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Low-powered ultrasound in the inhibition of tinnitus

R. J. Rendell, D. G. Carrick,* C. P. Fielder,† D. E. Callaghan and K. J. Thomas

Welsh Hearing Institute, University Hospital of Wales, Cardiff, Wales

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Abstract

An experiment was performed using low-level ultrasound in an attempt to inhibit tinnitus during and after stimulation. The method used a double-blind crossover technique with a placebo. Forty subjects were tested, and they generally reported little or no change in their tinnitus, the results from placebo and ultrasound not being statistically different. It cannot be concluded, therefore, that the ultrasound we were using has any beneficial effect on tinnitus. These results do not confirm the findings of the pilot study using the same ultrasound devices (Carrick *et al.*, 1986).

Introduction

Carrick *et al.* (1986) performed a pilot study in which low-powered ultrasound was assessed as a treatment for tinnitus. Following the positive results of that study, a prospective, randomised, double-blind study was set up to determine quantitatively any reduction or increase in tinnitus, using tinnitus matching procedures, following the use of an ultrasound device. We also wanted to analyse subject-reported changes in tinnitus as in the first experiment.

It is known that some forms of ultrasound can modify cell morphology, biochemistry or behaviour, typically through a significant rise in temperature, or through the hydrodynamic shear forces generated by cavitational activity (Williams, 1983; Sarvazyan, 1983). The beneficial effects on the tinnitus of a patient undergoing ultrasonic investigation of the maxillary antrum, reported in the pilot study, were of an undetermined mechanism.

Method

Data were collected from 40 subjects, selected from among patients who had suffered tinnitus for at least 1 year. Their tinnitus was reported as continuous and was due to a variety of aetiological factors; in most instances it was impossible to identify a particular cause. The subjects were all considered to be reliable witnesses; 22 were from the Swansea Tinnitus Group and 18 were from patients seen at the Tinnitus Clinic of the Welsh Hearing Institute. Of the total, 24 were males (mean age 59.8, s.d. = 6.3) and 16 were females (mean age 55.2, s.d. = 6.2). The group mean age was 57.8 years (s.d. = 6.6).

The ultrasound generator (Fig. 1) was identical to that used in the first study. It consisted of a box ($15 \times 10 \times 2$ cm) containing the electronics to generate an electrical signal, which in turn stimulated a piezo-electric crystal which emitted a 100 μs pulse of 500 kHz ultrasound at a repetition rate of 355 Hz. The device produced a peak pressure of 57 kPa at 1 cm in water, with a spatial peak temporal average of approximately 4 m W cm^{-2}. These figures are considerably less than those commonly found in medical applications of ultrasound, where scanning devices often produce outputs hundreds of times as great (Duck *et al.*, 1985; Carson *et al.*, 1978), although foetal monitoring devices use continuous wave ultrasound as low as 3 m W cm^{-2} (McDicken, 1981). The crystal was held in a headpiece similar to that used for bone-conduction audiometry. Contact with the mastoid bone was via a fluid-filled rubber sac coated with ultrasound

* *Now at the ENT Department, Gartnavel General Hospital, Glasgow, Scotland.*

† *ENT Department, University Hospital of Wales, Cardiff, Wales.*

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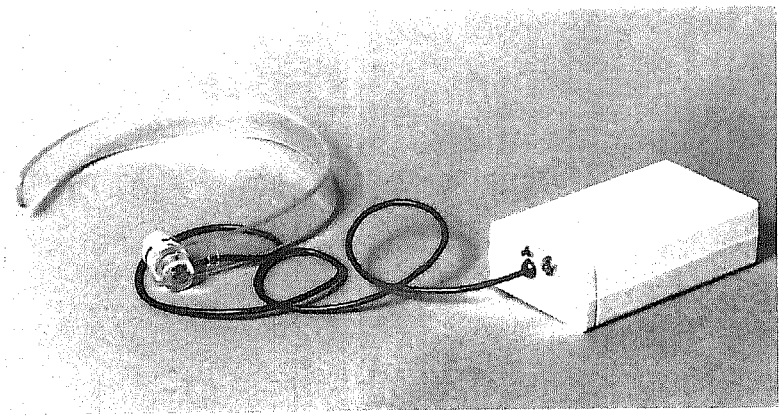

Fig. 1. The ultrasound generator.

transmissive gel (normal 'Neptic' EEG electrode gel).

