

A controlled trial of acupuncture in tinnitus

by

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Abstract

The relationship of tinnitus to pain is examined and a theoretical case made out for the possible use of acupuncture in the treatment of tinnitus. A double-blind cross-over controlled trial is described. The use of Visual Analogue Scales (V.A.S.) is discussed in this context. 35 per cent of patients described some benefit from the active treatment only, although we were unable to demonstrate this objectively. Statistical analysis of the group as a whole revealed no significant differences between placebo and active acupuncture treatment.

Introduction

Most patients presently seen complaining of tinnitus are told by their doctors that there is no treatment and that they will have to learn to live with this symptom. It is therefore not surprising that a number will seek help from less orthodox sources. One of those is the Acupuncturist. Individually they frequently claim a degree of success with tinnitus patients although no evidence of an objective nature has been produced. But why should acupuncture help this symptom? The rationale for this is a curious mixture of the scientific and the naive.

Within the auditory system well established pathways exist, which could constitute a reflex arc. Afferent and efferent components have both been demonstrated (Gacek, 1961; Iurato, 1974; Harrison and Howe 1974; Rasmussen, 1942). There are pathways in both directions connecting the brain-stem nuclei to the reticular formation, the thalamus and the cortex. This arrangement has marked similarities to the unusual neural pathways found in the mediation of pain. Here one finds elaborate feedback loops which when activated are capable of reducing the intensity of persistent pain (Chung and Dickenson, 1980). Afferents synapse profusely in the substantia

gelatinosa of the dorsal horn of the spinal cord and it is here that feedback may occur. There seem to be at least three descending pathways which act on these synapses, and so far they have not been shown to affect any sensory modality except pain (Basbaum and Fields, 1979).

What, then, suggests that tinnitus has any relation to 'pain' pathways? Firstly, Desmedt (1975) makes the point that it was the efferent neurones within the auditory system that acted as the paradigm of centrifugal neurones in sensory systems. Since their description this arrangement has become associated intimately with the modality of pain (Melzac and Wall, 1965). In the auditory pathway it has been shown that the efferent olivo-cochlear bundle of Rasmussen when stimulated reduced both sound-evoked and spontaneous activity in the auditory nerve (Galambos, 1956; Fex, 1962). This olivocochlear inhibition was also found to be reduced by strychnine and brucine (Desmedt, 1975). Both are specific antagonists of the glycineic post-synaptic inhibitions of the mammalian spinal cord. These factors demonstrate a physiological similarity between the distal auditory and pain pathways.

Secondly, there are the effects of local

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anaesthetic agents on tinnitus. Lignocaine in particular appears to have a transient (and occasionally prolonged) effect in reducing or abolishing tinnitus. Interestingly this effect was noticed when the drug was being given for chronic pain (Melding, Goodey and Thorne, 1978). The drug is thought to work on multisynaptic slow pathways, at the synapses, selectively blocking inhibiting synaptic influences (De Jong, Robles and Corbin, 1969). Why this should help tinnitus has not been explained.

Thirdly, there is the phenomenon of masking. It has been observed for centuries that counter-irritation may alleviate painful stimuli (Kane and Taub, 1975). In 1965 Melzac and Wall developed the 'gate theory' of pain. They postulated that the threshold to painful stimuli could be raised by suppressing the transmission of pain impulses in the dorsal horn. This was achieved by the activity of descending (efferent) pathways acting on these synapses. Masking may work in the auditory pathway in a similar fashion. In some patients it may even produce a refractory period, as occasionally seen after lignocaine injection. Both these events suggest that something has altered in the neural pathway since the immediate stimulus has ceased. It seems just possible that this could be 'hormonal' and a substance such as β Endorphin has been released and is acting on opiate receptors within the pathway. The effect of Endorphins now seems well established in pain (Chung and Dickenson, 1980). An analogue system may well exist in the auditory pathways.

Fourthly, Shea *et al* (1981) stress certain similarities between patients with chronic intractable pain and those with tinnitus. He describes them both as being rigid, neurotic, obsessive, insecure, chronically fatigued and depressed. The relevance of this is not clear, but if a cortical element is important in control of these symptoms it may be relevant.

Given these similarities between pain and tinnitus, what might acupuncture have to offer the tinnitus sufferer? The mechanism of acupuncture currently put forward to explain its action is that it stimulates the body's

endogenous opiates which work both centrally and also at a local level (Chung and Dickenson, 1980). The question then is: will these 'opiates' suppress tinnitus as well as pain?

