

Original Article**The effects of acupuncture on the inner ear originated tinnitus****Mehrdad Rogha¹, Mehran Rezvan², Ali Reza Khodami³***Abstract**

BACKGROUND: Tinnitus is a chronic and bothering problem which in some patients may lead to some psychological reactions. While tinnitus may be caused due to some definable structural abnormalities, sometimes no structural etiologic defect can be found. This study aimed to evaluate the therapeutic effects of acupuncture on the inner ear originated tinnitus in the latter mentioned group.

METHODS: This prospective clinical trial study has been done in Alzahra and Kashani hospitals in Isfahan, Iran during 2010-2011. Simple sampling was used to select patients who were then divided into two groups of true acupuncture group and placebo group. The number of patients in each group was 27. The hospital anxiety and depression scale (HADS), tinnitus severity index questionnaire, and tinnitus loudness scale were completed by the patients. Two latter questionnaires were completed again after the 5th and 10th sessions of acupuncture treatment. The case group was treated with effective acupuncture with true acupuncture needles while the control group was treated ineffectively, i.e. similar to the usual acupuncture method but with fake needles. Independent t-test was used to compare the mean of tinnitus severity index and loudness scores between the two groups. We also used repeated measures ANOVA test to compare the mean of tinnitus severity index and loudness for different assessments in either group.

RESULTS: After the 5th and 10th sessions of treatment, the mean of tinnitus severity index reduced significantly only in the case group ($p = 0.002$, and $p = 0.001$, respectively). In addition, the quality of life in the case group also improved after the treatment. Moreover, the mean of tinnitus loudness also reduced significantly only in the case group after 5 and 10 sessions of treatment ($p = 0.001$, and $p < 0.001$, respectively).

CONCLUSIONS: It seems that acupuncture can improve tinnitus in some selected patients.

KEYWORDS: Tinnitus, Acupuncture, Hearing Loss, Inner Ear.

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Tinnitus is a term to describe the perception of sound within the human ear in the absence of corresponding external sound. While the prevalence of tinnitus in people with normal hearing is 26.6%, it increases to 35.1% in people with hearing loss.¹ The incidence of tinnitus is not related with age or sex.² The problem is categorized into two types, namely objective and subjective. Objective tinnitus is recordable and mostly has a vascular or muscular origin. Subjective tinnitus is more common and cannot be heard by

the examiner. The 5 year incidence rate of subjective type is about 5.7%.³

The prevalence of tinnitus based on its definition and the population of study is estimated to be 8-30%.²⁻⁴ Although the underlying pathology idiopathic tinnitus is unknown, cochlear pathology and somatic modifications are all probable mechanisms. In patients with hearing loss, decreased neural input from cochlea toward cortex and chronic decrease in afferent neural activity lead to a change in brain stem activity which is in turn responsible

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for tinnitus sensation.⁵ Stimulation interferences, which restore the normal afferent input, may return the cortex tonotropism to the base level and therefore can be used for subjective tinnitus alleviation. Acoustic therapy is one of the treatment methods that might be effective in decreasing or removing abnormal cortex organization relating to tinnitus.⁶ Other treatment methods including acoustic desensitizing methods,⁷ behavioral cognitive treatments, transcervical magnetic stimulation,⁸ and pharmacological treatment (sedatives and anticonvulsants) have been already mentioned but these methods are not universally effective and should be selected based on individual responses. In addition, each treatment method has its own side effects (like sedation following sedative treatment).

Another treatment method for subjective tinnitus, especially for those with somatic triggers, is acupuncture. There is a theory stating that therapeutic effects might be elicited by placing certain needles in selected regions on acupuncture meridians relating to specific organs.⁹ In animal and human studies, acupuncture points (acupoints) stimulation led to neurohumoral changes and modification in neurotransmitters released in central nervous system (CNS) such as serotonin, oxytocin and endorphin.^{10, 11} Moreover, functional magnetic resonance imaging (fMRI) technique revealed alterations in the blood flow of different parts of the brain following acupuncture stimulation. We examined and treated the patients based on the diagnostic pattern of traditional Chinese medicine (TCM). In addition, acupoints were selected for each patient individually according to tinnitus related syndrome. Therefore, we think that this modification may have a role to make this modality more effective.