Three devices were constructed, together with 3 placebo units, identical in every respect except that the crystal was not connected to the power supply and hence could emit no ultrasound. The 3 pairs were colour-coded; red, blue and orange. Neither testers nor subjects could tell which unit of each pair was the placebo and which was the ultrasound device. Subjects were randomly allocated a unit on their first visit and its partner on the second visit, usually 6 weeks later.

Subjects were not told that one of the units was a placebo. Instead, the two units in each pair were described as similar but different ultrasound generators, and that one, both or neither might have an effect on tinnitus. In this way, we prevented subjects from guessing at the nature of the unit they were using, particularly during a second session where they might try to compare the two units in the light of the first results and the expectancy that one of the pair would be better than the other.

On arrival, the subjects were asked to complete a rating scale semantic differential description of the loudness and pitch of their tinnitus (Fig. 2) after time had been taken to explain the principle of the rating scale itself. They were asked to decide which of their tinnitus sounds (if multiple) was the main one, and in which ear it was predominant; this was defined as the most troublesome tinnitus. For the purposes of the experiment, the subjects were asked to concentrate on the most troublesome tinnitus. On the first visit an air-conduction audiogram was performed, together with a simple questionnaire about the nature of the tinnitus. This questionnaire was also of the rating scale type.

The subjects then performed a series of microcomputer-controlled tinnitus matches (Lutman, 1983), generally ipsilateral to the most troublesome tinnitus. Where the thresholds in that ear were too high for the psycho-acoustical testing (typically over 80 dB), contralateral matching was used. The subject could adjust the frequency of a continuously variable pure tone to attempt to match the pitch of their tinnitus. The subjects' audiometric thresholds were entered into the computer program, and the varying pure tone was always presented at a 'comfortable' level above threshold, this level having been determined by the subject. Then using a pure tone of 500 Hz or 2 kHz, whichever was closest to the tinnitus pitch-matched frequency, a tinnitus loudness measure and hearing threshold were recorded. The difference between these two measures gave a sensation level of the tinnitus, and this calculated level was used in the analysis.

Following these tests, the subjects indicated any change in their tinnitus on the rating scale and were fitted with the appropriate unit. This was worn for a period of 20 min, during which time the subject sat in a quiet room, generally alone. After 5 min and again after 20 min, the rating scale was completed. Subjects were also asked if they could feel or hear anything from the unit before it was removed. As well as completing the rating scale questions, subjects were asked the less formal question of whether or not their tinnitus had changed since wearing the unit, and if so was it now better or worse. They were allowed one of 6 replies: 'tinnitus gone', 'tinnitus much better', 'tinnitus slightly better', 'tinnitus unchanged', 'tinnitus slightly worse', 'tinnitus much worse'. This allowed for any change in the tinnitus that the subject was unable to describe in terms of pitch or loudness and was the method used in the earlier study, so allowing a direct comparison of our results with those of that investigation. The computer-controlled tinnitus matches were then repeated, giving an indication

Name..... Date.....

Please put an arrow where you feel it is most appropriate to describe your tinnitus.

Before test	Very quiet	_____	Very loud
	Low-pitched	_____	High-pitched
After test			
	Very quiet	_____	Very loud
	Low-pitched	_____	High-pitched
5 min into trial			
	Very quiet	_____	Very loud
	Low-pitched	_____	High-pitched
After trial			
	Very quiet	_____	Very loud
	Low-pitched	_____	High-pitched
After second test			
	Very quiet	_____	Very loud
	Low-pitched	_____	High-pitched

Fig. 2. The rating scale worksheet used for the patients' description of the loudness and pitch of their tinnitus.

of any residual inhibition of tinnitus, following the use of the device.

Three distinct sets of comparisons between changes in tinnitus associated with ultrasound and placebo could therefore be made: (a) Loudness match changes measured on the psycho-acoustical test rig. (b) Changes in loudness recorded on the rating scales. (c) Patient opinion of 'improvement' or otherwise in tinnitus. These comparisons are similar to those in a recent study on the use of acupuncture in the treatment of tinnitus (Marks *et al.*, 1984).

Changes in pitch were also determined by the psycho-acoustical matches and through the rating scales, but pitch changes were rarely reported and the data are not presented here.

