The effect of acupuncture on tinnitus handicap inventory (THI) score in tinnitus patients

Harry1, C Simadibrata1*, A Srilistari1 and W Alviandi2

1Department of Medical Acupuncture, Faculty of Medicine, Universitas Indonesia, Jakarta, 10430, Indonesia.
2Neurology Division, Department of Otorhinolaryngology, Faculty of Medicine, Universitas Indonesia, Jakarta, 10430, Indonesia.

*E-mail: christina.simadibrata@yahoo.com

Abstract. Tinnitus is the sensation of sound in the absence of any stimulation, electrical or mechanoo-acoustic, from the external environment. It typically occurs at least for five minutes and for more than once a week. The treatment of tinnitus has been empirical. The purpose of the present study was to determine the success rate of acupuncture in decreasing tinnitus handicap inventory scores (THI) in patients with tinnitus. Ten acupuncture therapy sessions were carried out in 16 patients and the mean THI scores were evaluated before and after the therapy. The success rate of the therapy was 56.3%. The mean THI score before the therapy was 30, which decreased to 21.63 after the therapy (p < 0.05). In summary, acupuncture decreased the THI scores in patients with tinnitus.

1. Introduction
Along with vertigo, nausea, and loss of hearing, tinnitus is one of the most important problems encountered in neuro-otology [1]. In daily practice, often, tinnitus patients are diagnosed by general practitioners and otorhinolaryngologists (ear, nose, and throat specialists) [2].

Tinnitus is defined as the sensation of sound in the absence of any stimulation, either mechanoo-acoustic or electrical, from the external environment [3,4], and is widely known as buzzing ear [5].

Tinnitus prevalence is known to a limited extent only, and ranges from 4.4%–15.1% in the population [6]. In England, it is reported that 10% of adults have tinnitus, while 5% of this number experiences moderate to severe tinnitus with 1% experiencing effects on the quality of life [7]. Tinnitus occurs more often in white men than in other populations [8]. Although tinnitus can happen at any age, it occurs most often in 40–80 year-olds [9], with the highest prevalence in 65–74 year-olds [8] Men and women have the same probability of suffering from tinnitus; [9] however, more men have been reported to suffer from this disease than women [7,10]. Furthermore, tinnitus prevalence has been reported to increase with increasing age, exposure to sound at workplaces, and low
socioeconomic status [7]. There are no definitive reports of tinnitus prevalence in Indonesia. In the neuro-otology division of Cipto Mangunkusumo Hospital, 100 tinnitus patients were reported to have visited the hospital during 2010.

The treatment for tinnitus treatment is complex and utilizes purely psycho-acoustic strategies [5]. The main treatment for tinnitus is the elimination of the etiology of the disease. Treatments include pharmacologic therapy, surgery, masking, psychological therapy [11], and acupuncture as alternative therapy [3,9].

Recently, based on a neuro-physiological approach, tinnitus retraining therapy (TRT), a combination of psychologic, acoustic, and pharmacologic therapy, has been developed [12]. It usually takes one and a half year to complete the TRT [8].

Herraiz et al. (2005) conducted a prospective study on 158 tinnitus patients using TRT. The intensity of tinnitus was assessed using the tinnitus handicap inventory (THI) and visual analog scale (VAS). The THI and VAS assessments were done before and after 12 months of therapy. The study found that the THI scores decreased from 48% to 32% and the VAS scores decreased from 6.6 to 5.3 with 82% of the patients reporting improvement in their tinnitus [13].

Podoskin L (1991) studied the effect of three types of medical treatments on tinnitus including acupuncture, biofeedback, and cinnarizine. Sixty six patients suffering from idiopathic subjective tinnitus were randomized and were divided into five groups to receive one of the three types of therapies mentioned above, placebo biofeedback, or placebo cinnarizine. Fifty eight people in this sample completed the study. The sites used for the acupuncture therapy were L1 4 Hegu, L1 5 Yangxi, SI 5 Yanggu, SI 19 Tinggong, KI 6 Zhaohai, TE 5 Waiguan, GB 12 Wangu, and TE 17 Yifeng. Auriculopuncture was done on vertigo and ear spots. The therapy was given 10 times every week, 30 minutes each time. The assessment used subjective severity ranking and tinnitus matching. The success rate of the acupuncture therapy was 30% and that of the biofeedback was 50%; the success rate of cinnarizine was 10% and that of the placebo cinnarizine was 0% [14].

