

Efficacy of Acupuncture as a Treatment for Tinnitus

A Systematic Review

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Background: Tinnitus is a prevalent condition for which patients may seek treatment with acupuncture since no conventional treatment has been shown to be effective.

Objective: To summarize and critically review all randomized controlled trials on the efficacy of acupuncture as a treatment for tinnitus.

Data Sources: Four independent computerized literature searches (MEDLINE, Cochrane Controlled Trials Register, Embase, and CISCOT) were conducted in December 1998 using the key words *acupuncture* and *tinnitus*.

Study Selection: All randomized controlled trials that compared any form of acupuncture with any control intervention in the treatment of tinnitus were included.

Data Extraction: Data were extracted by 2 authors independently. The methodological quality of the included randomized controlled trials was assessed using the Jadad score.

Data Synthesis: Six randomized controlled trials were included in the review, 4 of which used crossover design. Four studies used manual acupuncture and 2 used electroacupuncture. Five of 6 studies used inconsistent acupoints. Three studies scored 3 points or more on the Jadad scale.

Main Outcome Measures: Outcome measurements were visual analog scale scores for loudness, annoyance, and awareness of tinnitus; subjective severity scale scores for tinnitus; or Nottingham Health Profile scores.

Results: Two unblinded studies showed a positive result, whereas 4 blinded studies showed no significant effect of acupuncture.

Conclusion: Acupuncture has not been demonstrated to be efficacious as a treatment for tinnitus on the evidence of rigorous randomized controlled trials.

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TINNITUS IS common complaint; for example, a British study reported that 10% of adults have prolonged spontaneous tinnitus, 1% experience severe annoyance caused by tinnitus, and 0.5% of adults experience tinnitus that severely reduces their ability to lead a normal life.¹ A large-scale Swedish study found that 14% of adults reported experiencing tinnitus "often" or "always," and 2.4% reported that "tinnitus plagues me all day."² No effective drug therapy is available to reduce or eliminate tinnitus. Although a combination of counseling and behavioral approaches has been recommended, there is little rigorous evidence of the effectiveness of this combined therapy.

Acupuncture has been used to treat tinnitus for a long time in Far Eastern countries such as China and Korea. Its use is primarily based on anecdotal data. Ki-

yoshita³ has developed a hypothetical rationale for the use of acupuncture on the grounds that it may influence the function of the olivocochlear nucleus. Anderson and Lyttkens⁴ have reviewed the trials of acupuncture for tinnitus, but their narrative review is open to criticism because the literature was not searched systematically and uncontrolled studies were not excluded. We have undertaken a systematic review with the aim of summarizing all available rigorous trials on the subject.

RESULTS

Thirty-six references were found from the computerized searches, and none from the Korean or Japanese correspondents. Two articles were unobtainable owing to an error in the reference and the inability to access the journal through the British Library; one article was a duplicate publication. After these 3 references were

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METHODS

Computerized literature searches were conducted of the following databases: MEDLINE (1969-1998), Cochrane Controlled Trials Register (issue 4, 1998), Embase (1988-1998), and CISCOP (Centralised Information Service for Complementary Medicine), which includes the British Library Alternative Medicine database, AMED, as well as some complementary medicine publications that are not included in the standard databases (December 1998). In order to identify possible clinical trials of acupuncture as a treatment for tinnitus, the search terms *acupuncture* and *tinnitus* were used. No language restrictions were applied. In addition, the contents pages of all relevant Korean journals were searched by hand, and a Japanese researcher was contacted to obtain literature from Japan. Copies of the original reports were obtained, and reference lists of these articles were searched for relevant trials. Studies were included in the review if they reported randomized controlled trials in which any form of acupuncture was compared with any form of control intervention for the treatment of adults with chronic tinnitus. Data were extracted using a pre-defined form, and study quality was assessed by applying the Jadad method.⁵ This validated method of assessing quality initially awards 1 point in each category of randomization, blinding, and description of withdrawals and dropouts. A second point is awarded for randomization if the method was appropriate, but a point is deducted if the method was inappropriate. Similarly, a second point is awarded if the method of double-blinding was appropriate, but a point is deducted if the method of blinding was inappropriate. The maximum possible score is 5 points. Study selection and data extraction were performed independently by 2 authors (J.P. and A.W.). One disagreement arose over the inclusion of the study by Podoshin et al,⁶ which did not present any statistical evaluation of the comparison of interest. This matter was settled by discussion among all 3 authors, who agreed that sufficient data were presented to allow evaluation by the reviewers and that the study should be included. Initially, we intended to perform a meta-analysis of the data, but this proved impossible because of the inconsistency of outcome measures used and the absence of detail in results.

