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Acupuncture Treatment in Patients with Chronic Subjective Tinnitus: A Prospective, Randomized Study

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ABSTRACT

Objective: This study investigated the effect, onset, duration of action, and short-term outcomes of acupuncture therapy for treating patients with severe chronic subjective tinnitus.

Materials and Methods: This randomized controlled trial evaluated patients with chronic, idiopathic, and severe tinnitus. A total of 105 participants were divided into 2 groups using a randomization method: a study group who received verum acupuncture therapy ($n=53$) and a sham acupuncture group ($n=52$). Ten acupuncture sessions were given over 5 weeks. After treatment, each participant was monitored for up to 3 months according to changes on a visual analogue Scale (VAS), and Tinnitus Handicap Inventory (THI), and Pure-Tone Audiometry and Speech Discrimination (Interacoustics AC-40, Denmark) scores.

Results: The VAS and THI scores were evaluated. A statistically significant difference was noted between the sham and verum acupuncture groups at post-treatment follow-up ($P<0.001$). Decreases in the THI and VAS scores became significant in the second week of treatment ($P<0.001$ and $P<0.001$, respectively), but these scores increased again in the third month post-treatment ($P<0.001$ and $P<0.001$, respectively).

Conclusions: Acupuncture is an effective treatment for patients with severe chronic subjective tinnitus. Patient complaints, decreased beginning at the second treatment week; however, in the third post-treatment month, the complaints reappeared. Maintenance acupuncture therapy is necessary for patients with tinnitus; this approach should be investigated in future studies.

Keywords: complementary and alternative medicine, neurologic disorders, peripheral neuropathy, sham, otology

INTRODUCTION

Tinnitus is a common symptom encountered in otolaryngology practice; this symptom has a mechanism that has not yet been elucidated fully.[1] Tinnitus is often defined as the perception of sound without an external acoustic stimulus. It is seen in ~1% of adults, of whom 5%–15% are reported to have persistent symptoms that do not respond to treatment.[2] In addition, 1%–3% of the tinnitus population has mental stress, sleep disturbances, and reduced work efficiency.[3–5] Although many hypotheses have been proposed for tinnitus' etiology, the mechanism is not yet known fully. The sound perceived without an external stimulus is considered to be caused by abnormal neural activity along the hearing path from the cochlear apparatus to the auditory cortex.[6]

Complementary and alternative medicine treatments are often used to treat tinnitus, and one of the most frequently used options is acupuncture.[7] Acupuncture therapy in patients who have tinnitus has been described extensively in books[8]; however, scientific literature still lacks studies that support its therapeutic efficacy. Research has shown that stimulation with needles promotes an electrical conduction that triggers action potentials to rebalance the body's

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system,[8] but the effect of this stimulation on tinnitus remains unclear. In a literature review, 36 publications on this subject were analyzed, but only 6 of them were randomized controlled trials.[9] The authors of the systematic review noted that the points where acupuncture was applied were heterogeneous and that the results were controversial. In addition, it was noted that most studies reporting recovery after treatment had not followed the patients after treatment. Therefore, it is necessary to conduct further studies designed according to the highest methodological standards.

The goal of this study was to investigate the efficacy of acupuncture therapy in patients with severe, chronic subjective tinnitus, determine the onset of treatment, and report the short-term follow-up results of acupuncture as a treatment for tinnitus.

MATERIALS AND METHODS

This was a prospective, randomized controlled study, approved by the local ethics committee (ethics committee of Ankara Numune Training and Research Hospital, Ankara, Turkey) and carried out in a single center in accordance with the ethical principles of the Helsinki Declaration (ethics committee no: E-18-2165; registration number and name of trial registry: NCT04127708/aksarayUTRH; tinnitusacupuncture).

The inclusion criteria of the study for patients were determined as:

(1) Male or female, ages 18–60
(2) Unilateral or bilateral subjective tinnitus
(3) History of severe subjective tinnitus for at least 1 year
(4) Severe tinnitus according to the Tinnitus Handicap Inventory (THI) questionnaire (more than 38 points)
(5) undetectable etiology of tinnitus in an otolaryngology examination
(6) No treatment received within the last 6 months.

Patients who applied to the otorhinolaryngology clinic of the Ankara Numune Training and Research Hospital and who fit the criteria were included in the study. The THI and a visual analogue scale (VAS) were administered to the patients. Severity of each patient's tinnitus was determined by the THI questionnaire.

Exclusion criteria were having: received acupuncture therapy during the last 3 months for any reason; a history of medication/surgery due to heart disease; a disease that could cause objective tinnitus (such as Meniere's syndrome, otitis media, and otosclerosis); metal allergy or needle phobia; and/or psychotropic drug use. Pregnancy or nursing and not completing the THI survey were also reasons for exclusion.

