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The Effect of Acupuncture at Ear Shenmen on Heart Rate Variability: A Subject-Assessor-Blinded, Randomized, Sham-Controlled Crossover Study

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Auricular acupuncture is a widely used alternative medical treatment. One of the most recognized auricular acupuncture points is the Ear Shenmen (MA-TF1), which allegedly calms the mind and reduces stress. We therefore hypothesized that acupuncture at the Ear Shenmen may effectively enhance vagal nerve activity and/or suppresses cardiac sympathetic regulation. To test this hypothesis, we conducted a subject-assessor-blinded, randomized, sham-controlled crossover study to observe the effects of single-point acupuncture at the auricular acupoint Ear Shenmen on autonomic nervous activity. Twenty-eight healthy women were randomly distributed into two groups: the Ear Shenmen group and the control group. Subjects entered a two weeks washout period after receiving their group's treatment. After the washout period, the subjects switched groups. Autonomic cardiac function was evaluated by power spectral indices of heart rate variability. The results show that there were no significant differences between the two groups in the high-frequency component (HF, p = 0.92), the normalized low-frequency component (LF%, p = 0.94), and the low-frequency power to high-frequency power ratio (LF/HF, p = 0.93). The results suggest that auricular acupuncture on the Ear Shenmen has no significant effect on autonomic cardiac modulation in healthy women. Further studies are needed to fully determine the validity of auricular acupoint Ear Shenmen.

Key words: Auricular acupuncture, Ear Shenmen, heart rate variability

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1. Introduction

Auricular acupuncture is a widely used micro-system in acupuncture. In comparison to body acupuncture, auricular acupuncture is easier to perform and result in fewer side effects. There are two prominent systems of auricular acupuncture. The western system was developed by French neurologist Dr. Paul Nogier in 1950 [1]. The eastern system was derived from an ancient Chinese medical text dating to around 300 BC: the Huangdi Neijing, or The Yellow Emperor's Internal Classic [2]. The Chinese system is based on functional observations while the French system is based on neurological and embryological consider-ations. Each has its exclusive acupuncture points, but over twenty points overlap between the two systems.

It is believed that the auricular acupoint Ear Shenmen, a point originally exclusive to the Chinese acupuncture system, calms the mind and spirit [3]. In 1990, the Ear Shenmen was recognized by WHO's Report of the Working Group on Auricular Acupuncture Nomenclature [4] and has since been included in western auricular systems. Both eastern and western acupunctural texts now document the Ear Shenmen as a master point that tranquilizes the mind and reduces stress [5]. The acupoint is often used to treat insomnia, dream-disturbed sleep, pain, and withdrawal symptoms [6]. However, despite its popularity there is a lack of scientific evidence on the effectiveness of the Ear Shenmen.

While studies show that auricular acupuncture has beneficial effects on vagal activity, specificity and efficacy are still inconsistent, which may be due to lack of randomization, blinding, or sham control [7]. Since pain and insomnia are associated with autonomic dysfunction [8,9], we hypothesized that acupuncture at the Ear Shenmen enhances vagal nerve activity and/or suppresses sympathetic regulation of the heart. In order to test this we conducted a subject-assessor-blinded, randomized, sham-controlled crossover study to observe the effect of Ear Shenmen acupuncture on heart rate variability (HRV).

2. Materials and Methods

2.1. Study design

The study was conducted at the Chiayi Chang Gung Memorial Hospital. Subjects were examined after voluntarily signing a consent form. Those deemed appropriate for participation were randomly assigned to either the Ear Shenmen group or the control group. Random assignment was conducted using a computer-generated randomization list designed to balance the subjects between the two groups in a 1:1 ratio. Subjects entered a two weeks washout period after receiving their group's treatment. After the washout period, the subjects switched groups (figure 1). Treatment and assessment were performed independently, with practitioners uninvolved in assessing the outcomes. The subjects, the outcome assessors, and the statistician performing the data analyses were blinded to the group assignment throughout the study.

