least one month. This refers to chronic insomnia, which detrimentally impacts their mental health and quality of life.[3,4]

The medical actions of the auricular acupoints have been studied for a long time by both modern and traditional medicine. Some auricular acupuncture experts contend that the human ear is a self-contained microsystem that can affect the entire body.[18] The acupoints on the ears can be stimulated by needles or pressure. If the patients are prescribed acupuncture to treat insomnia, this normally requires them to have the acupuncture session for 30 minutes/session/day at the hospital or clinic, according to the Acupuncture technical process guidelines of the Ministry of Health. Since all participants in our study had chronic insomnia (lasted for 1 month and above), the length of the acupuncture treatment was likely to be lengthened more than the number of sessions for acute insomnia, which could negatively affect their daily life and work.

In this study, the research team used WBLX seeds with prepared plaster to attach to the position of the bilateral auricular points. This method was simpler and easier to apply to the NADA protocol. It was more flexible for the patients than using the needles as they were instructed to stimulate the seeds four times during the day. Furthermore, the ear seeds attached all the time during twenty days on the patients' ears stimulate the acupoints continuously without any inhibiting activities. This technique was not invasive so the risk for bleeding and infection at the acupoints' site were minimum. Semen Vaccariae are small globular seeds, so it is convenient to produce the exactly pressure onto the auricular acupoint. In Traditional medicine, Semen Vaccariae helps to invigorate blood movement in the meridians and channels, and reduce swelling.

The NADA protocol is a commonly – used acupuncture treatment in the United States, involving five bilateral auricular points: Shen Men, Sympathetic A, Kidney, Liver, and Lower Lung. This low-cost, easy-to-accept procedure offers a long-term, preventative effect and aids in ttreating many behavioral health problems.[11–13,19] Originating from an adjunctive therapy for addiction recovery in substance abuse patients, the NADA protocol has been further studied to investigate the benefits or outcomes in treating other mental conditions. Positive improvements have been noted in the application for insomnia, anxiety, hyperactivity, depression, emotional irritation...[19]

Shen Men (TF 2) or *Spirit Gate* is the acupoint that tranquilizes the Mind and allows a harmonious connection to the essential spirit. It regulates the excitation and inhibition of the cerebral cortex and is one of the most used points for detoxification from drugs or substance abuse. The Sympathetic (IH 4) (or Autonomic) acupoint balances sympathetic nervous system activation with parasympathetic sedation. Sympathetic acupoints calm smooth muscle tension, reduce visceral pain, and induce sedation effects during acupuncture. The kidney (SC 6) is the strengthening

point for the cerebellum and hematopoietic response and is associated with the relief of depression. In Traditional medicine, the kidney is the organ in charge of storing essence and governing reproduction and development. It also produces marrow, strengthens bones, and fills up the brain. Therefore, stimulating the Kidney auricular acupoint can tonify the kidney Qi deficiency, regulate fluid transformation and elimination, and enrich essence. The auricular Liver point helps with liver detoxification and is associated with relief of anger and irritability. It can also improve blood circulation and eyesight, relieve fainting, and regulate digestive disorders, hypertension, convulsions, and paralysis due to a stroke. Lower Lung acupoint (IC2) relieves the symptoms relating to respiratory disorders, drug detoxification, and skin diseases. It is associated with an anti-inflammatory response and with relief of anxiety.[19] When combined, these five auricular acupoints of the NADA protocol show the synergistic effect, which is more efficient than the sole effect of each point.

After 20 days of treatment, all patients' insomnia has been alleviated, including increased sleeping duration and efficiency. Our results are consistent with those of some previous studies. A pre-post research on 18 anxious adult participants was conducted to evaluate the effects of acupuncture in treating their insomnia (2004). the diagnosis of insomnia was taken according to DSM-4, and acupuncture was administered for five consecutive weeks. Results from this study show that the mean total sleeping duration at D0 and D35 was 5.1 and 6.5, respectively; the mean difference $\Delta_{0\text{-}35}$ was 1.4 ± 1.1; the difference was statistically significant ($p = 0.001$).[20] The sleeping efficiency at D0 and D35 was 76.1% and 88.6 %, respectively; mean difference $\Delta_{0\text{-}35}$ was 12.1 ± 14.7; statistically significant with $p = 0.002$.[20]

Several previous studies indicated that acupuncture and auricular acupuncture by NADA protocol positively affected sleep conditions by affecting the brain's connectivity network (cortical and subcortical structures) and limbic system. Stimulation on acupoints improves sleep quality and duration (reduces sleep latency, increases total sleep time and efficiency) by significantly increasing endogenous melatonin excretion. Simultaneously, it reduces the negative stimuli by increasing enkephalin secretion to alleviate pain sensation and increasing endorphin to reduce stress. Stimulating the Lower Lung point and Liver point also reduces the concentration of lactic acid, thus helping to reduce pain and fatigue and enhancing immunity. Stimulating the Lower Lung point or Shen Men point can increase the activity of the parasympathetic nervous system. Moreover, the Sympathetic A point balances the activities of the sympathetic and parasympathetic nervous systems, has a strong analgesic effect, and has a vasodilator effect on the internal organs to support improve circulation.[21–23]

Fatigue, decreased memory and concentration, dizziness, and anxiety are five prevalent associated symptoms with insomnia. In some cases, it might be difficult to distinguish whether these symptoms were the consequences of chronic insomnia or the comorbidities that interacted with and worsened the sleep problems. The findings from this study also suggest that these five self-reported symptoms were improved, and significant changes were witnessed after the intervention. These detrimental conditions can lead to harmful influences on the nervous system if left unconcerned or untreated.

V. CONCLUSIONS

This pilot study suggests that WBLX ear seed

auricular acupressure following NADA protocol is a safe and potentially effective therapeutic option in improving sleep quality, total sleep time, and some other insomnia-induced self-reported symptoms for primary insomnia. As a preliminary study, future well-designed trials with sufficient sample size, randomization with a control group, and defining the confounding factors are needed to clarify the implication of this therapy for primary insomnia.

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Declarations of interest

The authors declare that they have no conflicts of interest.

Abbreviations:

NADA: National Acupuncture Detoxification Association

WBLX: Wang Bu Liu Xing

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