The rating scale analysis was performed by dividing the lines of the scale into 10 equal parts and assigning numerical values to each subject's responses after the test session had finished.

Results

Results from the three pairs of devices were analysed together. The results from some subjects had to be discounted from some parts of the analysis for various reasons:

(1) Patients who exhibited differences in pre- and post-treatment threshold determinations of greater than 10 dB during the psycho-acoustical evaluation were excluded from the psycho-acoustical analysis. Such large apparent variations in threshold were not felt to be compatible with reliable descriptions of tinnitus loudness using this method, or likely to have been due to the treatment, although their inclusion in the analysis would not have changed the overall results.

(2) Inability to perform psycho-acoustical matches due to complexity of tinnitus sounds and difficulty in understanding the concept of loudness when applied to sounds within the ears also led subjects to be excluded from the psycho-acoustical analysis.

(3) The rating schedule and verbal opinion data were not collected from some subjects, due to tester oversights.

(4) The tinnitus of one subject disappeared following the use of both ultrasound and placebo devices, precluding the second psycho-acoustical matches and consequent analysis.

The three sets of analysis [(a) to (c) above] therefore contain different population sizes. The results were as follows.

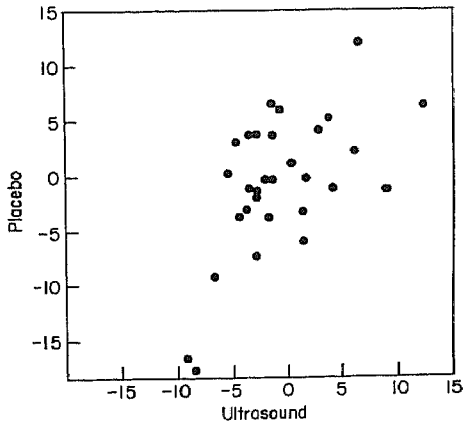

Fig. 3. Changes in tinnitus loudness measured on the psycho-acoustical test rig. Results for the placebo plotted against those for the ultrasound generator, showing the placebo effect. N = *31; correlation = 0.53.*

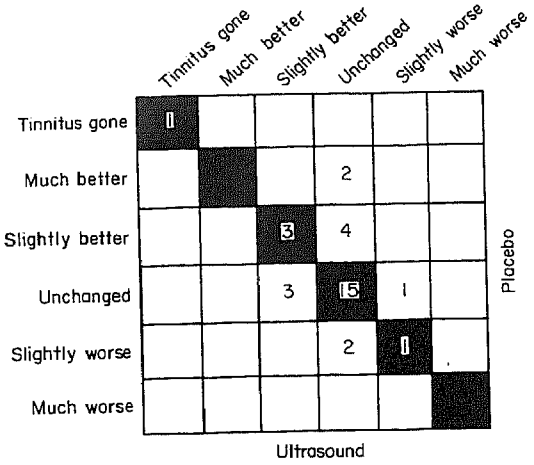

Fig. 4. Verbal opinion of the subjective change in tinnitus. Numbers in cells in the top right half of the table represent subjects who reported the placebo better than the ultrasound. Those in the bottom left half represent those who reported the ultrasound better than the placebo. Numbers on the shaded diagonal represent subjects who gave the same report for both units.

Tinnitus loudness match

Analysis of tinnitus loudness on the psycho-acoustical rig, before and after wearing a unit, showed a mean reduction in tinnitus of 0.35 dB (s.d. = 4.64) for the ultrasound and 0.69 dB (s.d. = 6.44) for the placebo. The results from 31 subjects were analysed using a paired *t*-test. The difference between these two treatments was not significant at the 5% level. The correlation coefficient when the effect of the ultrasound was plotted against that of the placebo was 0.53, which is significant at the 1% level. Subjects whose tinnitus matches showed a reduction with one unit tended to show a similar reduction with the other (Fig. 3). This finding is similar to that of Erlandsson *et al.* (1987).

Rating scale analysis

The rating scale was the least sensitive to tinnitus change of the 3 sets of results, and subjects who reported a significant change in their tinnitus would often mark only a small change on the rating scale. Marks *et al.* (1984) allowed subjects much more time to familiarise themselves with this type of scale prior to the experiment, which probably explains their greater success with this method.