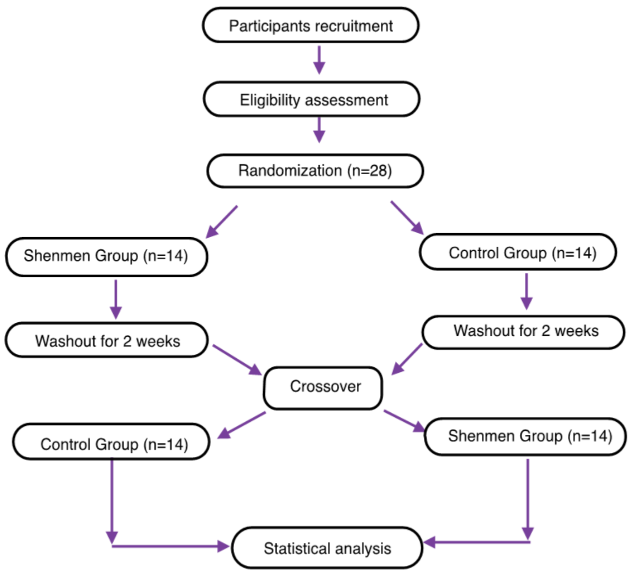

Fig. 1. Flowchart of the study design.

2.2. Participants

Twenty eight healthy female volunteers (mean age ± SD: 22.0 ± 1.1 years) were recruited from a university student population. None of the subjects drank alcohol, smoke, or had diseases affecting the autonomic nervous system (for example, diabetes). None of the subjects took medication affecting heart rate or blood pressure in the period of two weeks prior to the study. Subjects were prohibited from drinking caffeinated or alcoholic beverages 24 hours before each treatment session. The demographic and HRV measurements of the subjects are shown in Table 1.

Table 1. Demographic data and HRV measurements of the subjects (n = 28).

Characteristics	Mean ± SD	Range
Age (year)	22.0 ± 1.1	21 – 25
Height (cm)	159.6 ± 6.0	155 – 169
Body Weight (kg)	53.0 ± 4.2	45 – 64
Body mass index (kg/m^2)	20.8 ± 1.1	18.7 – 22.7
Heart rate (beats/min)	79.2 ± 4.7	71 – 86
Systolic blood pressure (mmHg)	112.8 ± 3.4	109 – 118
Diastolic blood pressure (mmHg)	67.1 ± 3.7	61 – 73
Variance [ln(ms^2)]	7.34 ± 1.00	5.23 – 9.29
Total power (ms^2)	7.14 ± 0.91	5.05 – 8.74
LF% (nu)	41.28 ± 13.84	15.0 – 74.4
HF [ln(ms^2)]	5.66 ± 1.26	3.24 – 7.67
LF/HF [ln(ratio)]	0.00 ± 0.68	-1.40 – 1.46
LF [ln(ms^2)]	5.65 ± 1.05	3.47 – 7.63

2.3. Power spectral analysis of heart rate variability

Various physiological measurements (blood pressure, skin temperature, plasma catecholamines, skin conductance) and autonomic stimuli (stress test, postural challenge) have been used as indices of ANS functions. However, the results are usually confounded by systems other than the ANS [10]. In contrast, sympathetic and parasympathetic nerves have their own hormone systems and frequencies which can be detected using power spectral analysis of HRV [11]. We chose power spectral analysis of HRV to assess autonomic cardiac function because it has been shown to be a non-invasive and non-stress-inducing measurement for autonomic control of heart rate [12–14]. ECG signal acquisition, storage, and processing were performed using a Autonomic Nervous System Analyzer (Wegene Technologies Inc., Taiwan). The sampling frequency for ECG recording was 256 Hz. QRS waves during each interval were detected and sorted by a computer using spike detection algorithms. These QRS waves were then grouped into normal and abnormal groups to eliminate premature contractions and noise. Continuous and normal R-R period variations were converted into a spectrum using the Fast Fourier transform algorithm.

The power spectral density (PSD) was calculated from the spectrum to obtain the frequency domain parameter. The range of frequencies included in the total power was from 0 to 0.4 Hz. The total power (TP) of the wave was divided into three separate regions: the high frequency as HF (0.15-0.40 Hz), the low frequency as LF (0.04-0.15 Hz), and the very low frequency as VLF (0.003-0.04 Hz). The normalized LF (LF%) was calculated as LF/(TP -VLF) × 100. HF and LF/HF were expressed in natural logarithmic form to adjust for distribution skew [15]. This measure of LF% maximizes changes in sympathetic regulation and minimizes changes in VLF power [16].

The HF power spectrum is synchronous with the respiratory frequency and attributed to vagal mechanisms as a marker of parasympathetic modulation [17], whereas the normalized LF (LF%) and the ratio LF/HF reflects sympathetic modulation or sympathovagal balance [18–20]. The HRV measurements were made at five minute intervals, with the first interval starting at five minutes before the needle once was inserted (N), the needle was inserted (A1), every five minutes after the needle was inserted (A2, A3, A4, A5), once the needle was removed (R1), and five minutes after the needle was removed (R2).