A researcher evaluated the patients meeting the sample criteria, informed them, and received their written consents. The patients who agreed to participate in the study were divided into 2 groups as follows: Participants were randomly assigned to either a manipulation or a non-manipulation group, with an assignment ratio of 1:1 according to the random number of an allocation sequence generated by a computer (using SPSS 21.0 statistical software package, IBM, Chicago, IL). The first group was comprised of patients who received verum manual acupuncture, and the second group, served as a control group who received sham acupuncture.

According to the randomization method, the group to which each participant was assigned was only known to the researcher who applied the acupuncture. The participants and the remaining researchers who administered the THI to the participants were blinded to the group assignments.

The data were obtained from the patients' responses to the VAS and THI. Each participant completed the VAS and THI questionnaires 7 times during the course of the 5-week treatment and the 3-month follow-up after treatment.

During the acupuncture therapy, the patients were also examined in terms of possible complications related to acupuncture, such as infections, nervous system damage, and heart damage. Patients who developed any of these complications were excluded from the study.

Intervention

The acupuncture style used was the Traditional Chinese Medicine model. Acupuncture was performed on 11 acupuncture points (TE 21, SI 19, GB 2, TE 22, ST 7, TE 17, and GB 20 of the affected side, and GB 20, TE 5, KI 3 of both sides), using sterile, single-use, 0.25 mm thick, 40-mm long needles (Dongbang Medical Co., Boryeong, Korea). The acupuncture points were selected according to a previous study as a reference.[2] The depth of the needle differed

Table 1. Pretreatment Characteristics of the Participants

Characteristics	*Verum acupuncture group* (n = *53*)	*Sham acupuncture group* (n = *52*)	P
Age (yrs ± SD)	50.70 ± 9.96	47.63 ± 11.35	0.144
Gender, (*n* %)			
Female	34 (%64)	35 (%67)	0.289
Male	19 (%36)	17 (%33)	
Hearing, (*n* %)			
Bilateral loss	43 (%81)	44 (%84)	
No loss	10 (%19)	8 (%16)	
Hearing loss grade, (*n* %)			
Normal with decrease	15 (%28)	16 (%31)	
Mild	12 (%23)	12 (%23)	
Moderate	13 (%25)	14 (%27)	
Severe	3 (%1)	2 (%1)	

yrs, years; SD, standard deviation.

Table 2. Intergroup and Intragroup Comparisons of THI and VAS Scores During Treatment Evaluation Sessions

	Verum acupuncture group (n:53)		*Sham acupuncture group (n:52)*			
Time	*THI (Mean ± SD)*	*VAS (Mean ± SD)*	*THI (Mean ± SD)*	*VAS (Mean ± SD)*	p**	p***
T1	61.11 ± 12.70	7.26 ± 0.98	59.25 ± 13.10	6.98 ± 1.12	0.461	0.174
T2	47.92 ± 13.65	4.92 ± 1.17	52.38 ± 14.19	6.02 ± 1.83	0.104	**< 0.001**
T3	35.92 ± 15.27	2.41 ± 1.09	56.52 ± 12.08	6.27 ± 1.56	**< 0.001**	**< 0.001**
T4	33.85 ± 14.93	2.20 ± 1.09	56.37 ± 12.20	6.39 ± 1.43	**< 0.001**	**< 0.001**
T5	32.30 ± 15.40	2.16 ± 1.12	57.87 ± 13.12	6.19 ± 1.57	**< 0.001**	**< 0.001**
T6	30.83 ± 15.90	2.06 ± 1.09	59.01 ± 13.35	6.75 ± 1.19	**< 0.001**	**< 0.001**
T7	40.26 ± 16.56	3.66 ± 1.38	60.71 ± 13.90	6.84 ± 1.18	**< 0.001**	**< 0.001**
*P**	**< 0.001**	**< 0.001**	0.090	0.078		

Times: T1, Pretreatment; T2, treatment 1st week; T3, treatment 2nd week; T4, treatment 3rd week; T5, treatment 4th week; T6, treatment 5th week; T7, Post-treatment 3rd month.

*P**, repeated measurements analysis of variance; *P***, Mann–Whitney-*U* test (THI); *P****, Mann–Whitney-*U* test (VAS). Significant results are shown in bold.

THI, Tinnitus Handicap Inventory; VAS, visual analogue scale; SD, standard deviation.

depending on the anatomical structure of the participant and the nature of the acupuncture points, but was ~5–10 mm. The acupuncture needles were applied until the participant experienced De Qi and removed after 20 minutes.

Acupuncture therapy was performed twice per week for 5 weeks, for a total of 10 sessions. The acupuncture treatment was conducted by an expert who was supervised by other researchers. None of the participants withdrew from the planned tinnitus treatment program during the study.

In the control group (sham acupuncture), false needles were used and no stimulation was applied. These needles were harmless to the skin.

