Critical Review:
The efficacy of ultra-high frequency bone conduction stimulation for the treatment of tinnitus

Karla Tucker
M.Cl.Sc. (AUD) Candidate
University of Western Ontario: School of Communication Sciences and Disorders

This critical review examined the literature relating to the efficacy of ultra-high frequency bone conduction stimulation for the treatment of tinnitus. The study designs reviewed included five single group studies with a pre-posttest experimental design (one of which also included a single subject case study), one nonrandomized clinical trial cohort study, and two prospective crossover experimental studies with a single subject design. Overall, the evidence did not support the use of bone conducted ultra-high frequency treatment for tinnitus and a change in current clinical practice is not recommended. Given the limited number of well-designed studies providing a high level of evidence, further research should be completed. Future studies should include patients with various types of tinnitus and use larger sample sizes, prospective within group crossover designs, double-blinding, and placebos. It would also be beneficial to compare treatment results for stimuli of different frequency ranges and to compare stimuli delivered via bone conduction to stimuli delivered via air conduction, to determine whether bone conducted stimuli is in fact more beneficial than traditional tinnitus masking methods.

Introduction

Tinnitus is a problem faced by over 36 million people in the United States and severe cases have been reported by approximately 8 million (Kantu and Sperling, 1999, p.109). Tinnitus is a symptom characterized by sensations in the head or ears in the absence of external stimuli and may include ringing, buzzing, or other noises (Tinnitus Association of Canada, 2007). Some sufferers report irritation, difficulty concentrating, difficulty sleeping, depression, and feelings of despair (Erlandsson, 2000, p. 26). Given the prevalence and effects of tinnitus, it is important to evaluate all treatment options to determine whether there is evidence to support the implementation of new therapies in clinical practice.

There are two main categories of tinnitus: objective and subjective. Objective tinnitus is physical sound that originates internally and can be detected by a physician. In contrast, subjective tinnitus is audible only to the patient suffering from the disorder (Kantu and Sperling, 1999, p.109 and Alpiner and McCarthy, 2000, p.392). This is the type that is usually being referenced when the term tinnitus is used.

There are several treatment options available to tinnitus patients such as Tinnitus Retraining Therapy (TRT), masking, amplification, and limiting tinnitus-inducing agents and environmental factors. TRT involves habituating the patient's reactions to tinnitus rather than attempting to eliminate the sounds (Lockwood, Salvi and Burkard, 2002). TRT involves counseling and educating patients and using sound therapy (e.g. sound generators or hearing aids) to enhance external sounds (Jastreboff and Hazell, 2004, p. 64-65 and Tinnitus Association of Canada, 2007). Tinnitus masking is another form of treatment that suppresses tinnitus by using external sound to reduce tinnitus perception (Jastreboff and Hazell, 2004, p.208 and Johnson, 1998, p.169). Devices used to produce tinnitus masking effects fit behind- or in-the-ear and are usually worn by normal hearing tinnitus patients. For some patients, it produces residual inhibition, or a period of tinnitus relief that is experienced after masking has been removed (Johnson, 1998, p.169-170). While masking is a common method of treatment, not all patients experience improvement (Lockwood, Salvi and Burkard, 2002). Given that a significant number of individuals with tinnitus have hearing loss, amplification can also be used as a treatment. Some studies have reported tinnitus relief in 25% of patients who used hearing aids, although the reason for this is unknown (Kantu and Sperling, 1999 and Jastreboff and Hazell 2004). Other treatments involve limiting factors that contribute to tinnitus including exposure to loud noise and using masking techniques such as soft, white noise at night to promote sleep (Kantu and Sperling, 1999). Patients may also be instructed to discontinue the use of tinnitus-inducing drugs and to manage metabolic or dietary disorders, which may involve the avoidance of nicotine, chocolate, coffee, or tea (Kantu and Sperling, 1999). The management of active ear conditions can also improve tinnitus and may be as simple as using topical antibiotics to treat otitis externa (Kantu and Sperling, 1999 and Sander, 2001).

Objective

The primary objective of this paper is to critically evaluate the efficacy of ultra-high frequency bone conduction stimulation for the treatment of tinnitus.