excluded, 33 articles were obtained. One report was translated from Swedish.⁷ Twenty-two articles did not report clinical trials and were therefore excluded. Of the remaining 11 articles that reported clinical trials, 5 studies were excluded because they were not randomized.^{3,8-11} Six studies met the inclusion criteria for this review,^{6,7,12-15} and their key data are shown in the **Table**. The total number of subjects enrolled in the trials was 185, of whom 112 received acupuncture. Two reports related to parallel-arm studies^{6,15} and 4 studies had crossover designs.^{7,12-14} Three studies^{12,13,15} obtained a Jadad score of 3 or greater (usually regarded as indicating acceptable quality). Two open studies found that acupuncture had a statistically significant effect,^{6,7} but in one of

these⁷ the effects had disappeared by 1-year follow-up. The remaining 4 studies (all with blinded subjects) found no effect of acupuncture in the treatment of tinnitus.¹²⁻¹⁵ The studies will be discussed in detail.

Hansen et al¹² carried out a subject- and evaluator-blind crossover study of 20 patients with a history of unilateral tinnitus for more than a year, and 17 patients completed the study. Schematically, the study was conducted for 5 periods of 3 weeks, with 1 period each for acupuncture and sham control and 3 for observation, including a washout period. Acupuncture treatment consisted of 5 needles to points on the affected side (face and hand) together with foot points tailored to the personality type. For sham control, needles were inserted subcutaneously into the same points. Evaluation was by daily diary of symptoms compared with normal level. Data were converted into a period index (PI). Improvements in PI were 6% (after acupuncture) and 8% (after sham) for those who received acupuncture first, and 25% (after acupuncture) and 16% (after sham) for those who received acupuncture second. None of the within-group or between-group changes in PI was statistically significant.

Marks et al¹³ used a similar study design (ie, a subject- and evaluator-blind crossover investigation) to treat 14 patients with chronic unilateral tinnitus. After randomization, patients received 2 treatments with either acupuncture treatment or sham 1 week apart; after a 3-week interval, patients received 2 sessions of the other treatment 1 week apart; finally, there was a 2-week observation period. Active treatment consisted of electroacupuncture with alternating low (6-10 Hz) and high (100 Hz) frequencies on a combination of points in the hand, arm, and face. Sham control consisted of pricking the skin and immediately removing the needle without the patient's knowledge. Three methods of assessment were used: patient's verbal description of any changes, tinnitus matching, and visual analog scales (VAS) of loudness of tinnitus. Five patients (36%) reported less troublesome tinnitus after genuine acupuncture, but none (0%) reported less troublesome tinnitus after sham acupuncture, a statistically significant difference. However, neither tinnitus matching nor VAS scores were able to confirm this finding, and the authors' overall conclusion was negative.

