Effect of traditional Chinese acupuncture on severe tinnitus: a double-blind, placebo-controlled, clinical investigation with open therapeutic control

Ole J. Viiholm[1], Kitty Møller[1] and Karsten Jørgensen[2]

[1]*Department of Audiology, Vejle Hospital, Denmark and* [2]*Department of Otorhinolaryngology, Odense University Hospital, Denmark*

(Received 3 April 1997, accepted 19 January 1998)

Abstract

This study aims to determine the effect of intensive acupuncture on severe tinnitus. The structure of the study was a randomized, double-blind, clinical investigation with open therapeutic surveillance and included 54 patients. All were subjected to 25 treatment sessions over a period of two months, each treatment lasting 30 minutes. Fifty-two patients completed the study. The variables used for self-registration were based on the visual analogue scale (VAS), where annoyance, loudness and awareness of the tinnitus were assessed. These were recorded twice daily over a four-month period starting one month before the first treatment and ending one month after the last treatment. Questionnaires, interviews and audiometry were carried out repeatedly. No statistically significant differences were found between the acupuncture group and the placebo group.

Key words: tinnitus, acupuncture, Chinese, randomized, placebo-controlled

Introduction

Tinnitus is a common condition; epidemiological studies from Sweden have shown that 14% of the population suffers from tinnitus, and that of these 17% have such severe tinnitus that the condition affects the daily life of the patient (Axelsson and Ringdahl, 1989). The disease has a strong influence on the social and psychological state of the patient.

Acupuncture is a form of treatment originating in China, where it is employed *inter alia* for the treatment of tinnitus. Seven investigations have been carried out in Europe during the past 15 years, but until now there have been no controlled studies of the effect of acupuncture given over a prolonged period. The investigations which have been carried out have been based on a maximum of 15 treatment sessions, which is stated by the Chinese to be too few when the condition is severe (Chinese acupuncture and moxibustion, 1987).

Seven research teams have been involved in the evaluation of acupuncture treatment of tinnitus. Hansen et al. (1982) carried out a double-blind, cross-over study. Placebo acupuncture was used, where acupuncture needles were inserted into non-acupuncture sites. The needles were inserted for 15 minutes; 20 patients participated in the study and each patient received six treatment sessions. It was impossible in this investigation to demonstrate any significant difference between the two groups. Marks et al. (1984) employed a similar study design: a 'double-blind', cross-over investigation. In this study the placebo needles were removed immediately after insertion. Fourteen patients took part in the study, and each received two treatment sessions of each type. No significant difference could be found; however, it was stated in the conclusion that the number of treatment sessions was too small.

Address for correspondence: Kitty Møller, MD, Department of Audiology, Vejle Hospital, 7100 Vejle, Denmark.

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Thomas et al. (1988) carried out a clinical study without employing a control group, where 12 patients were subjected to a course of 10 acupuncture treatment sessions. Six patients had a reduction in the tinnitus, but no effect could be observed at the follow-up examination three months later. In the investigation of Lindholm et al. (1991), 57 patients each received 15 treatment sessions, and this investigation showed a positive effect of therapy in 32 of them (56%). The investigation was designed without a control group and the effect measured was based on retrospective evaluation by the patients. Podoshin et al. (1991) evaluated the effect of acupuncture, biofeedback and cinnarizine on tinnitus in series of 60 patients. A total of nine patients received acupuncture. There was found no significant improvement. In the discussion it is emphasized that there is no ideal treatment for subjective idiopathic tinnitus. Nilsson et al. (1992) carried out a clinical study without a control group. Fifty-six patients were subjected to 10 treatment sessions over a period of 20 days. It was found that 21% of the patients had immediate improvement, measured in hours/days. However, 25% of the patients reported an exacerbation of their tinnitus following acupuncture. Axelsson et al. (1994) carried out a cross-over investigation with a control group. In contrast to earlier studies their investigation only included patients with noise-induced tinnitus. Twenty patients each received sessions of 15 treatments over a period of five weeks. The study was unable to demonstrate any statistically significant difference.

