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Short Communication

Combined sound conditioning therapy and counseling for tinnitus treatment: proof-of-concept study in Colombia

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ABSTRACT

Demonstrate the efficacy and applicability of sound conditioning therapy (SCT) with counseling for tinnitus treatment in subjects with normal hearing and mild-moderate hearing loss using therapeutic frequency modulated noise in a developing country. Retrospective cohort study evaluating 18 patients treated with SCT between 2018 and 2020 in a tertiary-care hospital outpatient tinnitus clinic in Bogotá, Colombia. Tinnitus intensity was quantified in decibels (dB) sound pressure level (SPL) and measured with the visual analogue scale (VAS) before and after treatment with SCT. Quality of life change after the intervention was evaluated with the tinnitus handicap index (THI) and the tinnitus reaction questionnaire (TRQ). Subjects received SCT for 2 to 7 months with two daily customized sound sessions and periodic counseling based on cognitive behavioral therapy (CBT) principles. After treatment there was a significant decrease ($p<0.01$) for all outcomes measured including a mean difference in tinnitus intensity of 7.6 dB (95% CI, 4.5-10.7), VAS score of 4.5 (95% CI, 3.5-5.5), TRQ score of 36.4 (95% CI, 29.8-43) and THI score of 33.1 (95% CI, 25.6-40.5) compared to baseline. SCT and CBT-based counseling should be available as an alternative in patients with tinnitus treated with a multidisciplinary team. This study shows the improvement in symptoms and quality of life after treatment. Future research is warranted with a larger sample size and longer follow-up periods to show the overall effect of SCT and CBT-based counseling.

Keywords: Tinnitus, Acoustic stimulation, Audiology, Inner ear, Quality of life

INTRODUCTION

Tinnitus is defined as the subjective perception of sound in the ear and/or head without a source outside of the body.[1] It can be either primary or secondary; primary tinnitus is subjective and originates from the central auditory system. It is idiopathic in nature and is mostly associated with sensorineural hearing loss. Secondary tinnitus involves sound generation from a mechanical source in the head or neck which is transmitted by bone conduction to the inner ear, where it is detected and interpreted as an external sound.[2]

Currently, the global prevalence of tinnitus is not completely known due to the vast heterogeneity of definitions.[3] Most studies have been conducted in Europe and North America reporting an approximate prevalence of 10-15% in adults.[4] In the United States, data from the population-based National Health And Nutrition Examination Survey (NHANES) showed an overall

prevalence of 25.3% in adults with a peak of 31.4% at 60-69 years of age.[5] Similarly, in Latin-America prevalence in older adults have been estimated to be within 28.5-32% while in Africa is about 32.9%.[6-8] Nevertheless, the prevalence of severe, debilitating tinnitus worldwide is about 1%.[8,9] There is an increased tinnitus association with diabetes mellitus, hypertension, ototoxic drug exposure, history of noise exposure and subjective hearing loss; reaching a prevalence higher than 40% in some groups.[9] Although, tinnitus can be underreported or overreported due to the subjective nature of the condition and the need to self-report.

Jastreboff and colleagues suggested that tinnitus is influenced by brain neuroplasticity in the limbic system and its relationship with the medial geniculate body and auditory cortex which are current targets for treatment.[10,11] Most types of tinnitus are generated in the central nervous system in response to damage to the inner ear or auditory nerve.[12] The interaction between auditory areas and areas processing emotions can contribute to tinnitus generation. Hence, the auditory and limbic system are interconnected playing a role for tinnitus generation or stabilization. For instance, there are subcortical connections from the ascending auditory system to the amygdala that can contribute to tinnitus pathophysiology.[13]

Currently, there is no therapeutic device that has demonstrated a complete suppression in tinnitus perception. Some available options are hearing aids and cochlear implants in patients with bilateral or unilateral sensorineural hearing loss.[14,15]