The results from the 38 subjects who completed this part of the experiment were as follows:

(1) Changes following wearing of the ultrasound device: mean = 0.29 units, s.d. = 1.21.

(2) Changes following wearing of the placebo: mean = −0.58 units, s.d. = 1.57.

(3) Changes following the first tinnitus matches, before unit had been worn (ultrasound session): mean = −0.05 units, s.d. = 1.47.

(4) Changes following the first tinnitus matches, before unit had been worn (placebo session): mean = −0.11 units, s.d. = 1.25.

None of the differences between figures for ultrasound and placebo, and between trial and matching procedures, was significant at the 5% level, when a *t*-test was performed.

The results from the rating scale analysis following the second tinnitus matches, after the units had been worn, were similar to those from the first matches, and are not presented here.

Verbal reports

Twenty of the 32 subjects gave the same response for both placebo and ultrasound devices. Fifteen reported no change in tinnitus from either unit. Seven subjects gave a more favourable report to the placebo, and 5 to the ultrasound (see Fig. 4).

Three subjects reported a worsening of their tinnitus on their return home which was not apparent in the clinic. In all cases, the worsening lasted for a few days. In one, this followed a test session using the ultrasound device, in another a placebo had been used, and in the third the phenomenon occurred after both ultrasound device and placebo.

One subject reported a reduction in tinnitus loudness contralateral to the side of the unit, with

both the ultrasound and placebo. No subjects reported an immediate effect on their tinnitus when the ultrasound device or placebo was fitted. All reported changes were gradual. Some subjects reported changes in tinnitus resulting from the audiometry, and even from sitting in a quiet waiting room before the tests started.

Discussion

One is left to speculate as to the reasons behind the apparent success of the pilot study. The subjects in the pilot study were all selected from the Swansea Tinnitus Group and had been told full details of the experiment, including the fact that one of the pair of units was a placebo. This may have modified their responses if they tried to guess which of the units was expected to work. In that study, subjects were often tested in small groups, with free discussion between them during test sessions. This again may have led to bias in the results if a subject found one particular unit beneficial and imparted this information to the others.

Our work demonstrated a notable placebo effect and demonstrated the difficulties some tinnitus sufferers have in assigning qualitative measures, or quantitative descriptions, to a very subjective phenomenon.

Conclusions

Our experiments did not confirm the results of the first study. The phenomenon of tinnitus inhibition by ultrasound was originally reported following a level typical of diagnostic ultrasound considerably greater than the levels we used. It was felt by the workers in the pilot study that the low levels of ultrasound used would have only limited transmission to the cochlea. It would be interesting to repeat the work using higher levels of sound, although this may raise ethical problems. Other variations could be to the frequency and pulse rate of the ultrasound used.

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References

Carrick, D. G., Davies, W. M., Fielder, C. P. and Bihari, J. (1986) Low-powered ultrasound in the treatment of tinnitus: a pilot study. *British Journal of Audiology*, **20**, 153–155.

Carson, P. L., Fischella, P. R. and Oughton, T. V. (1978) Ultrasonic power and intensities produced by diagnostic ultrasound equipment. *Ultrasound in Medicine and Biology*, **3**, 341–350.

Duck, F. A., Starritt, H. C., Aindow, J. D., Perkins, M. A. and Hawkins, A. J. (1985) The output of pulse-echo ultrasound equipment: a survey of powers, pressures and intensities. *British Journal of Radiology*, **58**, 989–1001.

Erlandsson, S., Ringdahl, A., Hutchins, T. and Carlsson, S. G. (1987) Treatment of tinnitus: a controlled comparison of masking and placebo. *British Journal of Audiology*, **21**, 37–44.

Lutman, M. E. (1983) Microcomputer-controlled psycho-acoustics in clinical audiology. *British Journal of Audiology*, **17**, 109–115.

Marks, N. J., Emery, P. and Onisiphorou, C. (1984) A controlled trial of acupuncture in tinnitus. *Journal of Laryngology and Otology*, **98**, 1103–1109.

McDicken, W. N. (1981) *Diagnostic Ultrasound*, 2nd edn. John Wiley & Sons, New York.

Sarvazyan, A. P. (1983) Some general problems of biological action of ultrasound. IEEE Sonics & Ultrasonics, **30**, 2–12.

Williams, A. R. (1983) *Ultrasound: Biological Effects and Potential Hazards*. Academic Press, London.