

Therapeutic Effect of Electrical Stimulation on Chronic Tinnitus: A Double Blind Randomized Controlled Trial

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Abstract- Chronic tinnitus is a disturbing condition that may affect different aspects of life. In this study, the therapeutic effect of electrical stimulation on chronic tinnitus was assessed. This was a clinical trial on 49 patients with persistent tinnitus for more than 6 months without a proper response to routine treatments. They were randomly allocated into two groups: the case group was treated with electrical stimulation for 6 sessions over 6 consecutive days, and the control group received a placebo. Before the intervention, one week and three months after the treatment sessions, patients were evaluated by comprehensive audiological assessments and hearing tests. The mean age of the participants was 40.37 ± 9.32 and 41.35 ± 9.24 in treatment and placebo groups, respectively. Tinnitus intensity was significantly decreased in the case group one week and three months after the treatment ($P < 0.05$). Tinnitus handicap inventory score significantly decreased in the treatment group one week and three months after the treatment ($P < 0.05$). There was no significant difference in tinnitus intensity after treatment, considering gender, age, tinnitus duration, and tinnitus type. Electrical stimulation could significantly reduce the severity of the tinnitus regardless of age, gender, duration, and type of tinnitus.

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Introduction

Tinnitus refers to the conscious perception of an auditory sensation when no external sound is present. It is a prevalent symptom in auditory system disorders. Epidemiological studies have shown that about 5-15% of the general population suffers from chronic tinnitus, and around 1-3% of the afflicted cases experience considerable impairment in their quality of life. Chronic tinnitus brings about a range of complaints such as irritability, depression, sleep disorders, lack of concentration, and discomfort (1,2).

Tinnitus is usually bilateral and, in many individuals, is associated with a sensorineural hearing loss. It has been shown that infections (68.5%), noise exposure (27.7%), and stress (23.4%) are the most common causes of tinnitus in patients aged less than 35 years. According to discordant damage hypothesis, tinnitus is related to basal membrane damage and occurs due to outer hair cells

injury or inactivation while inner hair cells are intact (3).

Different treatments for tinnitus have been proposed, including nutritional modification, behavioral therapy, antidepressants, anti-anxiety drugs, and herbal medicines (4). Given that none of these treatments alone or in combination with each other can completely cure tinnitus, food, and drug administration (FDA) has not yet approved any treatment for tinnitus (5).

Since chronic tinnitus is associated with the inappropriate organization of the auditory cortex, it is proposed that a change in auditory cortical excitability is probably effective in its improvement (6). It seems that electrical stimulations are transmitted through oval or round windows and stimulate hair cells, satellite ganglia, and the auditory nerve terminals through electrodes inserted into the ear canal; therefore, auditory nerve discharge synchronization increases, which may eventually lead to tinnitus suppression (7). Although many studies have shown the effect of electrical

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stimulation on improving chronic tinnitus, various degrees of improvements from 22% to 87% or even contradictory results have been reported in this regard (8,9).

Considering the high prevalence of this disorder, its debilitating effect on the individual's quality of life, and the absence of a well-documented therapeutic method, this study was conducted to evaluate the efficacy of electrical stimulation on suppressing chronic tinnitus.

Materials and Methods

This was a randomized, double-blind controlled trial on 85 patients suffering from chronic tinnitus who did not respond to routine treatments. Patients were consecutively selected from those referring to the otorhinolaryngology clinic and were randomly allocated into treatment (n=49) and placebo (n=36) groups. Randomization was performed using a random digits table. Inclusion criteria were: age between 18 and 75 years, and suffering from chronic mild, moderate or severe tinnitus (lasting more than 6 months). Patients with slight or catastrophic tinnitus, impaired cognitive abilities, malignant lesions in their ear, panic disorders, or psychotic symptoms, and those receiving any current treatments or a history of long-term consumption of psychiatric medications were excluded from the study.

After random allocation, medical history and complete clinical examination were made by an otolaryngology resident. All participants underwent audiological assessments and hearing tests including pure tone audiometry (PTA), speech audiometry (speech discrimination score (SDS), and speech reception threshold (SRT)), impedance audiometry, and psychoacoustic measures of tinnitus, including minimum masking level (MML), tinnitus loudness, residual inhibition (RI), and pitch matching test. All tests were done using a diagnostic audiometer (Interacoustic AC 40, Denmark, Headphone: TDH39).