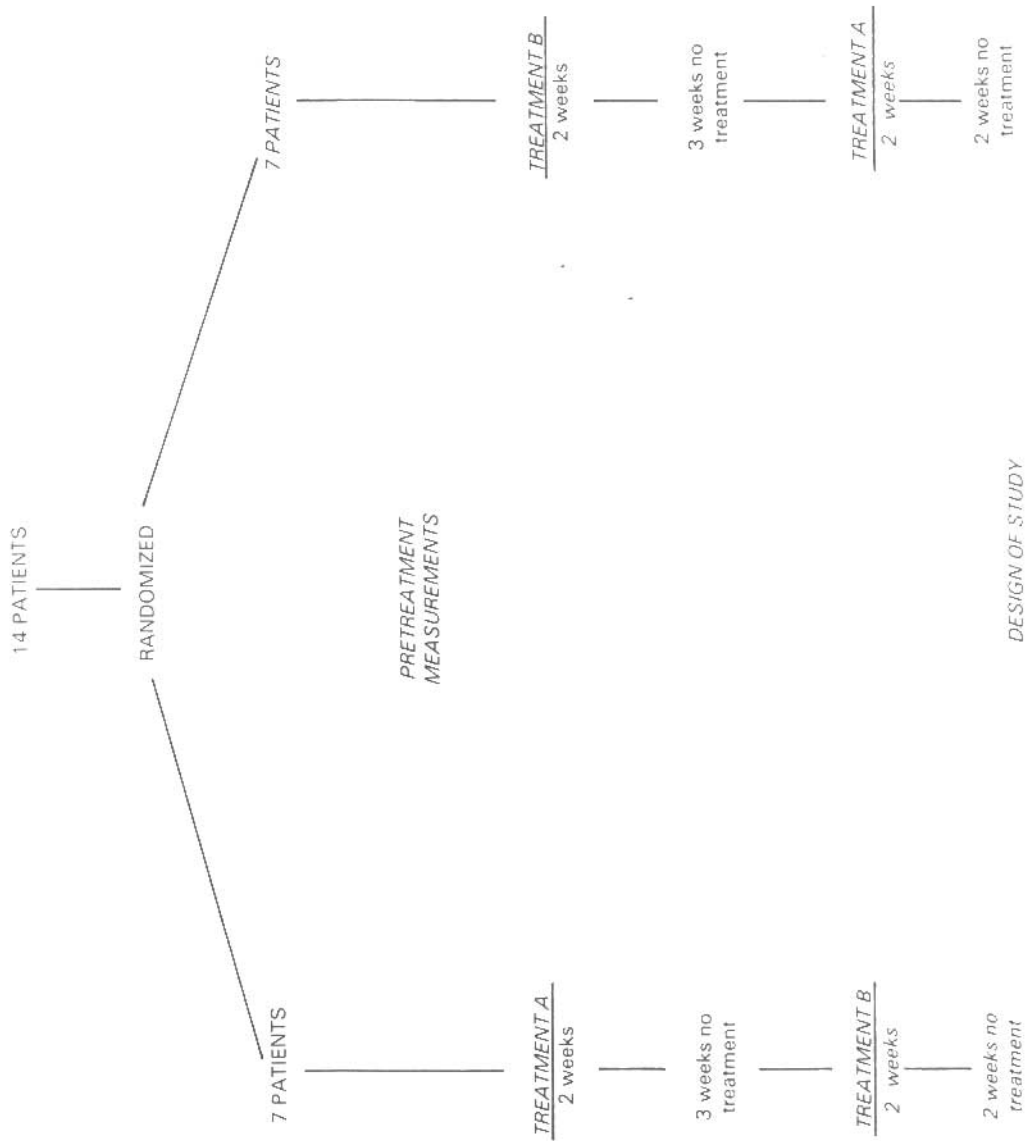
We have seen the occasional patient with tinnitus who commented on the diminution of his symptom when given an opiate premedicant. Trials of opiates are obviously not ethical, but acupuncture has no serious reported complications. There have been trials to assess its effect on hearing (Madell, 1975; Aber, 1974; Fairbanks, Wallenberg and Webb, 1974), which showed no change in hearing on audiometry. Some patients did describe an increase in 'clarity' of hearing which may have been due to improvements in tinnitus, but no mention is made of it.

This trial then was carried out to assess whether there was any therapeutic benefit to a group of tinnitus sufferers from acupuncture treatment.