Podoshin et al⁶ investigated the effect of 3 treatments for tinnitus: acupuncture, biofeedback, and cinnarizine. Patients with known pathologic conditions, such as Meniere disease, acoustic neuroma, or otosclerosis, were excluded. Sixty subjects with idiopathic subjective tinnitus were randomly divided into 5 groups to receive 1 of the 3 treatments mentioned above or placebo biofeedback or placebo cinnarizine tablets. Fifty-eight subjects completed the study. Acupuncture treatment was described as being based on the method used by Marks et al,¹³ although only treatment to points in the tragus and retroauricular region was listed. Treatment was given for 30 minutes every week for 10 weeks. Assessment was by subjective severity rating for tinnitus disturbance during activity and rest and by tinnitus matching. There was a nonsignificant trend toward improvement in tinnitus disturbance in the acupuncture group. The percentage of participants who were improved with acupuncture (30%) was greater than the percentage of participants who were im-

Key Data of 6 Randomized Controlled Trials (RCTs) on the Efficacy of Acupuncture for Tinnitus*

Study	No. of Subjects (No. Receiving Acupuncture)	Design	Intervention (No. of Sessions)	Control	Main Outcome Measure	Main Results	Jadad Score	Follow-up	Statistics
Hansen et al, ¹² 1982	17 (17)	RCT, CO, SB, EB	Manual acupuncture (6)	Sham (subcutaneous insertion)	Diary (better, normal, or worse)	NS	4	No	ANOVA
Marks et al, ¹³ 1984	14 (14)	RCT, CO, SB, EB	Electroacupuncture (2)	Sham (pricking)	VAS (loudness) and verbal description	NS, patients reported subjective benefit	3	No	χ^2 Test
Podoshin et al, ⁶ 1991	58 (10)	RCT	Electroacupuncture (10), biofeedback, and cinnarizine	Placebo, biofeedback and placebo, and cinnarizine	Subjective disturbance rating (0-4)	Biofeedback > acupuncture > cinnarizine or placebo controls	2	No	<i>t</i> Test
Axelsson et al, ¹⁴ 1994	20 (20)	RCT, CO, SB	Manual acupuncture (15)	Sham electroacupuncture	VAS (annoyance, loudness, and awareness)	NS, patients reported subjective benefit	1	No	Not stated
Furugard et al, ⁷ 1998	22 (22)	RCT, CO	Manual acupuncture (15)	Routine physiotherapy	VAS (annoyance, loudness, and awareness) and NHP	Significant improvement, but returned to pretreatment levels at 1-year follow-up	1	1 y	Not stated
Vilholm et al, ¹⁵ 1998	54 (29)	RCT, SB, EB	Manual acupuncture (25)	Sham (random points)	VAS (annoyance, loudness, and awareness)	NS	3	No	ANOVA

*CO indicates crossover study; SB, subject blinded; EB, evaluator blinded; NS, no significant difference; ANOVA, analysis of variance; VAS, visual analog scale; and NHP, Nottingham Health Profile.

proved with cinnarizine (10%) or with either placebo biofeedback (0%) or placebo cinnarizine (10%), but less than with biofeedback (50%). Tinnitus matching showed no objective difference after any of the interventions.

Axelsson et al¹⁴ used a single-blind crossover method to study 20 subjects with tinnitus associated with noise-induced hearing loss. Patients were allocated according to their birth date, ie, pseudorandomized. Active acupuncture was given for 30 minutes 3 times a week for a period of 5 weeks using points in the face, hand, and leg. The sham control intervention consisted of an electrical stimulator generating pulses at a low frequency (2 Hz), with audible and visible signals delivered via surface electrodes. During a few seconds at the start of the control session, weak electrical pulses causing a tactile sensation were given to the subjects. The output from the stimulator was then interrupted and no further electrical stimuli were given, although the light and sound signals continued throughout the session. The VAS of loudness, annoyance, and awareness of tinnitus was recorded by subjects. Mean improvements in VAS scores for loudness were 8% (after acupuncture) and 11% (after sham) for those who received acupuncture first, and 13% (after acupuncture) and 4% (after sham) for those who received sham first. This study did not find any statistically significant effect on measures of tinnitus, although there were some improvements in general health; for example, with sleep, muscle tension, blood circulation, and angina pectoris.