2.4. Interventions

Subjects rested in supine position on a bed for twenty minutes before the acupuncture treatment. Subjects were instructed to relax, breathe normally, and to refrain from speaking during acupuncture. The acupuncture was performed by an experienced doctor licensed in Traditional Chinese Medicine using sterile disposable stainless steel needles 0.5 cun in length and 30 gauge in thickness. Bilateral Ear Shenmen points and bilateral control points were needled during the respective treatment. Treatment was conducted in a quiet room at 25±1°C from 9:00 to 11:00 AM to minimize possible circadian fluctuations [21].

The Ear Shenmen is located deep in the triangular fossa of the auricle, inferior to the superior crus. The control point is located on the auricular helix and is not used for the treatment of any particular disorder [22,23]. The needle was sufficiently inserted to induce "*de qi*": a dull ache, numbness, or tingling sensation characteristic to acupuncture. The needle was then left in place for twenty five minutes before being removed.

A body acupuncturist unfamiliar with ear acupuncture may use unnecessary force to insert the needle and induce pain rather than *de qi*. However, we had the acupuncture performed by a licensed Chinese medicine practitioner with more than 30 years of ear acupuncture experience. Also, by following a standard ear acupuncture protocol [24], we were able to get *de qi* and smooth, pain-free insertion.

2.5. Statistical analysis

Statistical analysis was performed using R software (version 3.1.0 for 64-bit GNU Linux) [25]. The HF, LF%, and LF/HF components of HRV were transformed using the natural logarithm. To compare the effects of the two treatments, repeated measures ANOVA was performed on HF, LF%, and LF/HF values using the model formula value ~ treatment + Error (subject/treatment). To compare the effects of the two treatments over time, the values for HF, LF%, and LF/HF at the N and R1 time points were compared using the Welch two sample paired *t*-test. The two tailed P values from the *t*-tests were adjusted using the Benjamini-Hochberg method.

2.6. Ethics Statement

This study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of the Chang Gung Memorial Hospital in Chiayi, Taiwan. All participants gave written informed consent to participation in the study (CGMH IRB 97-0045B).

3. Results

There were no significant differences between the control treatment and the Ear Shenmen treatment for HF (p = 0.92), LF% (p = 0.94), and LF/HF (p = 0.93) (figure 2).

The control treatment showed significant differences in LF% and LF/HF at the R1 time point compared to the N time point (adjusted p = 0.0032 for LF% and LF/HF). This difference was not observed in the Ear Shenmen treatment (adjusted p = 0.96 for LF% and LF/HF). Moreover, there were no significant differences in HF at the R1 and N time points for the control treatment (adjusted p = 0.96) and for the auricular acupoint Shenmen treatment (adjusted p = 0.26).

The results from this study shows that manual acupuncture at the Ear Shenmen has no significant effect on HF, LF%, and LF/HF compared to the control point. Therefore we conclude that Ear Shenmen acupuncture has no significant effect on cardiac vagal modulation and sympathetic modulation when compared to control acupuncture in healthy women.