However, for patients with normal hearing, severe and debilitating tinnitus there is the possibility of using sound therapy, which increases the perception of environmental sounds by masking tinnitus and external sound perception.[16] This therapy was first introduced in 1970, followed by the first tinnitus maskers commercially available and then by mixed devices with amplification and generation of sound in 1990.[17]

Previous studies on tinnitus patients have shown a subjective benefit of sound conditioning therapy (SCT), a type of sound therapy that identifies the exact sound frequency where tinnitus is perceived and facilitates external stimulation in the affected frequency. Therefore, the use of SCT could decrease the hyperactivity of specific central auditory system regions and counteract the maladaptive response associated with tinnitus.[18,19] In addition, simultaneous use of cognitive behavioral therapy (CBT) principles, help patients understand the source of tinnitus by changing their false beliefs and interpretations about their condition, responsible for the reactions and distress associated with tinnitus.[20]

This proof-of-concept study aims to demonstrate the efficacy and applicability of SCT with CBT-based counseling for tinnitus treatment in subjects with normal hearing and mild-moderate hearing loss using therapeutic frequency modulated noise in a developing country.

METHODS

This retrospective cohort study was conducted in a tertiary care outpatient tinnitus clinic in Bogotá, Colombia from 01 January 2018 to 31 December 2020. Approval of the institutional review board was given by Fundacion Universitaria de Ciencias de la Salud (FUCS) (DI-I-0418-21). Tinnitus diagnosis, sound therapy, counseling and follow-up were performed by the lead audiologist of the audiology section of the department of otolaryngology. Inclusion criteria were having a previous diagnosis of primary severe and debilitating tinnitus, subjects older than 18-years-old, normal hearing or mild to moderate hearing loss assessed by 6 band audiograms. Exclusion criteria were subjects with a diagnosis of tinnitus with severe to profound sensorineural hearing loss or secondary tinnitus. Subjects that met inclusion criteria were offered sound conditioning therapy and counseling with cognitive behavioral therapy principles.

Demographic variables were evaluated including age, sex, and laterality. Type and degree of hearing loss and tinnitus were evaluated separately. Tinnitus evaluations was made with 134 band audiometry also known as micro audiometry including frequencies from 2.5-14 kHz to determine the affected frequency. Intensity was determined using dB SL (sensation level) and the visual analogue scale (VAS). The type of tinnitus was classified as pure tone, noise or complex noise. To evaluate the impact on quality of life two questionaries were conducted including the tinnitus handicap inventory (THI) and the tinnitus reaction questionnaire (TRQ). These questionaries were done previous and after SCT.

Subjects were given an MP3 player (Sony Walkman Nw-e393, Sony Corporation; Tokyo, Japan) with insert headphones, which had predetermined specific therapeutic sounds depending on their tinnitus characteristics (REVE134, Earlogic; Seoul, South Korea). Sound conditioning therapy is not covered by insurance in Colombia; therefore, treatment was provided to subjects free of charge. All subjects had two daily sessions of 40 minutes each during 15 consecutive days followed by 5 rest days. Following the first 20 days of therapy, subjects visited the tinnitus clinic to assess new tinnitus characteristics and establish a new frequency of therapeutic sounds in order to decrease cochlear fatigue. This new sound was used for another 15 days with 5 consecutive rest days. Subjects with bilateral tinnitus had the sound stimulus changed to the contralateral ear and those with unilateral tinnitus used the sound in the same ear. Additionally to sound therapy, subjects received CBT-based counseling therapy based on the principles of tinnitus retraining therapy and cognitive behavioral therapy for tinnitus.[21,22]

For statistical analysis, a Shapiro Wilk test was used to determine if the data analyzed was normally distributed. Linear regression analysis was done to adjust for possible baseline confounders such as age and duration of tinnitus. For parametric data, paired t-tests were used to calculate

the difference in score for THI and VAS before and after treatment with SCT. For non-parametric data, Wilcoxon signed rank test was used to calculate the difference in tinnitus frequency (Hz), intensity (dB) and TRQ before and after treatment with SCT. Spearman correlation was used to detect possible correlations between variables. Sample size calculation was done using a confidence interval of 95%, a margin of error of 5% and a population proportion of 1% for patients with severe and debilitating tinnitus worldwide, which resulted in a total sample of 16 patients required. An alpha level of 0.05 was used to determine statistical significance. Analysis was conducted using STATA 17 (StataCorp, College Station, TX, USA) and plots were constructed with Prism 9 (GraphPad Software, San Diego, CA, USA).