Methods

This double blind clinical trial study (Irct ID: IRCT201106036699N1) has been approved by the Ethics Committee of Isfahan University of Medical Sciences (project number: 389104). In

addition, written informed consents were taken from all patients.

The study population included patients referring to Alzahra and Kashani hospitals during 2010-2011 with chronic tinnitus whose history, physical examination, and imaging studies did not reveal any structural etiology for their complaint. They also had to accept the treatment schedule. However, patients with a certain structural cause of tinnitus or unwillingness to cooperate were excluded. Using simple sampling method, a total number of 54 patients were studied in two groups of 27. The patients were randomly allocated in the case and control groups. First, the patients were asked about their history. Then, physical examination was done and further diagnostic imaging modality such as MRI was applied whenever necessary. Tinnitus severity index questionnaire taken from 2005 Cummings textbook (a standard questionnaire with 13 items for quality of life in patients suffering tinnitus), tinnitus loudness questionnaire, and hospital anxiety and depression scale (HADS) were used to collect data. The patients of the case group took part in 10 sessions of effective acupuncture every other day. The control group underwent the same procedure but ineffectively (by fake needles). After sessions 5 and 10, all patients completed the tinnitus severity questionnaire and loudness questionnaire again.

Before acupuncture was performed, patients were examined based on the diagnostic pattern of traditional Chinese medicine (TCM). Then, the appropriate acupoints for treatment were selected according to tinnitus related syndrome. Basic points (according to the World Health Organization (WHO) format) which are manipulated in the acupuncture medicine include TE₁₇, GB₂, SI₁₉, and TE₂₁. However, according to TCM, several secondary (accessory) acupoints were also added as follows:^{12, 13}

- 1- TE₃, TE₅, TE₁₇, GB₈, GB₂₀, GB₄₃, LR₂
- 2- LI₄, SP₉, ST₄₀, SI₁₉, TE₃, TE₂₁, BL₂₀, GB₂₀, GB₂, CV₉, CV₁₂, TE₅

3- SP6, HT6, BL23, KI3, KI7, GB2, LR3, GV4, CV4

4- LU9, SI19, BL13, TE16, GV20, CV6, CV17

5- SP6, SI19, BL15, PC6, GV20, CV14

In this study, modified Park sham device and true Park needles (needle length: 25 mm; needle diameter: 0.25 mm) were used for the control and case groups, respectively (Figure 2).

The difference between modified park sham device and the real park sham device is in the spongy piece in the needle pedestal which can maintain the needle in its place even in case of body movement. In the case group, the true needle dipped in to the end of the pedestal and

then into the skin. However, in the control group the modified sham needle reached the skin but it did not enter the skin, i.e. the needle dipped in its handle like a trick sword. Patients were followed until the end of 10th session of treatment to compare the mean of tinnitus severity index and tinnitus loudness grade between the two groups. Independent t-test and covariance analysis were used for assessment of data, while ANOVA was used for comparing the variables at different times in the two groups. In order to control the blemishing effect of anxiety and depression, we used covariance analysis. A p value lower than 0.05