The patients were given acupuncture therapy by an acupuncturist with an acupuncture certificate and 5 years of acupuncture experience.

Visual Analogue Scale

This scale was administered verbally to determine the degree of discomfort caused by tinnitus for the patients. The scores ranged from 0, indicating no discomfort, to 10, indicating unbearable discomfort.

Tinnitus Handicap Inventory

The THI is a survey of 25 items with scoring based on 3 options: yes (4 points); sometimes (2 points); and no (0 points). The total THI score indicates the degree of tinnitus, classified as grade 1 (0–16 points), grade 2 (18–36 points), grade 3 (38–56 points), grade 4 (58–76 points), or grade 5 (78–100 points). Patients with grades 3, 4, or 5 per the THI score were considered as having severe tinnitus and were included in the study.

Pure-Tone Audiometry and Speech Discrimination

A Pure-Tone Audiometry (PTA) and Speech Discrimination test (Interacoustics AC-40, Denmark) was performed at the first, sixth, and seventh visits by the same clinical audiometrist.

Statistical Analysis

The data were analyzed descriptively and analytically. As the assumption of normality was not met, the data were shown as median and its quartiles (first–third). The categorical variables were obtained as absolute and relative frequencies.

The Shapiro–Wilk test was used to check the normality of the data. Mann–Whitney-*U* and Wilcoxon tests were used for nonparametric variables. Student's *t*-test and a paired samples *t*-test were used for parametric variables. All results

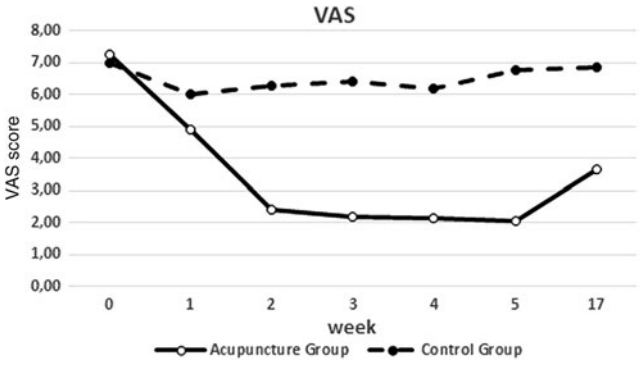

FIG. 1. Intergroup comparison of the visual analogue scale (VAS) scores during the treatment evaluation sessions.

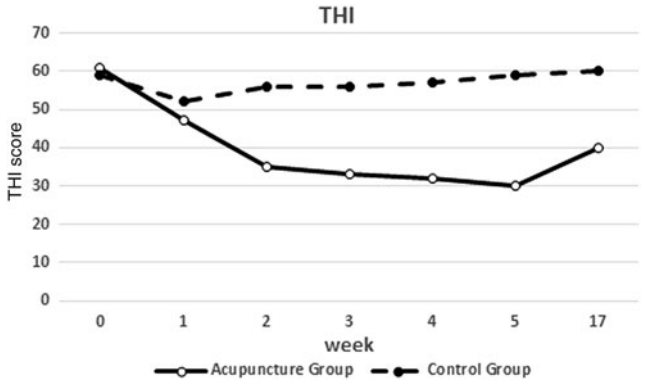

FIG. 2. Intergroup comparison of Tinnitus Handicap Inventory (THI) scores during the treatment evaluation sessions.

were analyzed with the intention-to-treat technique, using SPSS software version 21.0. Statistical significance was set at 5% ($P \leq 0.05$).

Given that there were 52 and 53 patients in the control and study groups, respectively, the power of this study was 0.95044 (95%).

RESULTS

A total of 179 subjects with chronic severe subjective tinnitus were initially evaluated. After applying the relevant criteria, 70 patients (39.1%) were excluded from the study. Of the remaining 109 participants (60.9%), 105 (92%) completed the study. The descriptive characteristics of the sample are shown in Table 1.The verum acupuncture group consisted of 53 participants, 19 males and 34 females, with a mean age of 50.70 ± 9.96 years. In the control (sham acupuncture) group, there were 52 participants, 17 males and 35 females, with a mean age of 47.63 ± 11.35 years.

When VAS score was evaluated as the primary outcome, a statistically significant difference was observed between the control group and the verum acupuncture group in the post-treatment follow-up ($P < 0.001$). This follow-up by weeks is given in detail in Table-2. The verum acupuncture group's pre- and post-treatment scores were compared, and the group's post-treatment scores were significantly decreased ($P < 0.001$). In this group, there was a significant difference between baseline VAS scores and VAS scores obtained immediately after treatment and at the 12th week post-treatment ($P < 0.001$; Table 2). In both groups, the data showed an almost 50% reduction in tinnitus intensity when comparing pretreatment and post-treatment scores (Table 2; Fig. 1).

