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Original Research Article

Android software-based tinnitus retraining therapy: efficacy in treatment of refractory tinnitus

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ABSTRACT

Background: Tinnitus is described as a perception of sound in the absence of a sound stimulus. Despite the availability of a number of management strategies, the cure for tinnitus remains elusive. Tinnitus retraining therapy (TRT) combines sound therapy with directive counselling to address subjective tinnitus. This study was done to assess the efficacy of TRT in management of subjective tinnitus that is refractory to various tinnitus treatment strategies. The objectives of this study were to assess the efficacy of Android software TRT in management of refractory tinnitus and to observe the association of hearing status on response to TRT.
Methods: Observational, analytical cohort study of 51 patients undergoing smartphone-based TRT. The assessment tools included comprehensive audiometric evaluation, two self -administered questionnaires tinnitus handicap inventory (THI) and tinnitus functional index (TFI) which were assessed at baseline (0), 6 weeks and at 12 weeks of TRT.
Results: Statistical data analysis revealed significant improvement in perceived severity of tinnitus following TRT, reflected by improvement of THI and TFI scores (statistically significant, $p<0.05$). Mean pure tone average threshold was 22.1Hz. Additionally, no significant association was found between the hearing loss and the severity of tinnitus.
Conclusions: There is significant improvement in self-perceived disability and severity following TRT as measured using THI and TFI. The results confirm the efficacy of TRT in management of patients with refractory tinnitus.

Keywords: Tinnitus, TRT, Sound therapy

INTRODUCTION

Tinnitus is a conscious perception of an auditory sensation in the absence of a corresponding external stimulus (McFadden).[1,2] It is prevalent in 10-15% of the population and associated with significant morbidity in certain patient groups. Both adults and children report experiencing tinnitus. Tinnitus may be described subjectively as hissing, buzzing and ringing sounds, but more complex sounds such as musical sounds and voices can also be perceived by some patients.[2] Tunkel et al described persistent tinnitus as one that exists for 6months or more.[3] Previous studies have individually described refractory tinnitus as one which is persistent for more than 6 months duration and not responding to any previous other forms of therapeutic interventions (Pharmacologic therapy, sound masking, herbal medications like Gingko Biloba etc).[4-6] A myriad of medical, psychological and device treatments are available for treatment of tinnitus but there is limited evidence of benefit. Currently, hearing amplification with education and counselling are encouraged by most physicians as a primary intervention for a patient with tinnitus and aid-able hearing.[2] TRT is based on the neurophysiological model of tinnitus. It comprises of sound therapy with retraining counselling.[1] Habituation is

a normal and important function of the brain, as despite the fact that the brain can detect very weak significant sound patterns like cry of a baby, it cannot concentrate on multiple tasks that require full attention at any given time. Habituation is achieved by blocking the neuronal activity from reaching the limbic and autonomic nervous systems. It decreases the negative reactions of the patient to Tinnitus, such as anxiety and annoyance. [7] The aim is to make the patient understand the origin of tinnitus as an auditory compensation. It is also essential for the patient to accept the goals of TRT as realistic and achievable. In present study, we refer refractory tinnitus as the subjective tinnitus which is responding to any previous form for tinnitus management and persistent for more than 6 months duration. This study has been carried out with the aim to assess the efficacy of computer based TRT in management of chronic, subjective tinnitus refractory to other forms of medicinal treatments.

METHODS

This was an observational analytical cohort study which included 51 patients above the age of 18 years, visiting the OPD of department of ENT at a tertiary care centre between November 2019 to November 2021. A minimum sample size of 43 (N) participants was estimated using statistical formula for a single proportion to have statistically significant results,

$N=Z^2 P(1-P)/d^2$

N=sample size, Z-statistic corresponding to level of confidence and P=expected prevalence, d is the precision.

Inclusion and exclusion criteria

Individuals reporting with unilateral or bilateral, bothersome, subjective tinnitus, causing mild/moderate/severe handicap (based on THI scores), refractory to any form of medical or behavioural therapy for more than 6months duration previously, were included in the study.

Patients with history of or diagnosed with known treatable causes of tinnitus like Meniere's disease, vestibular Schwannoma, CP angle lesion, AICA loop, patients with only slight handicap due to tinnitus, patients not compliant for follow up were excluded from study.