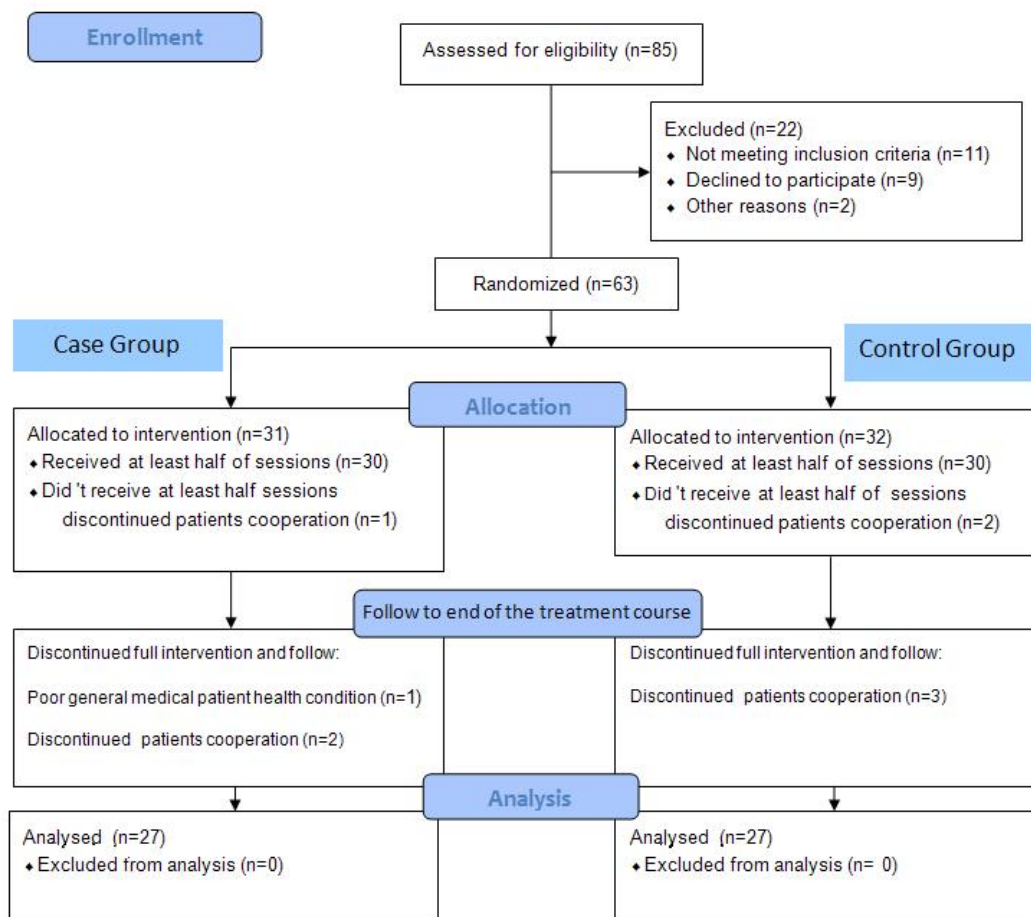


Figure 1. Flow diagram of initial randomized patients.

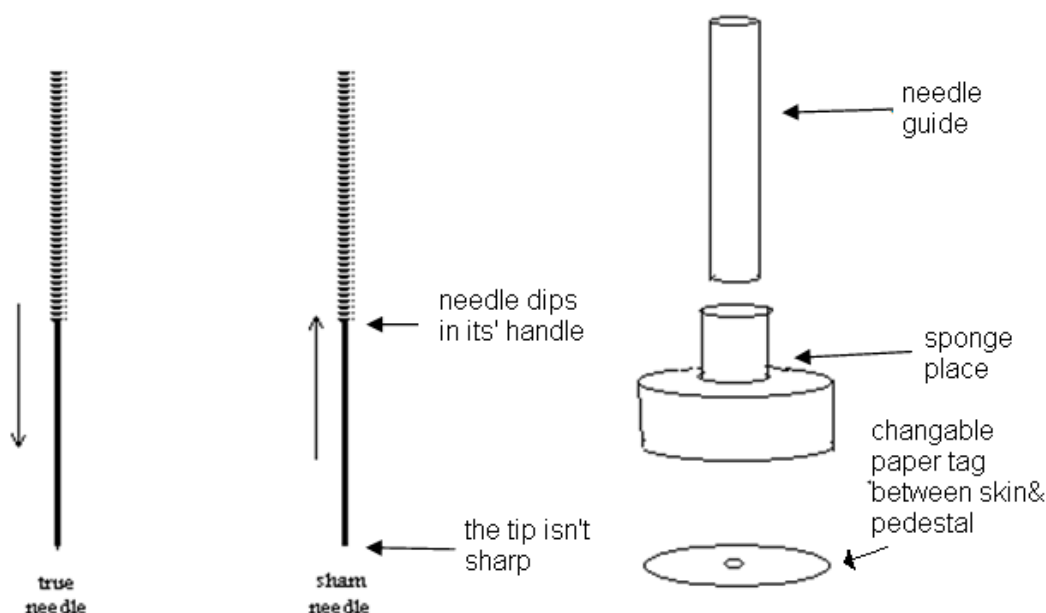


Figure 2. Sham and true acupuncture needles.

was considered as statistically significant in this study. SPSS 18 (IBM Company, Chicago) software was used for data analysis.