Methods

Search Strategy. Computerized databases including MEDLINE, SCOPUS, CINAHL, and PubMed were searched using the following search strategy: [(high-audio-frequency) OR (ultrasonic) OR (ultra-high frequency) OR (high-frequency bone conduction) OR (UltraQuiet) AND (tinnitus)]. The search was limited to 'English' and 'Humans'.

Selection Criteria. Studies included in this review examined the use of ultra-high frequency stimuli (i.e. stimuli that included frequencies above 10kHz) delivered via bone conduction for the treatment of tinnitus. Review articles were not included. Initial studies were selected by reviewing abstracts to determine which articles met the inclusion criteria. The reference lists in the articles selected were also examined.

Data Collection. The results of the literature search yielded eight articles for inclusion in the review: five single group studies with a pre-posttest experimental design (one of which also included single subject case study), one nonrandomized clinical trial cohort study, and two prospective crossover experimental studies with a within groups repeated measures design.

Results

Study #1. Goldstein, Shulman, Lenhardt, Richards, Madsen, and Guinta (2002) evaluated the residual inhibition of tinnitus following treatment with the *UltraQuiet* device in patients with mild to moderate high frequency hearing loss and severe, disabling high-pitched tinnitus. The study used a single group (n=9) pre-posttest experimental design.

The *UltraQuiet* treatment consisted of digitally processed music that was used to modulate a 10-20 kHz signal, delivered via a bone conduction transducer to the mastoid. The stimulus was presented at 6 dB above each subject's threshold. The subjects listened to the stimulus for 30 minutes (increasing to 60 minutes) a day, twice a week, for four weeks. Audiograms and tinnitus pitch matching procedures were performed pre- and post-treatment and a questionnaire was administered 2-8 months after the end of treatment. Based on the results of the questionnaires, all subjects reported improvement in their tinnitus and the duration of the improvement varied from subject to subject, lasting from 1 hour to 4 weeks. Two subjects reported no residual inhibition of the tinnitus. There were no significant changes in the patients' audiograms following treatment.

This study did not include randomization or controls and statistical analyses were not reported. The results should therefore be interpreted with caution.

Study #2. Lenhardt, Goldstein, Shulman, and Guinta (2003) examined the effectiveness of the *UltraQuiet* device for tinnitus treatment in a research report that included 3 different studies. Two experimental groups were used but there were no controls. One segment of the experiment used a single group pre-posttest experimental design (n=10) and another segment of the study used a single subject case study (n=1). The other participants (n=4) were used for calibration purposes and did not participate in the experimental aspects of the study.

Ten participants received high frequency stimulation and had moderate, high frequency hearing loss with a tinnitus pitch that ranged from 6-14 kHz. The treatment consisted of high frequency pulsed patterns delivered via bone conduction to the mastoid at frequencies above 6 kHz. The authors indicated that six of the ten participants receiving high frequency stimulation reported some relief from their tinnitus up to 2 months after treatment. Four patients experienced complete masking, one patient experienced partial masking, one patient experienced tinnitus relief without masking, and four patients dropped out of the study due to a lack of relief. The outcome measures used in the study were not discussed.

In addition to the study described above, a comfort test of the muscle vibration was performed. Four otologically normal adults were used to judge the dynamic range of the muscle vibration from 'detection' to 'annoying'. The low frequency muscle vibration consisted of swept tones from 50-110Hz delivered to the postaricular muscle using a magnetostriction transducer or audiological vibrator. The dynamic ranges were measured by: 1) determining thresholds through a method of limits and 2) instructing subjects over three trials to increase hand-held transducers until muscle vibration was 'uncomfortable but not intolerable'. The study reported that the vibration intensity was raised approximately 15dB before reaching an uncomfortable level.

Finally, a case study of a subject with the ability to modulate his tinnitus loudness through motor actions (clenching his teeth and fists) was described. The subject was used to judge the masking effectiveness and acceptability of the low frequency muscle stimulators. According to the patient's self report, vibration to the postaricular muscle was effective for

masking tinnitus and modulating its loudness when standard vibrators were used. However, the magnetostriction transducer was ineffective, as it became uncomfortably warm during treatment.