Okada DM et al. (2006) conducted a randomized clinical double-blind controlled test on 76 tinnitus patients. In the case group (n = 38), a puncture was done at a site 6.5 cm above the apex of the ear, which is a parietal auditory area. In the control group (n = 38), puncture was done 3 cm above the previous site. Before and after the puncture, the VAS score assessment (0–10) was performed. ANOVA showed a significant difference (p < 0.001) in the scores before and after therapy in the case group and, compared to those in the control group, the scores in the therapy group were better [15].

To the best of our knowledge, the present study is the only one in Indonesia to explore the effectiveness of acupuncture in tinnitus treatment. Widya K (1993) studied 22 tinnitus patients who were not responsive to betahistine mesylate. The sites TE 17 Yifeng, TE 3 Zhongzhu, GB 20 Fengchi, KI 3 Taixi, and LR 3 Taichong were used. Manipulation was done with manual stimulation once every five minutes, for 20 minutes. The result showed that 78% (n = 18) of the patients had improvements [16].

Acupuncture acts via local and central mechanisms to initiate vasodilation of blood vessels, to decrease pain, and to regulate the neuroendocrine system [17].

There is no objective assessment for tinnitus yet. Therefore, often, questionnaire-based methods (interview), psycho-acoustic testing, and physiologic testing are used in practice. New findings in imaging including functional magnetic resonance imaging (fMRI) and magnetoencephalography allow objective tinnitus detection, although they cannot be used for clinical assessment yet [12].

Several questionnaires have been developed to assess the severity of tinnitus, which can be used as a parameter for therapy success. One questionnaire that is used often is the THI. Based on Azevedo et al., the THI is known to have the highest validity and reliability [18].

The THI is a questionnaire consisting of 25 questions which can be differentiated into three subscales; functional, emotional, and catastrophic. The functional subscale consists of 11 questions related to stress, concentration, sleeping disorders, disruption of work, disruption of homework, and disruption of social activity. The emotional subscale consists of nine questions regarding anger, frustration, irritability, anxiety, depression, and insecurity. The catastrophic subscale describes the
most severe reaction, assessed by evaluating five questions related to loss of self-control, hopelessness, and helplessness [19].

The present study aimed to evaluate the effectiveness of acupuncture in tinnitus treatment based on decrease in the THI scores.

2. Methods

The present study followed a clinical trial design, involving assessment before and after acupuncture therapy. The subjects were men and women aged 18–70 years old, who had been diagnosed with a sensorineural disorder and tinnitus complaints at the Cipto Mangunkusumo Hospital ENT polyclinic with a THI score ≥18. The subjects provided their informed consent, and participated in the study until completion. The subjects were not undergoing any other therapy for tinnitus, and did not have contraindications for acupuncture therapy (including severe hypertension, diabetes mellitus, fever, or pacemakers). The subjects were disqualified if they did not attend the therapy on schedule for two consecutive appointments, and did not complete 10 appointments.

The subjects were allocated to one group, and were assessed for THI scores before treatment; then, they were treated with acupuncture therapy using needle TE 17 Yifeng, SI 19 Tinggong, LI 4 Hegu, ST 36 Zusanli, and scalp auditory line type Jiao Sun Fa for 20 minutes. The therapy was done twice a week for 12 appointments, and the THI scores were evaluated after the 10th puncture. During the acupuncture therapy, the patients were not given any other therapy.

The number of subjects needed for statistical power was determined by á = 5%, â = 10%, and SD = 77.5 (based on the Okada DM study) [15]. Using this formula, the number obtained was 16 patients.

The THI score assessment was performed before the puncture and immediately after the 10th puncture in the ENT polyclinic of RSCM.

The success criteria in the THI is decided as stated below (Megwalu UC, 2006): [19]
Success: in 10 appointments, ≥10 point decrease in the THI score
Failure: in 10 appointments, <10 point decrease in the THI score

The main table shows the data collected in the study. It was analyzed statistically using a paired T test if the data distribution was normal, and the Wilcoxon test if the data distribution was skewed. The statistical software package SPSS was used for the analysis.