Results

In the present study, the average age of the patients was 45.6 ± 13.55 and 49.2 ± 14.3 in the case and control groups, respectively. Independent t-test did not show meaningful significant difference in age between the two groups. While the case group consisted of 48.1% females and 51.9% males, the control group constituted of 51.9% females and 48.1% males. Chi-square test did not reveal a significant difference in sex distribution between the two groups ($p = 0.780$). The mean of anxiety scores were 9.7 ± 3.9 and 9.8 ± 3.8 in the case and control groups, respectively. In addition, the mean of depression grade was 9.1 ± 3.4 and 9.2 ± 3.2 in the case and control groups, respectively. Covariance analysis and independent t-test did not show a significant difference in the average anxiety scores in the two groups ($p = 0.976$). Moreover, no significant differences in the mean of depression grade ($p = 0.934$) and the mean of tinnitus severity index ($p = 0.89$) were found by independent t-test between the two

groups before treatment. However, after the 5th and 10th sessions of treatment, tinnitus severity index grade in the case group was significantly less than the control group, i.e. the case group responded better to treatment (Table 1). Analysis of variance with repeated observations showed that although the mean of tinnitus severity index in the case group after treatment decreased significantly, in the results were not significantly different from the control group by three-time assessments (Table 2).

Although mean loudness grade did not significantly differ in the two groups before treatment ($p = 0.66$), it was significantly less in the case group after 5 and 10 sessions. Analysis of variance with repeated observations indicated that the mean of tinnitus loudness/severity in the case group significantly decreased after the treatment ($p < 0.001$). However, the observed decrease in the control group was not significant ($p = 0.063$). Even though 5 patients in the case group experienced transient sedation following treatment and one case of vasovagal shock was observed in the first session of treatment in the case group, no major complications were detected in any of the two groups after the treatment.

Table 1. Mean and standard deviation of tinnitus severity index and tinnitus loudness range of variations following treatment in two groups (All numbers are expressed as mean (SD)).

| | Case group | | Control group | | P value* | p value** |
|-------------------------------------|-------------------------|----------------------------|-------------------------|----------------------------|----------|-----------|
| | Tinnitus severity index | Tinnitus loudness severity | Tinnitus severity index | Tinnitus loudness severity | | |
| After the 5th session of treatment | -8.3 (7.7) | -2.1 (1.7) | -2.4 (5.2) | -0.7 (1.1) | 0.002 | 0.001 |
| After the 10th session of treatment | -15.2 (11.2) | -3.6 (2.7) | -3.7 (8.2) | -1.2 (1.8) | 0.001 | |
| | | | | | | <0.001 |

* Tinnitus severity index range of variations p value

** Tinnitus loudness range of variations p value

Discussion

There is a wide variety of results from different studies on tinnitus treatment. In our study, male patients constituted 51.9% and 48.1% of the subjects in the case and control groups, respectively. In the study of Renta Fransson et al. more than 60% of patients were female.¹⁴ According to the latest scientific results, tinnitus incidence is roughly equal in men and women.² While Renata Fransson et al. reported the mean age of patients in the case and control groups to be 55 and 57 years, respectively,¹⁴ the corresponding figures were 45.6 and 49.2 in the present study. Anxiety and depression are common in tinnitus patients and there is a mutual relation between tinnitus and anxiety or

depression. All individuals in this study were evaluated for depression and anxiety according to HADS. Nevertheless, since the distribution of patients with the mentioned problems has been nearly equal in the case and control groups, there would depression and anxiety would not affect the results of the study.