RESULTS

The study enrolled a total of 18 adult patients with tinnitus who were treated with SCT and CBT-based principles for a mean time of 4.4 months (SD, 1.46). 67% were males and the population had a mean age of 54 (SD, 9.5). Duration of tinnitus was from 0-12 months in 50% of patients, 13- 48 months in 22% of patients and more than 49 months in 28% of patients. Most patients (72%) had pure tone tinnitus and the remaining patients had noise tinnitus (Table 1). Most patients had bilateral tinnitus with a sudden onset. Age and tinnitus duration did not have a significant effect on the outcomes measure after conducting a linear regression analysis ($p>0.05$). Among the 18 patients included in this study, 39% had moderate hearing loss and 50% had history of noise exposure.

After micro audiometry, it was found that the most affected region or area of major deflection was between 8 kHz and 12 kHz. Tinnitus was detected at a median frequency of 8.6 kHz (IQR, 11.01-7.7 kHz) for all patients tested and a median intensity of 13.3 dB (IQR, 18.5-9.75 dB) (Figure 1). The subjective tinnitus intensity assessed with the VAS showed a median of 7.5 (IQR, 6-9) across subjects. For the THI and TRQ questionnaires, scores were mild for 11% and 16% of patients, moderate for 50% and 55% of patients, severe for 22% of patients and catastrophic for 16% and 5% of patients tested, respectively.

After treatment with SCT there was a decrease in objective and subjective tinnitus intensity with a median of 5.6 dB (IQR, 2-6 dB) and a median VAS score of 2.9 (IQR, 2-4), respectively. The mean score for THI was 23 (SD, 19) and for TRQ was 13 (SD, 12) showing a decrease compared to scores before intervention with SCT (Figure 2). There was no patient with a THI or TRQ graded as catastrophic after intervention.

There was a median tinnitus reduction intensity of 7.6 dB (95% CI, 4.5-10.7) and a VAS reduction of 4.5 dB (95% CI, 3.5-5.5). For the quality-of-life outcomes, there was a median decrease in the THI and TRQ questionnaire of 33.1 (95% CI, 25.6-40.5) and 36.4 (95% CI, 29.8-43.0), respectively. These results showed a statistically significant difference compared to pre-intervention with SCT ($p<0.001$). After conducting a correlation analysis between tinnitus intensity and quality of life it was found that patients with lower TRQs tended to have lower levels of tinnitus intensity (dB) showing a significant moderate correlation ($R=0.49$, $p<0.05$) (Figure 3).

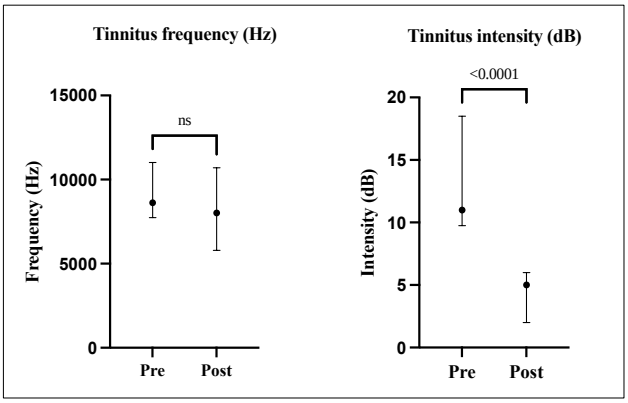

Figure 1: (A) Tinnitus frequency (Hz) and (B) intensity (dB) characterized pre-treatment and post-treatment with sound conditioning therapy, ns=no significant, p<0.0001