The study did not use randomization or controls, nor did it provide sufficient information about the measures used to evaluate treatment outcomes. Statistical analyses were not reported and the sample sizes for each experiment in this study were small.

Study #3. Shulman, Strashun, Avitable, Lenhardt, and Goldstein (2004) used positron emission tomography (PET) as an objective monitoring system to compare brain metabolism before and after the use of ultra-high frequency tinnitus therapy. They also compared the PET data with subjective behavioural responses of the subjects. The study used a single group pre-posttest experimental design (n=6). All patients experienced subjective idiopathic tinnitus and were randomly selected from 15 patients who were receiving *UltraQuiet* therapy. The experimental group (n=6) received 10-12 treatments with the therapy device for a period of 5-7 weeks. All patients were evaluated according to a medical-audiological tinnitus protocol, which includes ultra-high frequency and conventional audiometry, self-administered tinnitus questionnaires, tinnitus pitch and loudness matching, and minimal masking level measures. PET was completed 1 week prior to treatment and within 12 hours of the final treatment. PET scans were analyzed for twelve regions of interest (ROI): the left and right thalamus; the temporal, auditory, parietal, and frontal lobes; and the cerebellum. The Bonferroni correction for 12 paired t-tests was used and it was reported that normalized data for interhemispheric differences in the cerebellum (left versus right) were significant ($p=0.003$) before treatment but were not significant ($p=0.0052$) following treatment. However, based on the significance level used ($p>.05$), it appears that the pre- and post-treatment interhemispheric differences in the cerebellum were not significant. There were no significant differences found before or after therapy in all other ROI. Subjects reported varying degrees of tinnitus improvement on the questionnaires and minimal masking levels were found to be significantly reduced. The best subjective reports were from patients with thresholds of 50 dB or less from 10-14 kHz. The authors concluded that the correlation among PET and changes in minimal masking levels, ultra-high frequency audiograms, and the subjective reports suggest that treatment induced neuronal reprogramming in the cortex. However, this was not based on a statistical analysis of correlation.

This study did not use randomization or controls and the sample size was small. Although statistical analyses were reported, there were discrepancies between the significance level used and what was reported as being statistically significant, and claims were made about correlations that were not tested statistically.

Study #4. Goldstein, Lenhardt, and Shulman (2005) evaluated the long-term efficacy of *UltraQuiet* therapy for providing tinnitus relief, masking, and residual inhibition in patients with problematic tinnitus using a single group pre-posttest experimental design (n=15). All patients experienced severe, disabling subjective idiopathic tinnitus and had mild to moderate high frequency hearing loss and high frequency tinnitus, except for one patient with low frequency tonal tinnitus. The treatment consisted of digitally processed music from approximately 6-20 kHz delivered via bone conduction. Audiological evaluations were completed and included pure tone audiometry, speech audiometry, tinnitus pitch and loudness matching, residual inhibition measurement, and minimal masking level measurement. Outcome questionnaires including the tinnitus intensity index, annoyance index, and the tinnitus severity index were also administered. Audiologic evaluations and outcome questionnaires were completed prior to treatment and one week after the last session. Outcome measures were also completed before and after each treatment session and a follow-up questionnaire was administered 8 weeks after therapy. Subjects were randomly assigned to one of three groups, receiving 10, 12, or 14 treatments. The first session for each group consisted of a 30 minute treatment and other sessions consisted of 60 minute treatments. Self reports indicated that eleven patients experienced tinnitus improvement and the other four patients reported improvement on measures of tinnitus intensity or severity after the treatment was completed. A significant improvement ($p=0.006$; $t=2.98$) in tinnitus severity was reported in the questionnaires following treatment but the questionnaire results for tinnitus intensity and annoyance were not significantly different after treatment. The authors stated that the most notable change was the reduction in the minimal masking levels but no statistical analyses were reported. Six patients reported residual inhibition, lasting from 4.5-6.2 minutes. The patients receiving 10 treatments averaged slightly above ‘no change’ and those patients receiving 12 or 14 treatments averaged slightly above ‘slight improvement’.

Although the authors indicated that patients were randomly assigned into three groups, all patients

received the same treatment, with only small differences in the treatment periods and no controls were used. In addition, the study did not provide sufficient information about the measures used to evaluate treatment outcomes.