The mean of tinnitus severity index before the beginning of the study in did not significantly differ in the two groups. However, after 5 sessions of treatment by acupuncture, tinnitus severity index in the case group was decreased. An improvement of quality of life was also observed in this group. On the contrary, 5 sessions of treatment did not significantly reduce tinnitus severity index in the control

Table 2. Triple tinnitus severity index and tinnitus loudness according to timetable in the two groups (All numbers are expressed as mean (SD)).

| | Case group | | Control group | | P value | P value# |
|--------------------------------|-------------------------|----------------------------|-------------------------|----------------------------|---------|----------|
| | Tinnitus severity index | Tinnitus loudness severity | Tinnitus severity index | Tinnitus loudness severity | | |
| Before the treatment | 46.9 (7.9) | 8.9 (1.3) | 46.6 (7.6) | 8.7 (1.1) | 0.89* | 0.66** |
| After 5 sessions of treatment | 38.6 (9.1) | 6.7 (2.4) | 44.2(9.1) | 8 (1.4) | 0.03 | |
| After 10 sessions of treatment | 31.7 (11.1) | 5.3 (3) | 42.9(10.4) | 7.5 (2.2) | 0.001 | 0.004 |
| P ## | < 0.001 | < 0.001 | 0.07 | 0.063 | | |

* Tinnitus severity index p value

** Tinnitus loudness p value

Independent T test

Analysis of variance with repeated observations ANOVA

group. In a study by Hansen et al., the symptoms considerably improved in both control and case groups after 6 sessions of acupuncture which undermines the hypothesis of acupuncture being effective in improving tinnitus severity.⁹ Marks et al. reported only a partial improvement in the control group after 2 sessions of treatment by acupuncture which was not confirmed by objective tests. In addition, they did not find a significant difference between pre- and post-treatment states.¹⁵ Podoshin et al. compared the treatment effects of acupuncture, cetirizine and biofeedback after 10 sessions of treatment. Although they declared the three methods to be 30%, 10% and 50% effective, respectively, but there was not any considerable treatment objectively.¹⁶ In the study of Axelsson et al. acupunctured the patients 3 times a week for 5 weeks. They stimulated the control group by electrical pulses to arise a false sense of needle punctures in these patients. The study results showed no significant improvement of tinnitus, although a little improvement was observed in general conditions of the patients.¹⁷ In a study conducted by Wang K et al., the results after 6 sessions of treatment indicated no statistically significant difference between the effects of manual and electrical acupuncture on tinnitus treatment efficacy.¹⁸

Latifpour et al. observed a great decrease of tinnitus using acupuncture accompanied with somatosensory stimulation.¹⁹ Ji and Fang reported acupuncture to have a 60 to 80% success in tinnitus treatment.²⁰

In our study, after 5 sessions of treatment, tinnitus loudness/severity in the case group decreased significantly which suggests the effectiveness of the treatment. The decrease in tinnitus loudness/severity among the patients of the control group was not significant. In Marks et al. performed two sessions of acupuncture and noticed a statistically insignificant change in sound loudness in both groups.¹⁵ Vilhom et al. studied 54 patients who have been suffering tinnitus for at least 6 years.

They were treated by 25 sessions of acupuncture and a minimal change in all parameters was seen. They found a 4% change in tinnitus loudness in the case group and no difference in the control group.²¹ Furugard et al. evaluated the treatment by NHP profile in which a considerable improvement was seen in tinnitus loudness/severity and patient's quality of life of the case group compared with the control group. However, the control group (receiving physiotherapeutic treatment) did not show a considerable improvement.²² In a systematic review of 6 studies in 2000 by Park et al., four studies reported acupuncture ineffective for treatment of tinnitus while the other two declared the effectiveness of this treatment method.²³ Although previous studies are quite controversial about the efficacy of acupuncture as a therapeutic modality for tinnitus, the present study revealed that after only 5 sessions of acupuncture, the tinnitus severity index and tinnitus loudness grade decreased considerably in comparison with the control group patients. Some previous studies indicated acupuncture ineffective in treatment of tinnitus because the researchers used constant acupoints for all patients. Moreover, some others did not divide their patients according to subtypes of tinnitus (subjective or objective). In our study however, due to the selective treatment based on diagnostic pattern of TCM, the treatment was performed more effectively, because the therapist selected a proper plan of acupuncture for each patient individually.

Conclusion

We conclude that acupuncture is beneficial as a treatment modality for tinnitus, even though the effects may not last for a long period of time.

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Conflict of Interests

Authors have no conflict of interests.

Authors' Contributions

All authors have carried out the study. All authors read and approved the final manuscript.

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