Only one of the seven studies mentioned claims a positive effect of acupuncture (Lindholm et al., 1991). However, this study was not a controlled one and therefore does not allow any conclusions.

Andersson and Lyttken (1996) carried out a review of the previous studies on the topic and found no evidence of long-term effects of acupuncture.

The types of placebo used in three of the above-mentioned studies were:

- Retention of superficially positioned acupuncture needles at sites not normally employed in acupuncture for a period of 15 minutes (Hansen et al., 1982).
- Pricking the skin with needles at non-acupuncture sites (Marks et al., 1984).
- Electric stimulation via surface electrodes, which had been disconnected (Axelsson et al., 1994).

The aim of this investigation was to determine whether more prolonged use of acupuncture has an effect on severe tinnitus.

Method

The investigation was carried out at the Department of Audiology, Vejle Hospital, Denmark. A pilot study was initially performed as a double-blind, cross-over investigation with open therapeutic surveillance. As there was some doubt as to the feasibility of employing a cross-over technique, a larger double-blind, placebo-controlled investigation, with open therapeutic surveillance was commenced.

The patients participating in the investigation were from the Department of Audiology, Vejle Hospital, and those referred to the department by ENT surgeons in practice in the county of Vejle.

All the patients wishing to participate in the study signed a form giving informed consent.

Admission criteria

Patients must have suffered from a severe, treatment-resistant tinnitus, unilateral or bilateral, with a duration of at least one year. Severe tinnitus was defined as a very uncomfortable sensation of noise or sound in the ear, which affected the patient's psychological condition, ability to concentrate or working capacity, as well as affecting normal daily life, and thus lowering quality of life. The patients were not permitted to have received acupuncture treatment at an earlier date, and they were not allowed to receive other forms of treatment for tinnitus during the investigation.

Subjects

Fifty-four patients participated in the investigation (n = 54). Sex distribution was 35 men (20 in the acupuncture group, 15 in the placebo group) and 19 women (9 in the acupuncture group, 10 in the placebo group). Two patients failed to complete the study and were excluded from the investigation. Average age was 53.1 years (range 23–79 years). The average age of those in the acupuncture group was 51.8 years, in the placebo group 53.6 years. Duration of tinnitus was, on average, 9.1 years (acupuncture group 9.4 years and placebo group 7.4 years). The number of

patients in the acupuncture group after randomization was 29 and there were 25 in the placebo group. The uneven distribution resulted from two pairs of patients being enrolled into the study after the initial randomization, this led to both pairs drawing lots putting them into the acupuncture group. As can be seen from Table 1, the distribution of the diagnoses is such that the two groups are comparable.

Procedure

Patients were divided into two groups (Fig. 1). The acupuncture group was treated with traditional Chinese acupuncture and was given 25 treatment sessions over a period of two months. The sessions were distributed over three treatment periods of 10, 5 and 10 treatments separated first by a pause of one week, and then by a pause of two weeks. The treatment was given each day and its duration was 30 minutes.

The acupuncture points selected for all patients were Tinggong (SI 19), Tinghui (G 2), Yifeng (SJ 17), Head-luxi (SJ 19) and Baihui (DU 20), the distal points and the methods of manipulation were selected individually, based on differentiation of signs and symptoms in accordance with the theories of traditional Chinese medicine. In this investigation localization of points was based on anatomy; no skin resistance measurements were employed. Bilateral treatment was given, irrespective of whether the patients suffered from unilateral or bilateral tinnitus. Chinese acupuncture needles were used; these penetrate to a distance of 0.5–3 cm. The depth to which the needles were inserted was dependent upon achieving a characteristic needle sensation. The placebo group was treated with placebo acupuncture. A placebo treatment that was as close to the actual acupuncture as possible was chosen; thereafter the effect of

Table 1. Distribution according to aetiology

Diagnosis	Placebo	Active
Sensorineural hearing loss of unknown cause	8	9
Noise-induced hearing loss	9	11
Ménière Mb.	3	2
Otosclerosis	1	2
Hereditary sensorineural hearing loss	2	1
Sequelae after chronic otitis media	2	2
Presbyacusis	–	2
Total	25	29