Furugard et al⁷ performed a randomized crossover study of 22 subjects with disabling tinnitus. Fifteen treatments with manual acupuncture were given using points on the head, hands, and legs. Control intervention consisted of individualized physiotherapy. The VAS scores for

loudness, annoyance, and awareness of tinnitus together with the Nottingham Health Profile (NHP) were used for evaluation of effects. There was immediate, significant relief in terms of loudness and annoyance after acupuncture and significant improvement in NHP scores. There were no significant changes after physiotherapy. No subjects in either group rated themselves as "cured." The percentages of subjects who rated themselves as "greatly improved" by acupuncture and physiotherapy were 45% and 16%, respectively, while the percentages of subjects who rated themselves as "improved" were 55% and 84%, respectively. However, annoyance and NHP scores returned to pretreatment levels at 1-year follow-up.

Vilholm et al¹⁵ evaluated the effect of acupuncture in 54 patients with severe, treatment-resistant tinnitus, unilateral or bilateral, with a duration of at least 1 year. The active treatment group received 25 treatments of manual acupuncture on the head and around the ear over 2 months. The sham control group was needled at randomly selected nonacupuncture points. Run-in and follow-up observation periods lasted 1 month each. The VAS scores for loudness, annoyance, and awareness of tinnitus were used to evaluate treatment response. Changes in all outcomes were minimal in both the acupuncture group and the sham group. For example, the percentages of change in VAS scores for loudness were 4% and 0%, respectively. There were no statistically significant differences between groups for any outcome.

COMMENT

Perhaps the most striking finding of this systematic review, relative to the common usage of acupuncture, is the

paucity of randomized controlled trials identified. Six studies seem to document an embarrassing lack of research activity. Of the 6 studies we included in our review, 2 open trials found a positive effect of acupuncture treatment for tinnitus, whereas 4 patient-blinded, sham-controlled studies did not find significant difference between treatment with acupuncture and placebo. This suggests that any benefit that acupuncture may have on an individual patient with tinnitus is caused by nonspecific effects, such as expectation, suggestion, therapeutic relationship, etc, rather than a specific effect of needling.

The methodological quality of the included studies was variable but, on average, disappointing, with 3 not reaching the minimum acceptable standard of 3 points on the Jadad scale of assessment. In particular, the poor quality of reporting was regrettable; for instance, in 2 trials there was no description of the statistical methods used to evaluate the results. All 3 of the studies that were of better quality (ie, Jadad score ≥ 3) reported negative results.^{12,13,15} A variety of sham procedures was used without information regarding their validity from earlier studies, yet the success of blinding was checked in only 1 study.¹⁵ Various outcome measures were used in the earlier studies; the later studies were consistent in using the VAS for annoyance, loudness, and awareness of tinnitus, but no author mentioned whether the VAS had been validated for the measurement of tinnitus. Future studies might take advantage of the development of the subjective tinnitus severity scale that has been validated.¹⁶

A further weakness of some of the trials lies in the fact that the crossover design cannot be regarded as appropriate, since acupuncture (or, indeed, control procedures) might be anticipated to have prolonged effects. These are likely to reduce the difference of the effect seen in the 2 groups, since carryover effects reduce the apparent effectiveness of the second intervention. (One subject in the study by Axelsson et al¹⁴ showed remarkable and lasting improvement after acupuncture and therefore was withdrawn from the study and did not undergo the control intervention.) Moreover, subjects can often recognize the difference between real acupuncture and sham control, as reported by Vilholm et al.¹⁵

The studies are also not homogeneous in terms of the acupuncture prescriptions used. This might be explained by the fact that acupuncture can be practiced according to a number of different theoretical frameworks. However, the rationale for point selection was not stated in some reports, and no author quoted classic literature or pilot studies to justify the points used or the procedure for choosing individualized acupoints. Future research should use clear treatment schedules that are already tested and backed by evidence from case series studies.

CONCLUSION

The belief that acupuncture is a specifically effective treatment for chronic tinnitus is not based on the evidence of rigorous randomized controlled trials. Further research on this subject seems to be warranted but should be conducted according to the highest methodological standards.

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