Study #5. Goldstein, Shulman, and Lenhardt (2005) presented the results of their patient selection criteria for predicting success in patients receiving ultra-high frequency therapy with the *UltraQuiet* device or ultrasonic acoustic therapy with the *HiSonic* device. The study was a nonrandomized clinical trial cohort study that included 52 consecutive patients with severe, disabling subjective idiopathic tinnitus whose ages ranged from 30-74 years. All patients were evaluated according to the medical-audiological tinnitus patient protocol, as was described above. High frequency audiometry was used to measure thresholds from 10-20 kHz and patients were divided into two groups based on the researcher's selection criteria, which suggested that patients with thresholds less than 40-50dB SPL from 10-14 kHz should be treated with the *UltraQuiet* device and patients with thresholds greater than 50-60dB SPL from 10-14 kHz should be treated with the *HiSonic* device. The *UltraQuiet* treatment group received bone conducted stimulation from 10-20 kHz and the *HiSonic* treatment group received bone conducted ultrasonic stimulation from 20-26 kHz. Each individual received a trial of 0.5 to 1 hour. Following treatment, 22 of the 52 patients reported some tinnitus relief. The researchers' reported that the patient selection criteria predicted relief in 20 of these 22 patients (i.e. patients who were successful in the treatment met the audiometric criteria outlined prior to the study). However, it was unclear as to why the selection criteria was successful in predicting relief when the most of the patients did not experience relief after the criteria was applied for assigning patients to the different treatment groups.

This study did not use randomization or controls, it did not provide sufficient information about the treatment selection criteria or outcome measures, and no statistical analyses were reported.

Study #6. Lenhardt, Shulman, and Goldstein (2008) analyzed the activity of the insula cortex in tinnitus and tinnitus treatment. The study used a single group (n=6) pre-posttest experimental design. All patients had severe disabling tinnitus and the age range was 35-72 years. Subjects were evaluated using the medical-audiological tinnitus patient protocol described above and outcome questionnaires were completed pre- and post-treatment. The participants had mild to moderate high frequency hearing loss and their tinnitus pitch was 5-16 kHz. Treatment with the *UltraQuiet* was provided over 14 sessions (twice per week for 8 weeks). Position emission tomography (PET) was performed within 1 week prior to the treatment and at the end of 8 weeks of therapy. The images were interpreted in a 'blinded fashion' by a neuroradiologist. The percent metabolic change in the insula of the medial temporal lobe (MTL), final physiologic state (hyper- or hypometabolic), and the laterality (right versus left) was determined. Five of the six subjects reported tinnitus relief on the outcome questionnaires and all subjects showed a reduction in minimal masking levels. The study reported that 'some effect' was observed in the final scan in comparison to the initial scan for all subjects.

The study used a small sample size, did not use randomization or controls, and statistical analyses were not reported.

Study #7. Carrick, Davies, Fielder, and Bihari (1986) evaluated whether a low dose of ultrasound applied to the mastoid would result in subjective tinnitus improvements. The study was a prospective crossover experimental study that used a within groups repeated measures design (n=40). The subjects' ages ranged from 35 to 72 years and all patients experienced tinnitus for at least one year and were evaluated by an ENT. Only 28 patients completed the study, as the remainder failed to attend sessions or submit questionnaires. Pure tone audiometry and tinnitus matching were completed prior to the treatment. Two devices were used in the study: one device delivered an ultrasound signal of 500 kHz through a transducer placed on the mastoid and the other device was a placebo that was identical to the ultrasound device in appearance but did not emit a signal. Each patient received one treatment with either the ultrasound device or placebo for 10 minutes. Following treatment, the patient completed a four-point rating scale to assess the response to treatment (complete improvement, slight improvement, unchanged, or worse). One to two months after receiving the treatment, patients returned for a second treatment with a different device. The subjects and experimenters were unaware of which device was the placebo. The study reported that tinnitus was improved in eleven patients but that two of these were also improved by the placebo. The Binomial test was used and showed that the ultrasound device was significantly better for improving tinnitus than the placebo ($P = 0.012$).