All the patients underwent detailed clinic-audiological assessment at initial presentation. A baseline tinnitus evaluation was done using self-administered tinnitus questionnaires, THI and TFI along with tinnitus pitch-matching and masking. After explaining the procedure involved, written and informed consent was obtained from all the patients in the study. 51 patients fulfilling the inclusion criteria received TRT using a software (Tinnitus trio) installed onto an Android smartphone. Patients were followed up for a period of 12 weeks at an interval of 06 weeks each. At each follow up visit THI and TFI were recorded along with documentation of clinical response. SPSS (Statistical package for social sciences) version 20. [IBM SPSS statistics (IBM corp. Armonk, NY, USA released 2011)] was used to analyse the statistical data. Repeated measures of ANOVA were applied to test the statistical significance of the data.

RESULTS

The 51 participants, all more than 18 years of age, were studied. The mean age of the study population was 41.96 years with the median age being 43.5 years (Table 1). The study comprised of 19 females and 32 males.

Table 1: The age distribution frequencies of the study population.

Age (Years)	Frequency	Percent (%)
21-30	14	27.5
31-40	9	17.6
41-50	10	19.6
51-60	18	35.3
Total	51	100

The 58.9% (30 participants) lateralised their tinnitus to both ears, while 41.2% (21 participants) lateralised tinnitus to either left or right ear (Table 2). 21 participants had a mild grade of tinnitus which was intrusive, 29 participants had a moderate grade of tinnitus and only 01 participant reported severe grade of tinnitus at the beginning of the study (Table 3).

Table 2: Frequency distribution of the laterality of tinnitus in the study population.

Laterality	Frequency	Percent (%)
Bilateral	30	58.9
Unilateral	21	41.2
Left	11	21.5
Right	10	19.6
Total	51	100

Table 3: Frequency distribution of study population based on severity of tinnitus (THI score).

Severity	THI score	Frequency
Slight (Grade1)	0-16	0
Mild (Grade 2)	18-36	21
Moderate (Grade 3)	38-56	29
Severe (Grade 4)	58-76	1
Catastrophic (Grade 5)	78-100	0

TRT response is equivocal across different hearing thresholds (Table 5). Statistically significant decrease found in average THI and global TFI scores at follow up of 12 weeks post initiation of TRT (with $p<0.05$) (Table 5). There was clinically significant improvement in annoyance, sleep and anxiety subscales of TFI along with statistically significant improvement in global TFI scores.

Table 4: Comparison of improvement of tinnitus severity (THI, TFI) with respect to the baseline pure tone average hearing threshold using repeated measures of ANOVA.

Tinnitus severity and duration (Weeks)		Normal				Mild				Moderate			
		Mean	S. D.	N	P	Mean	S. D.	N	P	Mean	S. D.	N	P
THI	Baseline	53.47	10.90	34	0.001	58.17	11.13	12	0.002	61.20	4.14	5	0.003
	6	42.65	10.54	34		51	9.667	12		54.80	3.63	5	
	12	36.53	9.925	34		40	10.12	12		44.80	5.58	5	
TFI	Baseline	41.59	14.29	34		50.42	16.48	12		41.20	9.36	5	
	6	30.97	17.33	34		38.33	15.38	12		22.80	8.13	5	
	12	29.65	17.13	34		35.33	13.67	12		22.00	6.70	5	

Table 5: Results of comparison of baseline THI scores and TFI scores with 12 week follow up scores.

Laterality		Time duration (Weeks)		Mean difference	Std. error	P value	95% CI for difference	
							Lower bound	Upper bound
Unilateral	THI	Baseline	6	8.762	1.583	0	4.627	12.896
			12	16.857	1.813	0	12.12	21.594
		6	12	8.095	1.134	0	5.133	11.057
	TFI	Baseline	6	12.952	2.876	0.001	5.438	20.467
			12	15.095	2.777	0	7.839	22.351
		6	12	2.143	0.566	0.003	0.664	3.622
Bilateral	THI	Baseline	6	10.067	1.168	0	7.098	13.036
			12	17.400	1.774	0	12.893	21.907
		6	12	7.333	1.156	0	4.396	10.271
	TFI	Baseline	6	10.867	2.402	0	4.763	16.97
			12	12.200	2.462	0	5.945	18.455
		6	12	1.333	0.609	0.11	-0.214	2.881
Total	THI	Baseline	6	9.529	0.942	0.000	7.197	11.862
			12	17.176	1.271	0.000	14.027	20.326
		6	12	7.647	0.819	0.000	5.619	9.675
	TFI	Baseline	6	11.725	1.831	0.000	7.190	16.261
			12	13.392	1.838	0.000	8.839	17.946
		6	12	1.667	0.427	0.001	0.608	2.725