Materials and Methods

The selection of patients and the technique of tinnitus matching used was the same as that described in Marks, Onisiphorou and Trounce (1981). These patients had a chronic unilateral tinnitus that was characterized by its constancy. All had had previous treatments. None had produced any subjective change in these patients. The design of the trial was a double-blind cross-over controlled trial. The two forms of treatment were given by one doctor. One of these was genuine acupuncture, the other a placebo acupuncture. These treatments were coded A and B, half the group starting with A and the other with B.

After one week of measurements (see below) two treatments were given, one week apart. The patients then had a three-week period without treatment, which was followed by two treatments of the other type a week apart. Assessment of the efficacy of treatment was carried out by a second doctor who did not know what treatments had been used (Fig. 1).



Three methods of assessment were used:

1. A verbal description by the patient of any changes.
2. Tinnitus matching. This was carried out prior to the trial, and after each treatment.
3. By Visual Analogue Scales (V.A.S.)

Because the effects of acupuncture are so poorly defined it is not possible to say when the effects of treatment should occur. It is therefore necessary to use a mode of evaluation that is continuous and will demonstrate even transient changes in symptoms at any time after the treatment sessions. Tinnitus matching will give measures that are semi-objective, but these are limited to an instant, usually after treatment. V.A.S. were filled in for two criteria:

1. The loudness/severity of tinnitus at a particular time each day.
2. The loudness/severity of tinnitus taking the day as a whole.

The V.A.S. was a horizontal line 10 cm. long on which the patient marks a site relating to the severity of their tinnitus. The extremes were marked as follows:

SILENT—————LOUDEST EVER

thus giving two anchor points that were within the experience of the patient. They were carefully instructed in the use of these scales and a trial period of one week allowed them to get accustomed to their use, making a score every three to four hours. This also gave a baseline measurement of their tinnitus, and its consistency. They were instructed that, should their tinnitus get louder than it had ever been before, they should make a mark beyond the right hand end of the line. This eventually did not arise. The V.A.S. then provided a continuous assessment of the patient's tinnitus for the whole duration of the trial until two weeks after the last treatment.

The results were analysed blind prior to the knowledge of whether the treatment was active or placebo.

The Treatment: Acupuncture and Placebo

Patients were told at the outset that they

were to receive acupuncture treatment which would differ on different occasions. Because random siting of acupuncture needles has been shown to have an effect equal to acupuncture (Gaw, Chang and Shaw, 1975), it was decided to use non-penetrating 'acupuncture' for the placebo treatment. In this method points were sited out of the patients' line of vision. The needles were used to prick the skin and were immediately removed without the patients knowledge. At the end of the treatment period the procedure was covertly repeated, giving the sensation of the needles' removal. Patients were not informed about deqi. This is the sensation that occurs when an acupuncture needle is correctly placed. At the end of the trial the patients were interviewed. None had been aware that they had not received acupuncture during the placebo treatment periods.

Active acupuncture varied according to assessment. A combination of the following points were used: Colon *4, *5, small intestine *4, *5, 19, Kidney *6, pericardium *9, gall bladder 11, 12 and triple heater 17, together with an auricular point for vertigo. (Points marked * are visible to the patient). Electro-acupuncture was used with alternating low (6–10 Hz) and high (100 Hz) frequencies. It is suggested that the former increases CSF β (Clement Jones *et al.*, 1980), whilst evidence from the treatment of heroin addicts suggests that the latter raises serum Met. Enkephalin (Clement Jones *et al.*, 1979). Each treatment period lasted twenty minutes and all treatments were carried out by one doctor.

Results

Overall the impression gained was that there was little general effect on the whole group. However, five patients noticed a subjective improvement on treatment A—genuine acupuncture (see Table of Results). There were no changes for the worse in any of the patients. A rate of improvement of five out of fourteen on one treatment versus none out of fourteen with the other treatment was tested using a χ^2 test with Yates' modification.

TABLE OF RESULTS

Sex	Age	Diagnosis		Tinnitus ear	First treatment	Subjective change	Second treatment	Subjective change
		Right ear	Left ear					
1	F	54	Otosclerosis Fenestration	Right	A	More relaxed Tinnitus less	B	N/C
2	M	43	Normal	Left	B	N/C	A	N/C
3	F	25	Otosclerosis with S-N loss	Right	A	N/C	B	N/C
4	F	34	SSN	Right	A	N/C	B	N/C
5	M	70	Mild presbycusis	Left	B	N/C	A	N/C
6	M	57	Mild symmetrical high-tone loss	Left	A	Tinnitus went for several hours after treatment	B	N/C
7	M	65	Mild symmetrical high-tone loss	Left	B	N/C	A	N/C
8	F	53	NAD	Right	B	N/C	A	Quieter for day or 2 after treatment
9	F	34	Normal	Left	B	N/C	A	Silent at times* generally quieter
10	F	56	Normal	Left	A	N/C	B	N/C
11	F	47	S-N loss ? cause	Right	A	Some improvement	B	N/C
12	M	58	Symmetrical high-tone loss	Central	A	N/C	B	N/C
13	M	53	Normal	Left	B	N/C	A	N/C
14	M	60	Normal	Left	B	N/C	A	N/C

* Was now able to suppress tinnitus by listening actively for it. Continued to improve after end of treatment A, then got worse. Normal on treatment B.