The THI score, which was the secondary outcome, represented improvement in the patients' quality of life. When the sham acupuncture and verum acupuncture groups were compared in terms of THI, the verum acupuncture group was found to have statistically significant improvement after the 2nd week of treatment ($P < 0.001$). A detailed comparison of the groups in terms of THI is given in Table-2. Within the verum acupuncture group, there was a statistically significant difference between pretreatment and post-treatment THI scores ($p < 0.001$; Table 2). According to the THI scores, the severity of tinnitus in the verum acupuncture group decreased from grade 4 at baseline to grade 2 after treatment. In the shame acupuncture group, the THI values did not differ statistically significantly before and after treatment ($P = 0.090$; Table 2). There was no statistically significant difference between the 2 groups concerning baseline THI scores ($P = 0.461$). However, when the two groups were compared in terms of post-treatment THI scores, the results in favor of the verum acupuncture group were statistically significant ($P < 0.001$; Table 2; Fig. 2).

Evaluation of the third outcome (i.e., PTA and Speech Discrimination values) revealed no statistically significant difference within the verum acupuncture group before and after treatment ($P = 0.159$ and $P = 0.176$, respectively; Table 3). Similarly, the pretreatment PTA and Speech Discrimination values did not significantly differ between the verum and sham acupuncture groups ($P = 0.805$; $P = 0.519$, respectively; Table 3).

DISCUSSION

Ten sessions of acupuncture therapy were applied to patients with severe chronic subjective tinnitus over 5 weeks,

Table 3. Intergroup and Intragroup Comparison of PTA and Speech Discrimination Scores

	Verum acupuncture group (n = 53)		*Sham acupuncture group (n = 52)*			
	PTA (Mean ± SD)	*Speech discrimination (Mean ± SD)*	*PTA (Mean ± SD)*	*Speech discrimination (Mean ± SD)*	p**	p***
T1	31.47 ± 20.53	80.86 ± 15.52	30.25 ± 21.72	81.11 ± 15.60	0.768	0.935
T7	31.03 ± 19.99	81.47 ± 15.66	30.03 ± 21.15	79.54 ± 14.94	0.805	0.519
*p**	0.159	0.176	0.129	0.615		

Times: T1, pretreatment; T7, post-treatment 3rd month.

*P**, repeated measurements analysis of variance; *P***, Mann–Whitney-*U* test (PTA); *P****, Mann–Whitney-*U* test (Speech Discrimination).

PTA, Pure Tone Audiometry (Interacoustics AC-40, Denmark); SD, standard deviation.

and the patients were followed up for 3 months after treatment. The THI and VAS scores were significantly lower in the group who received verum acupuncture compared to the group who received sham acupuncture. However, the THI and VAS scores began to increase again at the third follow-up month.

One of the parameters commonly used in studies to monitor the severity of tinnitus is VAS score. In a previous study, VAS score was reported to decrease from 9.56 to 2.88 in tinnitus patients who underwent acupuncture therapy.[10] In another study, the mean pretreatment VAS score was 8, which was reduced to 4 after treatment.[8] Similarly, in the current study, the mean post-treatment VAS score of the study group was statistically significantly reduced compared to the baseline value.

Another parameter used to determine the severity of tinnitus complaints is theTHI.[2,5,8] THI score has also been evaluated in studies investigating the effectiveness of acupuncture therapy.[2,8] For example, in a randomized controlled study by Laureano et al., the efficacy of acupuncture therapy for patients with tinnitus was compared based on the THI scores of treated and untreated groups, and a statistically significant decrease was observed after treatment compared to the baseline values.[11] In another study including 50 patients with tinnitus,[8] the severity of the disease was monitored using the THI. The authors of that study reported that the THI score of the acupuncture group was reduced from 56 at baseline to 28 after treatment.[8] Similarly, in the verum acupuncture group of the current study, the mean THI score before treatment was 61, which was decreased to 30 after treatment.

Unlike other studies in the literature, the THI measure was also utilized to determine the onset of action of acupuncture; the decrease in the THI score became significant in the second week of treatment. Increases in THI scores were also detected at the third follow-up month after treatment. Thus, acupuncture therapy was an effective treatment for tinnitus, but the effect appeared to be temporary, diminishing over time.

CONCLUSIONS

Based on the results of this study, verum acupuncture is an effective treatment, compared to sham acupuncture for treating severe chronic subjective tinnitus. However, despite the significant benefits of this acupuncture therapy, the patients' tinnitus symptoms began to increase again at 3 months after treatment. Therefore, in future studies, the current authors recommend that maintenance acupuncture sessions be added to the 5-week acupuncture therapy for patients with tinnitus to investigate the effectiveness of this treatment over a long-term follow-up.

AUTHOR DISCLOSURE STATEMENT

No financial conflicts of interest exist.

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