The study was approved by the Health Research Ethics Committee, Faculty of Medicine, Universitas Indonesia-Cipto Mangunkusumo Hospital (266/Pt02.FK/ETIK/2010). All the subjects participating in the study provided their non-disclosure and informed consent voluntarily.

This study was performed on 16 patients with sensorineural hearing disorders with tinnitus complaints, and THI ≥ 18. During the study, two patients dropped out because they could not finish all 10 appointments on schedule. Two new patients were, then, recruited to attain the number of samples needed for statistical analysis.

3. Results

This study was performed on 16 patients with sensorineural hearing disorders with tinnitus complaints, and THI ≥ 18. During the study, two patients dropped out because they could not finish all 10 appointments on schedule. Two new patients were, then, recruited to attain the number of samples needed for statistical analysis. Table 1 shows the patient characteristics.

Table 2 shows the mean functional THI subscale score before and after acupuncture. Based on the statistical analysis using paired T test, there was a significant decrease in the mean functional THI subscale score before and after acupuncture (p <0.05).
Table 1. Patient characteristics.

| Characteristics          | Number | %  |
|--------------------------|--------|----|
| **Age (years)**          |        |    |
| ≤20                      | 0      | 0  |
| 21–30                    | 5      | 31.3|
| 31–40                    | 0      | 0  |
| 41–50                    | 4      | 25 |
| 51–60                    | 3      | 18.8|
| 61–70                    | 4      | 25 |
| **Gender**               |        |    |
| Male                     | 10     | 62.5|
| Female                   | 6      | 37.5|
| **Education**            |        |    |
| Junior high school graduate | 1    | 6.3 |
| High school graduate     | 7      | 43.8|
| Undergraduate degree     | 1      | 6.3 |
| Bachelor degree          | 7      | 43.8|
| **Occupancy**            |        |    |
| Government employee      | 1      | 6.3 |
| Employee                 | 8      | 50 |
| Housewife                | 2      | 18.8|
| Entrepreneur             | 3      | 12.5|
| Retired                  | 2      | 12.5|
| **Complaint site**       |        |    |
| Bilateral                | 5      | 31.3|
| Left ear                 | 6      | 37.5|
| Right ear                | 5      | 31.3|
| **Duration of the complaint (years)** | | |
| <1                       | 7      | 43.8|
| 1–2                      | 6      | 37.5|
| 2–3                      | 0      | 0  |
| 3–4                      | 1      | 6.3 |
| 4–5                      | 0      | 0  |
| >5                       | 2      | 12.6|

After acupuncture

Table 2. Mean Functional THI Subscale Score before and after Acupuncture.

| Mean F Subscale | SD    | p   |
|-----------------|-------|-----|
| Before Acupuncture | 14.63 | 1.777 | 0.000 |
| After Acupuncture   | 9.75  | 1.548 |

Table 3. Mean Emotional THI Subscale Score before and after Acupuncture.

| Mean E subscale | SD    | p   |
|-----------------|-------|-----|
| Before Acupuncture | 8.88  | 7.446 | 0.002 |
| After Acupuncture   | 7     | 7.155 |
Table 3 shows the mean emotional THI subscale score before and after acupuncture. Based on the statistical analysis using paired T test, there was significant decrease in the mean emotional THI subscale score before and after acupuncture (p < 0.05).

| Mean C subscale | SD   | p   |
|-----------------|------|-----|
| Before Acupuncture | 6.50 | 5.586 | 0.003 |
| After Acupuncture  | 4.88 | 5.265 |

Table 4 shows the mean catastrophic THI subscale score before and after acupuncture. Based on the statistical analysis using paired T test, there was significant decrease in the mean catastrophic THI subscale score before and after acupuncture (p < 0.05).

| Mean total THI | SD   | p   |
|----------------|------|-----|
| Before Acupuncture | 30.00 | 14.715 | 0.000 |
| After Acupuncture  | 21.63 | 15.042 |

Table 5 shows the mean total THI score before and after acupuncture. Based on the statistical analysis using paired T test, there was a significant decrease in the mean THI score before and after acupuncture (p < 0.05).