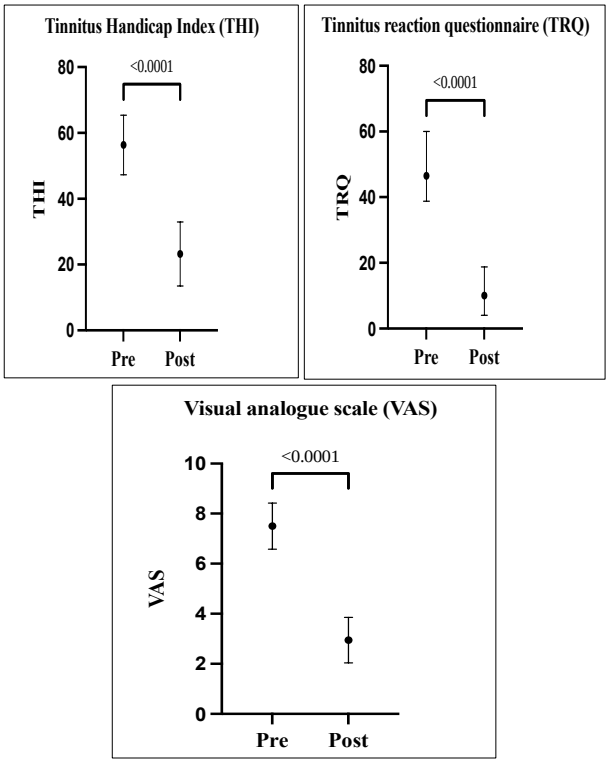

Figure 2: (A)Tinnitus handicap index (THI) score, (B) tinnitus reaction questionnaire (TRQ) score and (C) visual analogue scale (VAS) score pre-treatment and post-treatment with sound conditioning therapy, p<0.0001.

Table 1: Demographic characteristics of study participants.

Subject	Gender	Age	Side	Onset of tinnitus	Tinnitus duration (months)	Type of tinnitus	Treatment (months)
1	Male	56	Bilateral	Sudden	3	Noise	6
2	Male	56	Bilateral	Progressive	120	Noise	6
3	Male	62	Right	Progressive	300	Pure tone	4
4	Female	78	Bilateral	Sudden	2	Noise	6
5	Male	63	Bilateral	Progressive	48	Pure tone	6
6	Male	48	Bilateral	Progressive	72	Pure tone	4
7	Male	57	Bilateral	Sudden	8	Pure tone	4
8	Male	37	Right	Sudden	12	Pure tone	2
9	Female	47	Bilateral	Progressive	12	Pure tone	5
10	Male	43	Bilateral	Sudden	4	Noise	3
11	Male	47	Bilateral	Progressive	6	Pure tone	6
12	Male	45	Bilateral	Progressive	1	Pure tone	4
13	Male	54	Bilateral	Sudden	3	Pure tone	4
14	Male	Unknown	Bilateral	Sudden	16	Pure tone	2
15	Female	54	Right	Progressive	120	Noise	7
16	Female	48	Bilateral	Sudden	48	Pure tone	4
17	Female	62	Bilateral	Sudden	24	Pure tone	4
18	Female	52	Central	Sudden	24	Pure tone	3

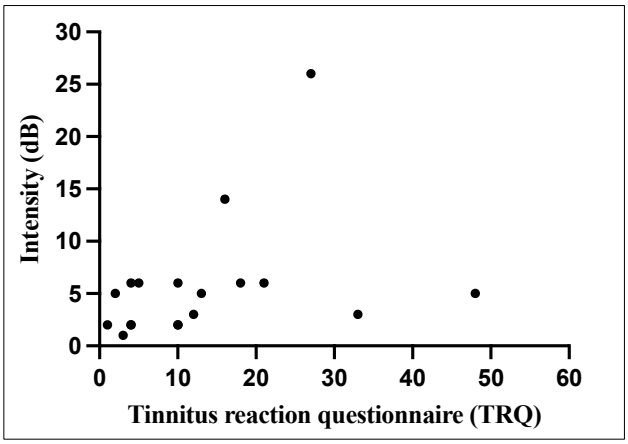

Figure 3: Spearman correlation between tinnitus intensity (dB) and tinnitus reaction questionnaire (TRQ) score, R=0.49, p<0.05.

