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Low-powered ultrasound in the treatment of tinnitus: a pilot study*

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Abstract

The aim of this study was to determine whether a low dose of ultrasound, applied over the mastoid bone, caused a subjective improvement in the level of tinnitus in long standing tinnitus sufferers. Forty patients from the Swansea Tinnitus Association volunteered to take part in a double blind crossover trial. They received a 10-minute treatment with an ultrasound generator and an identical placebo device on two separate visits. The devices were randomly allocated on the first visit. At each visit the patient noted whether their tinnitus was completely improved, slightly improved, unchanged or made worse by the treatment. Forty per cent of patients who completed the trial were improved by ultrasound, 7% by placebo. Low powered ultrasound was significantly better at producing improvement than placebo ($P < 0.02$ Binomial Test).

Introduction

The concept of low-powered ultrasound as a treatment for tinnitus is a new one and was discovered accidentally. A patient undergoing ultrasonic investigation of his maxillary antrum claimed to experience improvement in his tinnitus during the procedure. The improvement was short-lived but repeatable.

It was felt that this finding was of sufficient interest to warrant further investigation. Before embarking on a large scale study, a small pilot study was planned to determine whether this was a chance finding or occurred in a reasonable proportion of tinnitus sufferers.

An ultrasound generator was designed and built in the Medical Physics department at the Singleton Hospital, Swansea. The device consists of a box, approximately 15 cm × 10 cm × 2 cm which generates an electrical signal 100 μs wide at a Pulse Repetition Frequency of 350 Hz for 10 minutes. The signal stimulates a piezo-electric crystal which emits a 100 μs pulse of 500 KHz ultrasound. The crystal is held in a headpiece, similar to a bone conductor hearing aid. Contact with the mastoid bone is via a fluid filled rubber sac coated with ultrasound transmissive gel.

The power output is approximately 4 mW/cm^2 (SPTA) (at 1 cm in H_2O) over the 10-minute period. This is less than that used in conventional diagnostic ultrasound. When ultrasound is used in selective destruction of the vestibular labyrinth approximately 10 000 times this dose is applied directly to the thinned lateral semicircular canal.

Measurements of the output of our generator were made at the Wessex Regional Medical Physics service. Pressure profiles of the ultrasound beam were measured in a scanning tank at a depth of 2.5 cm. However, ultrasound is conducted extremely well in fluid. The half intensity power distance of 1000 KHz ultrasound is 15 metres in water but only 0.5 mm in temporal bone and is zero in air (Angell James, 1968).

The amount of ultrasound actually reaching the cochlea in our study would be expected to be immeasurably small.

We felt that the treatment would not only be non-toxic but would be completely ineffective.

Case material

An enthusiastic group of 40 patients from the Swansea Tinnitus Association volunteered to take

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part in the study. Their age range was 35 to 72 years and no account was taken of the aetiology or frequency of their tinnitus.

Criteria for inclusion were:

(a) The tinnitus was of at least one years duration.
(b) The patient had previously been investigated by the ENT department to exclude serious or correctable disease.
(c) A few volunteers who were receiving treatment for anxiety or depression, or who were thought might be unreliable witnesses, were excluded from the trial. We now feel that this is not justifiable and in a larger study, now being started, all 150 volunteers are being asked to complete an Eysenck Personality Inventory. The results of this will be analysed at the end of the study.

Twenty-eight patients completed the study.

Reasons for exclusion were:

(1) Five patients repeatedly failed to attend for the second treatment.
(2) Seven patients failed to return their completed questionnaire.

Method

Two sets of identical devices were numbered and coded by a technician in the Medical Physics department who had no other involvement in the trial.

All patients had pure tone audiometry and tinnitus match performed before starting the test.

For each test the patient sat in a quiet room and a ultrásound/placebo device was fitted over the mastoid and switched on for 10 minutes. Each generator has a small light which flashes to indicate a signal is being emitted, whether a crystal is present in the headpiece or not. After 10 minutes the patient filled in a form giving name, age, sex, number of device and the response to treatment (complete improvement, slight improvement, unchanged or worse). The patients kept the forms for a further 24 hours in case they wished to make other comments on the treatment and its effects.

Each patient returned for a second treatment one to two months later when a different device was used.

All persons involved in the trial, both subjects and experimenters, were unaware which devices were ultrasound or placebo. This could not be detected without dismantling the headpiece.

Results

The results are shown in Table I.

Eleven patients were improved by ultrasound, two of these were also improved by placebo. No patient was improved by placebo but not improved by ultrasound. One patient was temporarily worse after ultrasound. Statistical analysis using the Binomial test showed ultrasound to be significantly better than placebo at improving tinnitus ($P = 0.012$, Binomial test.)

Age, sex, aetiology and tinnitus frequency had no obvious effect on the results but no attempt was made to analyse these factors statistically as the subgroups were too small.

In two cases the improvement in the tinnitus lasted about 12 hours. However, one of these patients commented that any improvement in his tinnitus resulted in a sense of well-being, which made him better able to cope with his problem. In all other cases improvement only lasted while the device was being worn.

Discussion

Tinnitus is a difficult symptom to quantify and often more difficult to treat. No cure exists at present although some patients can be improved and helped by certain treatments, notably masking. In the UK 0.5% of the adult population (approximately 200 000) report that their tinnitus prevents them from leading a normal life. Eight per cent (four million persons) claim to experience tinnitus which causes moderate to severe annoyance and interferes with their getting to sleep (Coles, 1984).

Ultrasonic destruction of the labyrinth has been described as a treatment of vertigo due to Meniere's disease (Angell James, 1968). In reviewing his results Angell James noted that 70% of his patients had complete or partial improvement of their tinnitus post-operatively, although only 15% had improved hearing. It is proposed that ultrasound may have a therapeutic effect by enhancing blood flow and

Table I. Cross tabulation of grade of response to ultrasound by grade of response to placebo

			Placebo			
1. Complete improvement of tinnitus			1	2	3	4
2. Slight improvement	Ultrasound	1	0	1	0	0
3. No improvement		2	0	1	9	0
4. Worse		3	0	0	16	0
		4	0	0	1	0

increasing vascular permeability (Angell James, 1968; Binder *et al.*, 1985). In high doses it alters membrane permeability resulting in changes in potential differences across membranes and it affects intracellular pH and enzyme activity.

In our study a dose of ultrasound 10 000 times smaller than that used in destruction of the labyrinth was applied over the mastoid. It seems unlikely that any change in hair cell or nerve cell potential occurred.

However, 40% of our patients, who completed the trial, were subjectively improved by ultrasound and for this reason we are embarking on a more major study with a larger number of tinnitus sufferers.

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