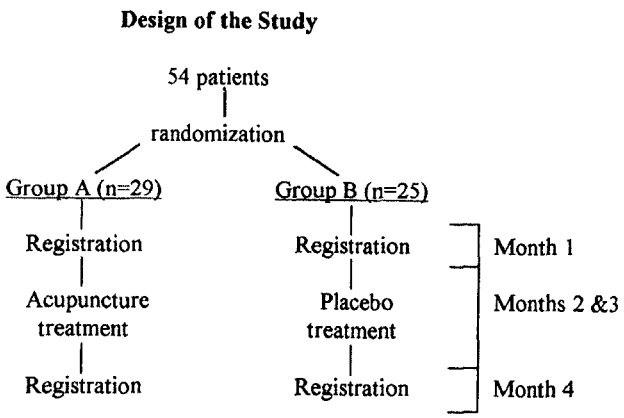

Fig. 1. The randomization, the duration and the design of the study.

blinding could be determined retrospectively. The non-penetrating placebo method was used, where thin Japanese acupuncture needles were inserted superficially into the skin at random non-acupuncture sites. The needles were removed after 30 minutes. These punctures create a sensation in the skin which has no therapeutic effect. Otherwise, the placebo group was treated in the same manner as the acupuncture group.

Effect variables

The patients recorded twice a day (morning and evening) throughout the whole investigation (four months) the following on the visual analogue scale (VAS): annoyance, loudness and level of awareness. The patients were given thorough instruction in the use of the VAS, some two weeks before the start of the actual recording patients were asked to fill in a 'training form'. These forms were then surveyed by one of the authors (KM), in order to ensure that they were completed correctly.

Patients underwent a physical examination prior to the treatment so that the cause of the tinnitus might be determined as far as possible; thereafter the diagnosis was made according to traditional Chinese medicine, by the therapist (OV). In addition, the patient's age, duration of tinnitus, audiogram and a description of the tinnitus as well as drug consumption were recorded. Furthermore, a questionnaire elucidating other aspects was completed by the patient. A status of the tinnitus and a new audiogramme were made after 15 treatment sessions as well as at completion of treatment. An additional questionnaire was completed by the patient immediately after the treatment. A further status statement was compiled one month after cessation of treatment. Control was carried out as to whether the blinding of each individual patient had been effective.

Statistical methods

Repeated measure analysis of variance (ANOVA) was used for analysis of the difference between the VAS scores between the acupuncture group and the placebo group. Post hoc tests were applied in case significant interactions occurred.

Results

Two-way ANOVAs showed no significant differences in the VAS scores for the acupuncture and placebo groups. Period means and standard deviations for annoyance, loudness and awareness are shown in Table 2.

A survey showing the total deviation in the level of intensity of the two groups is shown in Figs 2–7; morning and evening recordings are handled separately in these six figures. No statistically significant difference was found between the deviation in either group. The SD for the curves varies between 10.5 and 19.4.

Table 2. Results of visual analogue scale (VAS) registration

Variable	Period	Period means (SD) Acupuncture	Placebo	F
Annoyance	Pre-treatment	64.5 (30.5)	67.1 (30.2)	
	Treatment	63.5 (30.0)	67.3 (30.7)	
	Post-treatment	62.0 (28.8)	67.0 (31.7)	1.37 NS
Loudness	Pre-treatment	78.5 (25.9)	76.5 (23.1)	
	Treatment	75.2 (25.7)	77.0 (24.0)	
	Post-treatment	74.1 (25.9)	77.5 (23.8)	1.25 NS
Awareness	Pre-treatment	69.2 (29.6)	65.1 (31.1)	
	Treatment	67.1 (29.6)	66.2 (30.2)	
	Post-treatment	64.5 (28.8)	66.5 (32.5)	1.34 NS