DISCUSSION

This study investigated the efficacy of implementing SCT and CBT-based counseling in an outpatient tinnitus clinic of a tertiary care center in Bogota, Colombia. Subjects were followed between 2-7 months, with an intended time to treat of at least 1 month. Some subjects finished treatment earlier because they felt a subjective improvement without the need of continuing therapy. This treatment modality seems to be an option for patients with tinnitus who have normal hearing and mild-moderate hearing loss. Tinnitus induction by hearing loss is the most common form observed, secondary to acoustic trauma or aging.[23,24] After treatment there was no difference in tinnitus frequency but there was a significant decrease in tinnitus intensity. This improvement could be explained by the motor capacity of the outer hair cells to manage repetitive environmental stimulation and used this to dampen the perception of auditory stimulation as a protective effect.[25]

The most suitable candidates for sound therapy are patients with some degree of hearing loss or clinically normal hearing.[26] Patients in the present study, had normal to moderate hearing loss with low intensity tinnitus identified in the higher (8-12 kHz) frequencies. We used 134 band micro audiometry because it allows for a better characterization of microstructure auditory thresholds.[27] Indeed, it is proposed that tinnitus spectrum fits within the region where there is hearing loss and tinnitus pitch might influence the outcome of acoustic stimulation treatments.[28-30] Therefore, having the possibility to identify high frequency tinnitus and using acoustic stimulation at the same frequency allows for a subjective decrease in loudness.

Prior studies have validated the use of sound therapy for the treatment of sensorineural hearing loss, hyperacusis and chronic tinnitus. Enriched acoustic environmental stimulus can decrease auditory hypersensitivity after a few weeks of acoustic stimulation.[31] Similarly, in patients with sensorineural hearing loss the use of threshold sound conditioning generates an improvement in a narrow band frequency threshold in most of the subjects tested.[32] For patients with chronic tinnitus (>12 months), the use of

transcutaneous vagus nerve stimulation paired with music therapy at the same tinnitus frequency resulted in improvement in tinnitus loudness and awareness.[33] In a randomized clinical trial, the use of tinnitus retraining therapy (TRT) using sound therapy and counseling also showed significant improvement in overall quality of life after 18 months of treatment.[34]

Our study confirms the previous findings showing that a decrease in tinnitus intensity is directly correlated with an improvement in quality of life. There was a significant improvement after treatment in overall quality of life, as shown in both validated THI and TRQ questionnaires. This highlights the importance of tinnitus reduction on patient's improvement in their activities of daily living and their wellbeing. Additionally, there was a significant decrease in subjective (VAS) and objective (dB) tinnitus intensity. Demonstrating that tinnitus masking with sound conditioning therapy provides enough contrast between the background noise and subjective sound to decrease loudness and perception, even after finishing active treatment.

Limitations of this study include the retrospective nature of the study, the need to directly compare the results with other non-invasive treatments for tinnitus, the combination of two therapies in the same group, and the relatively small sample size. Future studies should implement participant randomization and a direct comparison between SCT and CBT-based counseling in a larger patient population for longer follow-up periods to confirm these results.

CONCLUSION

SCT combined with CBT-based counseling should be available as an alternative to patients with tinnitus treated by a multidisciplinary team including an otologist and audiologist. This study demonstrates the decrease of intensity and improvement quality of life expressed as a decrease in THI and TRQ scores after treatment with SCT as a safe and feasible therapy in patients with tinnitus. Larger prospective studies are needed to allow further analysis and compare SCT with CBT-based counseling to other available therapies.

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Ethical approval: Not required

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