Although this study was a double-blinded experiment that used a placebo, patients received only one

treatment with each device and the number of dropouts was high.

Study #8. Rendell, Carrick, Fielder, Callaghan, and Thomas (1987) administered an ultrasound treatment, quantified changes in tinnitus through tinnitus matching procedures, and evaluated subject self-reported changes. The study was a prospective crossover experimental study that used a within groups repeated measures design (n=40). The group mean age was 57.8 years and all subjects had experienced tinnitus for at least one year. Patients were randomly assigned to receive treatment from either an ultrasound device that delivered a signal of 500 kHz or an identical placebo unit that did not emit a signal and double blinding was used.. Six weeks later, the subjects returned for treatment with a different device. Tinnitus matching procedures and audiograms were completed prior to treatment and after each treatment session. Participants completed a tinnitus questionnaire at the beginning of the study and completed a rating scale to assess the tinnitus pitch and loudness at the beginning of the treatment session. During each treatment session the subjects wore an ultrasound transducer over the mastoid for 20 minutes and answered rating scale questions 5 minutes and 20 minutes after the session began, providing subjective opinions about whether they felt their tinnitus had changed. The study reported that there were no statistically significant differences between the placebo and the ultrasound devices.

This study is the most suitable for answering the proposed research question, as it was a prospective, double-blind experiment with a placebo condition and statistical analyses were reported.

Discussion

The authors of the Lenhardt et al studies reported that ultra-high frequency stimuli delivered via bone conduction can result in improvement and residual inhibition of severe, disabling tinnitus. They also suggested that patients with thresholds of 50 dB or less from 10-14kHz report the most benefit. However, these results should be interpreted with caution, as the studies did not provide a high level of evidence and were not well-designed. All of these studies met level 3 of the levels of evidence provided by Archibald (2009), with the exception of the single subject case study (in study #2) and the nonrandomized clinical trial cohort study (study #5), which met levels 4 and 2c, respectively. One of the major flaws these studies was that no controls were used. Only one of the studies used randomization to assign patients to one of three groups receiving the same treatment, with only small differences in the treatment periods for each group. None of the studies used blinding and the sample sizes were small. Moreover, the authors suggested that distortion-free high frequency stimulation is difficult to achieve through air conduction in the presence of hearing loss and that it is important to have high tinnitus frequencies in a masker; however, they did not provide detailed information about how the treatment device provides tinnitus relief or residual inhibition or why the high frequency stimuli and bone conduction delivery was used. There also appeared to be a conflict of interest, as the studies were completed by the research group responsible for the commercially available *UltraQuiet* device.

The two studies by Carrick et al were provided a higher level of evidence than the Lenhardt et al studies, meeting an evidence level of 2b (Archibald, 2009). They also provided a more logical rationale for selecting this treatment by citing research suggesting that some forms of ultrasound can alter cell morphology, biochemistry or behaviour (Williams, 1983 and Sarvazyan, 1983). However, the two pilot and the follow-up studies presented conflicting results: the pilot study reported that the high frequency ultrasound device was significantly better for improving tinnitus than the placebo but the follow-up study did not confirm this finding. In the follow-up study, Rendell et al (1987) discussed some factors about the pilot study that may have influenced the results. These included the fact that patients were aware that one of the devices was a placebo and that they were tested in small groups, which provided an opportunity to discuss the treatment.

Conclusion

As a result of the major flaws of the Lenhardt et al papers and the conflicting results of the Carrick et al studies, a change in current clinical practice is not recommended. Given the limited number of well-designed studies providing a high level of evidence, further research should be completed. Future research studies should include patients with various types of tinnitus and should use larger sample sizes, prospective within group crossover designs, double-blinding, and placebos. The subjective nature of tinnitus evaluation would require the use of tinnitus matching procedures and questionnaires and it is important to measure conventional and ultra-high frequency hearing thresholds, as it is unlikely that ultra-high frequency stimuli will benefit patients with poor thresholds in this range. It would also be beneficial to compare treatment results for stimuli of different frequency ranges and to compare stimuli delivered via bone conduction to stimuli delivered via air conduction, to determine whether the former

method is in fact more beneficial than traditional tinnitus masking methods.

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