NS = not significant

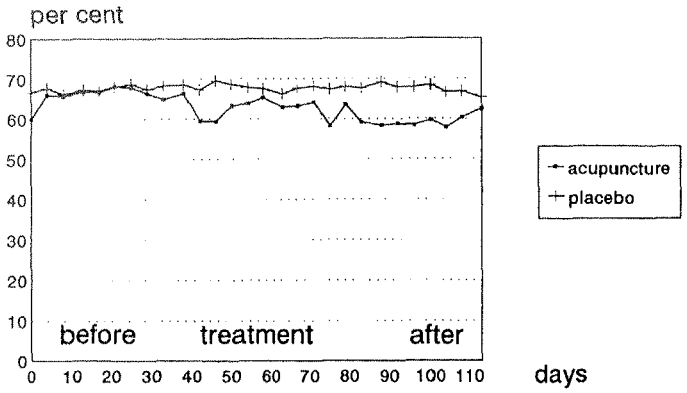

Fig. 2. Annoyance in the morning.

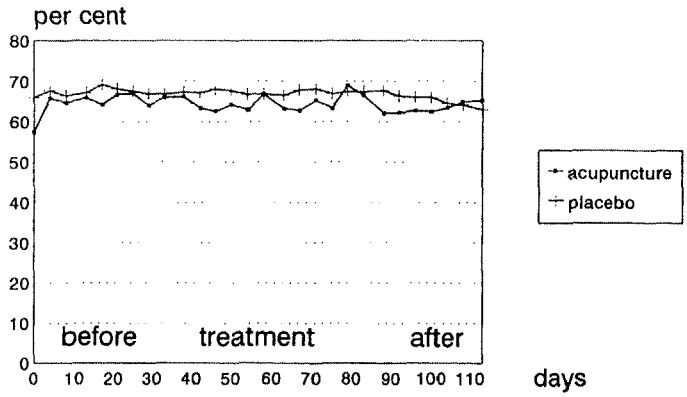

Fig. 3. Annoyance in the evening.

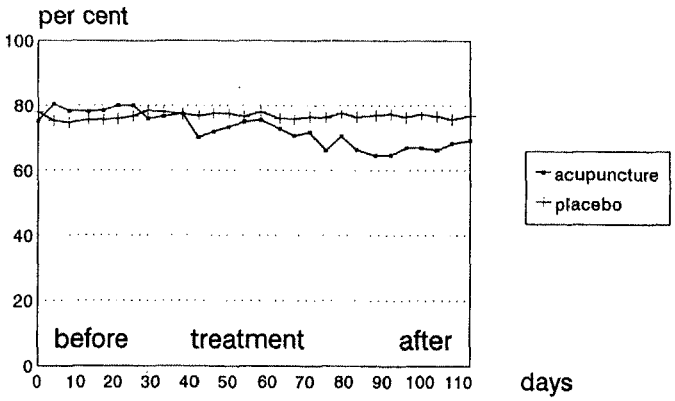

Fig. 4. Loudness in the morning.

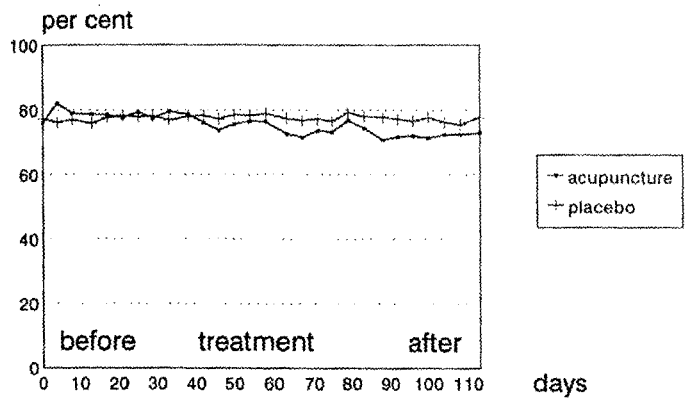

Fig. 5 Loudness in the evening.