As the figure 1 above shows, the functional, emotional, and catastrophic subscale scores were found to be decreased and, thus, the total THI score also decreased from 30 to 21.63.

| Patient number | %  |
|----------------|----|
| Success        | 56.3 |
| Failed         | 43.7 |
| Total          | 100 |
Table 6 shows the success rate of the therapy; out of 16 patients, nine patients (56.3%) showed a decrease in THI score of ≥10, while seven patients (43.7%) did not.

![Success Rate of the Therapy](image)

4. Discussion
The present study was focused on the effect of acupuncture on decreasing the THI scores in 16 patients with sensorineural hearing disorders with tinnitus complaints. The THI assessment was performed before and after the acupuncture, and the initial THI scores were ≥18.

Patients who met the inclusion criteria were included in the study. Manual stimulation acupuncture therapy was performed on the sites TE 17 Yifen, SI 19 Tinggong, scalp acupuncture auditory line, while the sites LI 4 Hegu and ST 36 Zusanli were subjected to electroacupuncture at 2 Hz frequency with dense disperse waves.

Puncture at the acupuncture sites stimulates changes at the local level and at the central nervous system level. At the local level, acupuncture causes heightened permeability of cell membranes, causing excitation of free nerve endings. Furthermore, vasoactive neuropeptides including calcitonin gene-related peptide (CGRP), P substances, and endorphin may be secreted, which activate mast cells to secrete histamine and serotonin. In the blood, CGRP would affect vasodilation through stimulation. Then, heightened vasodilation would initiate the functional healing of the organ [17].

At the central level, stimulation of the medulla spinalis through the ventroposterior thalamus would be transmitted to the thalamus, then, to the raphae nucleus (serotonergic), which would affect the limbic system (emotional management). Apart from the thalamus, stimulation of the medulla spinalis would also be transmitted to the hypophysis, which would secrete β-endorphins into the blood, decreasing pain. Increased β-endorphin secretion may be achieved with medium acupuncture stimulation and low frequency electroacupuncture (2 Hz) [17]. Moreover, acupuncture has been shown to specifically affect the limbic system [20,21].

The above mechanisms may mediate the effect of acupuncture in tinnitus patients by repairing organ functions, affecting emotions, and analgesia. The definite mechanism of the role of acupuncture in tinnitus patients has been unclear.

To the best of our knowledge, no study has explored the differences in the effect of acupuncture on tinnitus patients based on patient characteristics. The threshold of the mean THI score decrease was set as 10 points based on a study by Megwalu UC et al [19]. The statistical test used was paired T test with a confidence interval limit of 95%. The decrease in THI score after acupuncture therapy compared to that before therapy was found to be statistically significant (p<0.05). The mean functional subscale, emotional subscale, and catastrophic subscale scores were decreased. The decrease in mean was assessed statistically, and showed a significant difference (p < 0.05).

The success rate of the acupuncture therapy was found to be 56.3%, indicating that the present study had a good outcome. This was lower than the success rate reported in a study performed by
Widya DK (78%), [16] and higher than that in a study performed by Podoskin L (30%) [14]. However, a direct comparison of the studies is not possible because they used different methods, acupuncture sites, and assessment criteria.

A study performed by Herraiz C showed that TRT over 12 months decreased the mean THI score from 48% to 30%. In the present study, the mean THI score decreased from 30% to 20.63% due to a shorter series of acupuncture therapy [13]. Thus, the TRT appears to cause a larger decrease in the mean THI score, but with a longer period of therapy compared to acupuncture therapy.

The primary benefit of acupuncture therapy is its relative safety. In the present study, no hematomas were found after acupuncture, and the duration of therapy was shorter (one month) compared to TRT (1–1.5 years). The drawback of this therapy is that patients may be reluctant to undergo needle punctures.

The limitations of the present study include the fact that the study was not randomized and that a control group was not included, and the number of samples was limited. However, the results indicate that acupuncture therapy decreases mean THI with a significant success rate. We hope that there would be advanced studies with a larger number of samples and a randomized controlled trial design to validate our findings.

5. Conclusion

Acupuncture therapy showed beneficial effects in tinnitus patients, with a success rate of 56.3%. The mean THI score before therapy was 30 and that after therapy was 21.63 (p < 0.05).

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