Tinnitus type was defined as tonal and noise. In addition, each participant completed the Tinnitus Handicap Inventory (THI) in collaboration with an audiologist to determine tinnitus intensity (10). Participants should select one of the following options for each question: "Yes", "No", and "Sometimes". Each participant's overall score was calculated by adding all of his/her scores. The overall score ranged from 0 to 100, and grading was done as follows:

Grade 1: slight (THI= 0–16), only heard in a quiet environment.

Grade 2: mild (THI= 17–36), easily masked by

environmental sounds, and easily forgotten with activities.

Grade 3: moderate (THI= 37–56), may be noticed, even in the presence of background or environmental noise, although daily activities may still be performed.

Grade 4: severe (THI= 57–76), almost always heard, rarely, if ever, masked, with disturbed sleep, and interfering with the ability to carry out normal daily activities.

Grade 5: catastrophic (THI= 77–100), all tinnitus symptoms worse than grade 4.

Therapeutic intervention

After the complete initial evaluation, patients in the treatment group were treated with electrical stimulation for 6 sessions over 6 consecutive days. Each session lasted 20 minutes. Electrical stimulations were provided using ActivaDose II Device (Activa Tek, USA). For electrical stimulation, each patient laid down on the bed or sat on an armchair, his/her affected ear was cleaned with alcohol, and a special electrode, covered with a damp cloth, was placed in the mastoid part of the temporal bone. Considering the patient's tolerance, the electrical stimulation was conducted at a current intensity of 2 mA. After the last treatment session, each patient was fully examined in terms of side effects and changes in tinnitus.

In the placebo group, after inserting the electrode, the electrical current was not conducted.

Outcome measurement

One week and three months after the last treatment session, participants were evaluated again by the same audiological and psychoacoustic tests and THI.

Data analysis

Data were analyzed by SPSS software (version 20) using Student's *t*-test and *chi*-square test. A $P < 0.05$ was considered statistically significant.

The study was approved by the ethics committee of Shahid Sadoughi University of Medical Sciences (ethics code: IR.SSU.MEDICINE.REC.1395.180). The study protocol was explained, and then a written informed consent was obtained from each participant. The study protocol was also registered in the Thai Clinical Trial Registry under the following number: TCTR20190320001.

Results

Table 1 shows the baseline information of the

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participants in two groups. Age and male to female ratio were not significantly different between the two groups. The frequency of tinnitus severity categories was significantly different between the two groups.

Tinnitus type was tonal in 57.1% and 56.2% of treatment and placebo groups, respectively. Totally tinnitus was improved in 52% of the treatment group. Tinnitus intensity significantly decreased in the treatment group one week and three months after the treatment ($P < 0.001$) (Figure 1).

THI score significantly decreased in the treatment group one week and three months after the treatment ($P < 0.001$ for both follow-up assessments), but this decrease was not significant in the placebo group ($P = 0.067$ and $P = 0.069$ for follow-up assessment after 1 week and 3 months, respectively).

There was no significant difference in the response rate after treatment, considering gender, age, tinnitus duration, and tinnitus type (Table 2).

Table 1. Comparison of baseline information between two groups

Variable	Study group		P*
	Treatment	control	
Age (year)	40.36 ± 9.3	41.35 ± 9.2	NS
Gender	27 males 22 females	19 males 17 females	NS
Tinnitus intensity (THI)	Mild 19 (38.8%) Moderate 16 (32.6%) Severe 14 (28.6%)	Mild 16 (44.5%) Moderate 11 (30.5%) Severe 9 (25%)	S
Tinnitus intensity (dB)	5.48 ± 1.13	5.31 ± 1.12	NS
Tinnitus duration (year)	2.5 ± 1.2	2.6 ± 1.2	NS

S: significant, NS: not significant

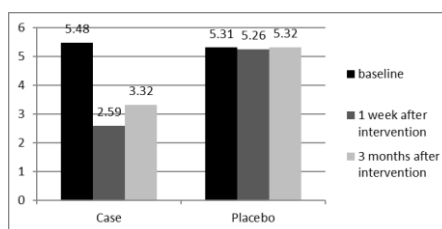


Figure 1. Comparison of tinnitus intensity before and on two occasions after the intervention.