Key: N/C = no change.

B = placebo treatment.

A = acupuncture treatment. NAD = no pathology found to explain symptom.

SSN = sudden sensory neural hearing loss of unknown aetiology.

TABLE OF PATIENTS AND THEIR RESPONSE TO EACH TREATMENT

Of 14 patients 5 noticed a change after treatment—all on treatment A
 3 when A given first
 2 when A given second

$\chi^2 = 3.9$

1 df

$P < 0.05$

$$\chi^2 = 3.9 \quad df = 1 \quad P < 0.05$$

It is therefore possible that a minor change occurred for the better as a result of acupuncture.

Neither objective tinnitus-matching tests nor V.A.S. were able to confirm this finding.

(1) Analysis of Tinnitus Matching Scores. Firstly the number of patients improving, staying the same and worsening were compared for each treatment by a χ^2 test. There was no significant difference. The mean scores in dB before were compared with those obtained during each treatment by a paired t test. Neither treatment produced a significant change from the pre-treatment values. Also evaluated was the loudness above threshold (for the good ear) of the tinnitus.

Mean value before treatment = 25 dB

Mean value after treatment A = 21 dB

Mean value after treatment B = 21 dB

A t test also showed no significant difference between the loudness of the tinnitus when compared between treatment groups in this way.

(2) Analysis of the Visual Analogue Scales.

Within the group as a whole there was no significant change in the average weekly scores with either treatment. Both the 'instantaneous' scores and whole day scores displayed a similar lack of change.

Where particular individuals said they had less tinnitus, this was reflected by a lower score that day. However, these generally did not influence the weekly mean.

Individuals were also analysed separately, each week's scores being compared by a t test. Although there were significant falls in these scores in some weeks, they did not correlate with particular treatments.

Discussion

Each of our patients was chosen particularly because of the constant nature of the tinnitus. All had been seen on several previous occasions, and had reproducible tinnitus-matching results. All had had previous treatments with *no* effect. Any

change they described was therefore the more striking. The problem of any trial of treatment for a symptom is the multiple aetiology likely to be encountered. It may well be that with some aetiologies a particular treatment will work, but not with others. To distinguish a small group of responders (e.g. 15 per cent of the total tinnitus population) by whole population comparisons requires very large numbers. The only other way around this problem is a longitudinal comparison of each patient's scores for both treatments. Despite the suggestion that a significant number of our subjects noted a change with acupuncture, we could not demonstrate a definite improvement in any of them by our tests.

With tinnitus-matching this is probably not surprising, as a noticeable subjective change (e.g. 3 dB) might be within the error of the test. In fact on several occasions when patients said they were better, their tinnitus matching was identical.

The visual analogue scales presented a slightly different problem. There may well have been a degree of baseline drift over the course of the trial, hence it is difficult to feel confident about comparing the initial scores with a treatment some weeks later. Despite this, there appeared to be no constant drift with time, most of the patients' symptoms remaining static. There were definite episodes after acupuncture treatment where the patients' scores did improve for a day or two, but these did not alter significantly the statistical comparisons.

Since this study was completed, Hansen, Hansen and Bentzen (1982) published a trial with a very similar protocol and also found no objective or subjective differences in tinnitus with real and placebo acupuncture. They found a drift to improvement with time which was independent of treatment. This is contrary to the consistency of our patients' scores.

In principle we agree with the results of Hansen *et al.*, but would make a proviso. It seems that there was a small group of sufferers (up to 35 per cent) who may have benefited if active treatment had been extended. We would recommend, therefore,

that any further studies of this type should have much longer treatment sections to the trial as any positive effects seemed to occur rather slowly.

In summary, it seems that for the general tinnitus sufferer, acupuncture probably does

not have much to offer. However, we are reluctant to close the door on this harmless method of treatment and condemn it outright. There is a suggestion that a few patients might respond to courses of longer than two weeks.

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