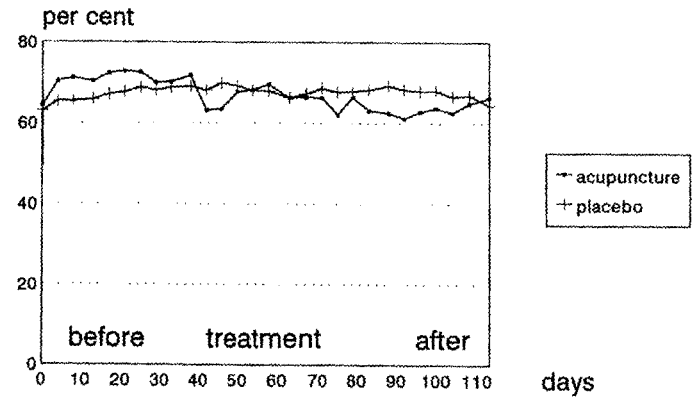

Fig. 6. Awareness in the morning.

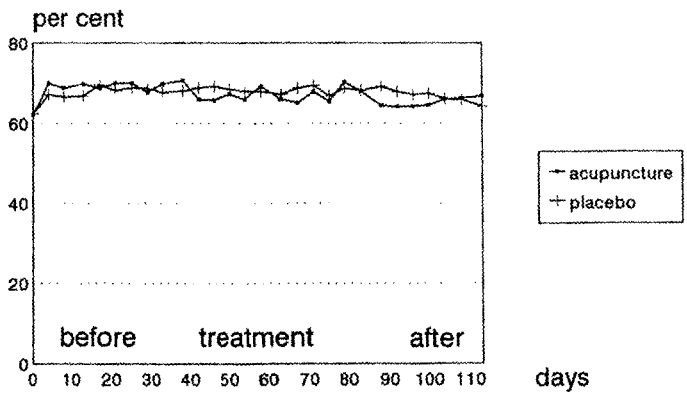

Fig. 7. Awareness in the evening.

Discussion

We have been unable to demonstrate any statistically significant effect of acupuncture on severe tinnitus. A pilot study was carried out prior to the main investigation in order to determine the feasibility of employing a cross-over technique. This revealed that a cross-over model is not particularly well-suited for studying the effect of acupuncture, because patients subjected to acupuncture first and placebo acupuncture later were able to distinguish between the two types of treatment. A characteristic sensation is experienced following stimulation by means of acupuncture. If this feeling is not present the patient is able to sense which of the treatments is active and which inactive.

VAS recording (Aitkin, 1969; Gift, 1989; Wewers and Lowe, 1990) is frequently used and one of the most accepted methods of describing psychological phenomena as well as the symptoms of the person in question. This method is particularly useful for recording pain.

Good patient compliance was seen in connection with the present investigation. Only two of 54 patients were unable to complete the intensive and time-consuming course of treatment, indicating that patients were highly motivated. It should also be borne in mind that our patients were severely incapacitated by their tinnitus and were therefore willing to accept considerable inconvenience in order to achieve relief in what has, up to the present, been a treatment-resistant disease.

The final physical examination included a study of the efficacy of blinding. Only one patient thought with certainty that she was able to indicate the type of treatment given. This patient was in the placebo group, and was convinced that she had received placebo treatment. The records of this patient were excluded from the final analysis, although she was included in the calculation of the number of patients. It may be concluded that the placebo treatment functioned as intended.

A weak trend was observed with regard to the strength of the tinnitus (Figs 4 and 5). There is the possibility that the improvement was related to an effect on a secondary illness, such as headache, tension in the neck and other conditions of a similar nature. Alternatively, this could be the placebo effect which is documented in tinnitus treatment (Duckert and Rees, 1984).

It is noteworthy, however, that only a slight placebo effect could be demonstrated during the investigation. We have two possible explanations of this. Either the condition is not affected by the mental state, as presumed at present, or a possible placebo effect has been masked due to the intensive recording, which has resulted in the patients paying more attention to their condition during the course of the investigation.

We chose to carry out 25 acupuncture treatment sessions and thus complied with the prerequisites of traditional Chinese medicine. Furthermore, we have employed a double-blind, clinical investigation model with open therapeutic surveillance. This model has not previously been used for the evaluation of the problem in question.

Conclusion

We have been unable by means of this investigation to demonstrate any statistically significant effect of acupuncture on severe tinnitus. The results of this study are in agreement with previous investigations, and we must conclude that acupuncture treatment of patients with tinnitus is not generally indicated.

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