Table 2. Comparison (P-value) of response rate after treatment considering gender, age, tinnitus duration and tinnitus type in the treatment group

Time of follow-up	Gender	Age	Tinnitus duration	Tinnitus type
1 week	0.45	0.21	0.13	0.07
3 months	0.26	0.07	0.32	0.24

Discussion

Mechanisms and possible causes of tinnitus are not well understood yet. Considering the high prevalence of this symptom and the fact that tinnitus can be annoying to affected individuals, many attempts have been made for its treatment or management (11). In the current study, the effect of external electrical stimulation on the improvement of tinnitus was investigated. The results of the current study indicated that tinnitus intensity and THI scores were significantly decreased one week and three months after electrical stimulation, but this effect was not observed in the placebo group. According to the results,

there was no significant difference in the response rate considering gender, age, tinnitus duration, and tinnitus type in the treatment group. However, the relationship between response rate and type of tinnitus was more impressive than other factors.

Farhadi et al. found that auditory electrical stimulation was a useful and effective therapeutic intervention in patients with tinnitus. In this clinical trial on 32 patients with moderate to severe persistent tinnitus, the patients received bipolar stimulation under 600-Hz burst currents (square waves) presented for a duration of 0.5 seconds in seven sessions of 30 minutes (12). The results were consistent with the results of the current study, although

their therapeutic protocol was somehow different from our protocol. Graham *et al.*, evaluated the electrical stimulation of the human cochlea using a trans-tympanic electrode and found that tinnitus was temporarily suppressed in two out of nine cases (13). Their results were in agreement with the current study, although they didn't assess long-term effects, in the current study, both temporary and long-term effects were evaluated one week and three months after treatment sessions.

In another study conducted by Berjis *et al.*, the efficacy of electrical stimulation of skin was investigated in patients with tinnitus. They found beneficial effects for transcutaneous electrical nerve stimulation in the treatment of tinnitus, especially in young people with a short history of high-frequency tinnitus (14).

Engelberg *et al.*, evaluated transdermal electrical stimulation to treat tinnitus in an experimental study. A single-blind protocol with 20 subjects comprising 33 ears with tinnitus was carried out. At last, 82% of 33 ears showed improvement (15). The rate of improvement in this study was higher than the present study.

In the present study, no significant difference was observed before and after the treatment with electrical stimulation with respect to tinnitus pitch, which is in agreement with findings of Watanab's *et al.*, study (16). Different studies have achieved a 50% to 87% improvement in tinnitus after electrical stimulation. In the present study, comparable to other studies, this measure was about 52%; although it should be considered that different treatment protocols with different devices have been used in different studies (Portman achieved 87% improvement, Watanabe 52%, Mahmudian 53.4%, and Chanals 54%).

In the present study, tinnitus loudness decreased significantly following electrical stimulation. In the Forogh *et al.*, study, consistent with the results of the current study, the efficacy of electrical stimulation in the suppression of symptoms accompanied by tinnitus was proved (17), although they used only questionnaires, we used psychoacoustic measures as well as a questionnaire. Kathleen *et al.*, evaluated the differential effect of low-versus high-frequency random noise stimulation in the treatment of tinnitus in 154 patients with chronic tinnitus. Similar to the current investigation, tinnitus severity was assessed by psychoacoustic measures in their study (18). The only difference between these two studies was that Kathleen *et al.* regarded stimulation intensity as one of the investigated variables. The currents of 1.5 mA and 2 mA were used in their study. The results indicated the efficacy of 2 mA stimulation for suppressing tinnitus. Yadollahi *et al.* explored the effect of electrical stimulation on 17

patients with chronic tinnitus. Patients received electrical stimulation for 5 consecutive days, and then they were examined one week and one month later. They found tinnitus improvement after one week, but no significant difference was observed between improvements that occurred after one week, and those occurred after one month (19).

According to the results of this study, electrical stimulation can probably improve tinnitus or reduce its severity.

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