Fig 2a

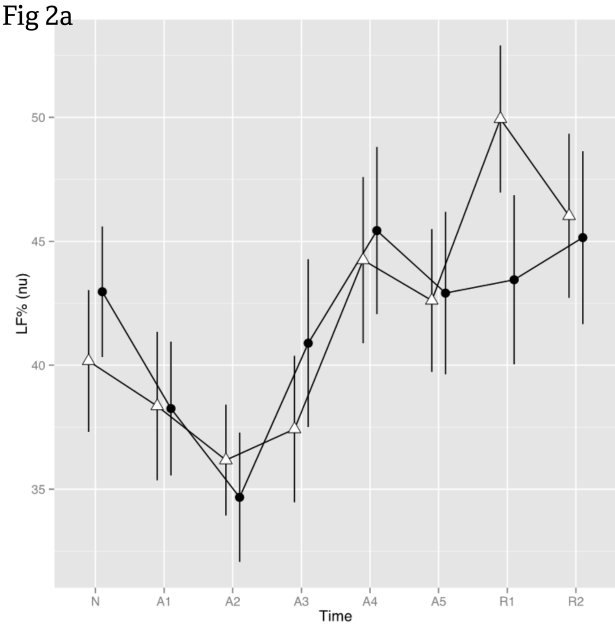

Fig 2b

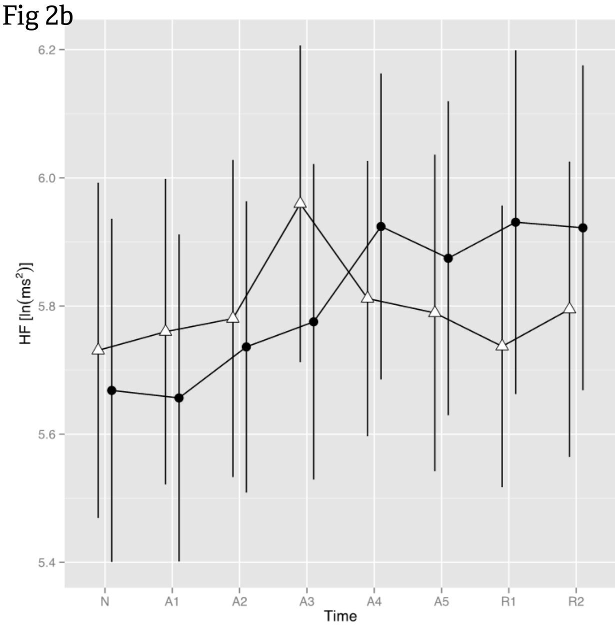

Fig 2c

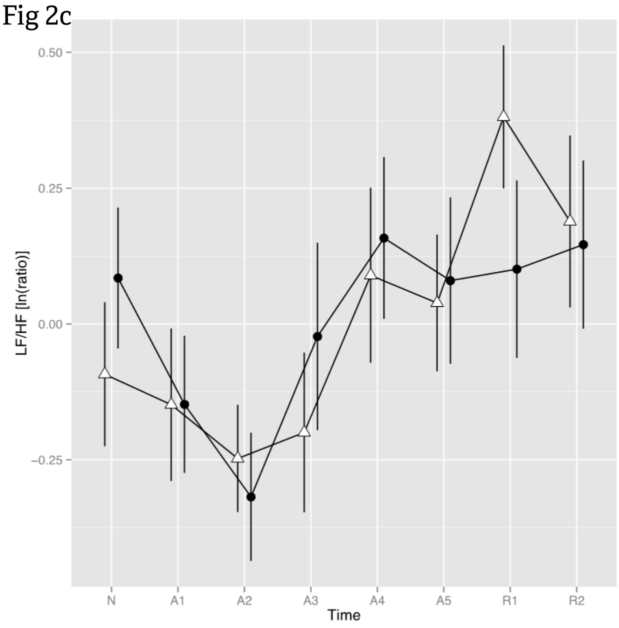

Fig. 2. Mean HRV parameters over the course of treatment. Points represent the mean (a) LF%, (b) HF, and (c) LF/HF ratio for twenty-eight subjects undergoing the control treatment (white triangle) and Shenmen acupuncture treatment (black circles) at five minute time points. N, five minutes before needle insertion. A1, A2, A3, A4, A5, sequential measurements taken after needle insertion. R1, R2, measurements taken after needle removal. Vertical lines represents the standard error of the mean. LF%, normalized low-frequency power; HF, high-frequency power; LF/HF, ratio of LF to HF; nu, normalized units.

4. Discussion

Scientific evidence of acupoint specificity is clinically important, and studies on single-point treatment can help clarify the value of auricular acupuncture. There are very few studies published in English language journals using Ear Shenmen exclusively. In a previous study [26], acupressure on the left Ear Shenmen point did not significantly affect the LF/HF ratio before, during, and after acupressure stimulation. Another study investigated the effects of scalp and auricular acupuncture on subjects' electroencephalogram, HRV, and pulse rate variability [27]. Ten healthy volunteers (age 23 ± 6 years old) received control treatment, experimental test I (Sishencong), and experimental test II (Ear Shenmen) sequentially and on consecutive days. This study concluded that Ear Shenmen acupuncture decreased LF while increasing HF.

The main purpose of our study is to examine the effects of auricular acupuncture at the Ear Shenmen in a controlled crossover trial while controlling several variables including gender difference, age difference, and circadian variation, as these physiological components are important determinants of HRV in in healthy subjects [28,29]. In order to minimize control bias, the subjects, outcome assessors, and the statistician were blinded to the group assignment over the entire study period. Only the physician uninvolved in assessing outcomes was aware of the subjects' assigned groups.

It has been suggested that minimal acupuncture (with merely superficial needle insertion) is not a valid form of placebo control due to the activation of sensory afferents [30,31]. Therefore we selected a point unrelated to auricular acupuncture to use as the control. The control point rests on the auricular helix, a region deemed to be the most appropriate site for a control due to less apparent activity [32, 33].

To the best of our knowledge this is the first subject-assessor-blinded, randomized, sham-controlled crossover study to investigate the effects of acupuncture at Ear Shenmen on power spectral analysis of HRV. The influence of between-patient variation is reduced because each participant acts as his or her own matched control [34,35]. A washout period of two weeks was selected in our study to prevent bias associated with potential carryover effects [36]. Together this should provide additional confidence relating to the internal validity of findings and will aid in the analysis of data.

In our study we expected that acupuncture at Ear Shenmen may effectively enhance vagal nerve activity and/or suppresses cardiac sympathetic regulation compared with the control point and were surprised that no differences were found.

The difference between the clinical and the observed effects in this study may be due to the acupuncture method. The Ear Shenmen acupuncture point is rarely used alone in clinical practice and acupressure on the left Ear Shenmen point did not significantly affect the LF/HF ratio before, during, and after stimulation. The results suggest that Ear Shenmen is not sufficient to induce the beneficial effects by itself. Since people with high vagal and low sympathetic activity have a tendency to sleep [37], we suspected that the needling of multiple acupoints are required for a synergistic effect to arise.

In addition, the vagus nerve includes a

sensory auricular branch that innervates the concha, tragus and cymba concha of the ear [38] but the Ear Shenmen is situated at the apex of the triangular fossa. It is possible that the lack of significant difference between the Ear Shenmen and the control is because both points are innervated by the same auriculotemporal branch of the mandibular nerve. Furthermore, transcutaneous vagus nerve stimulation (tVNS) on the tragus has shown that tVNS can increase HRV and reduce sympathetic nerve outflow [39]. Recent advances in the understanding of neuroanatomy and acupuncture mechanisms suggest a scientific basis for western acupuncture and would appear to support its use [40].

The subjects are also likely to have been in cardiac autonomic balance favoring a higher vagal tone as they were lying down in a relaxed and non-challenging environment. A significant difference in the HF power spectrum may have been hard to detect. Additionally, the effects of auricular acupuncture may only be prominent when associated body parts are in dysfunction. Patients may have a different response to acupuncture compared to healthy individuals.

One limitation of this pilot study is that we only examined a small sample of young females. The present results cannot be generalized to the entire female population as a whole or to men. Also, the study sample might have been too small to detect a small difference between the Ear Shenmen and the control point. As this was designed to be a preliminary study, the sample size and observation duration are limited. Despite the negative results, we think our study has important implications on treatments involving the Ear Shenmen acupoint and the connection of acupuncture to neuroanatomy and physiology. Further studies with a larger sample size and combined treatment with other acupuncture points would further clarify the effects of Ear Shenmen acupuncture on HRV.

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Author Disclosure Statement

No competing financial interests exist.

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針刺耳神門穴對於自律神經功能的影響：受試者及評估者雙盲、隨機、偽穴對照臨床交叉研究

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耳針是一種廣泛應用於互補醫學的臨床治療方法。其中最常被應用的耳穴之一是耳神門穴（MA-TF1），臨床經常應用於穩定情緒和減輕壓力。因此，我們推測針刺耳神門穴可以有效提高迷走神經活性和/或抑制交感神經調節功能。為了測試這一假設，我們進行受試者及評估者雙盲、隨機、偽穴對照的臨床交叉研究，觀察針刺耳神門穴對於自律神經功能的影響。二十八個婦女被隨機分成兩組：耳神門穴組和對照組。受試者在各組分別接受針刺，經過兩週後，再交換進入另組接受針刺。利用心率變異性頻譜分析儀在針刺前(N)、針刺後每隔5分鐘，連續五次(A1~A5)及取針後每隔5分鐘，連續兩次(R1~R2)的階段分別評估自律神經功能。結果顯示兩組之間在高頻 (HF, p = 0.92)、低頻 (LF%, p = 0.94)，和低頻高頻功率比 (LF/HF, p = 0.93) 沒有顯著差異。比較各組在R1與N時期的LF%及LF/HF，耳神門穴組沒有顯著差異(adjusted p = 0.96)，偽穴對照組有顯著差異 (adjusted p = 0.0032)。比較各組在R1與N時期的HF，耳神門穴組 (adjusted p = 0.26) 與偽穴組 (adjusted p = 0.96) 都沒有顯著差異。綜合上述，我們的研究認為針刺耳神門穴對於自律神經活性調節沒有顯著的效果，未來還需要進一步的研究來完全確定耳神門穴的有效性。

關鍵字：耳神門穴、心率變異性頻譜分析

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