DISCUSSION

Tinnitus has a wide range of effects on the quality of life (QoL) of the individual. It effects the functions of sleep, concentration, thoughts and emotions. It may be associated with hearing difficulties and sound intolerance. Among the tools for evaluation of subjective and psychosomatic aspects of the disease, essential are the self-administered questionnaires for tinnitus such as tinnitus handicap inventory (THI), tinnitus questionnaire, TFI.[2] THI was recommended by the tinnitus research initiative (2006) for use in evaluation of tinnitus handicap and the outcomes of therapy.[8]

TFI is as a quality tool in assessment of multiple domains of tinnitus severity. It contains 8 subscales-intrusive, control, cognitive, sleep, auditory, relaxation, quality, emotional; of which seven contain 3 items each and one contains 4 items each.[9] As seen with other studies, the higher the THI score, the more likely the patients suffered with disorders of sleep and anxiety as per the TFI scores. There was positive statistically significant correlation found between the mean THI and TFI scores which further consolidates the association of quality of life with the severity of tinnitus.[8,9]

Jastreboff reported statistically significant improvement in severity of tinnitus in patients treated with TRT. This improvement was found to be more consolidated after at least 3 months of therapy and patients did not feel tinnitus as problem of their life.[10,11] Similar results were observed in our study which was statistically significant and also clinical improvement seen among study population post 12 weeks of TRT. A higher gain was observed in patients who had presented with higher distress symptoms due to tinnitus. After 12 weeks of TRT, the emotional subscale of THI and the annoyance subscale of TFI reported maximum improvement. THI and TFI are excellent tools of classification and evaluation of the therapeutic outcomes of any mode of tinnitus management.

Davis postulated that hearing loss may influence tinnitus severity. But there is little directed evidence that hearing loss has any effect on severity of tinnitus. Searchfield et al studied 79 subjects using THQ and correlated with their audiometric findings. The study proposed that higher tinnitus handicap associated with low frequency hearing loss due to reduction in masking of tinnitus by ambient low frequency sound.[12] Coles showed that groups with tinnitus have worse hearing than the non-

tinnitus groups. The study found that the prevalence of tinnitus increased with severity of hearing loss, regardless of the frequency affected by the hearing loss. In subjects with unilateral tinnitus, a higher prevalence on the side with greater hearing loss was found.[13] Chung et al found higher incidences of hearing difficulties among patients with tinnitus.[11] Henry conducted a randomised controlled clinical study comparing the efficacy of tinnitus masking and TRT in 118 military veterans divided into two groups, given over 18 months. The outcomes were evaluated using self-administered tinnitus questionnaires (THI, THQ, TSI) and verbally administered tinnitus interview forms. The study concluded that patients having serious (high degrees of) difficulty with their tinnitus, may benefit most from TRT and also that the level of hearing loss was not associated with improvement or differential treatment effectiveness.[14] Our present study found no significant difference in incidence of tinnitus between those with normal hearing sensitivity or those having any amount of hearing loss. Literature also states that tinnitus is not fully explained by cochlear pathology and poor correlation between hearing thresholds and self-reported distress has been observed. [15]

Bauer concluded that TRT participants reported a significant reduction in the tinnitus impact, i.e., the associated negative reactions to tinnitus without any significant change in the tinnitus sensation level. Also, the study observed a subjective decrease in loudness of tinnitus post TRT as expected from habituation as it does not change the signal level but rather the interpretation or response to the signal.[16]

Limitations

The small size of study population and short duration of follow up could be a limitation for the validation of the above findings.

CONCLUSION

In our present study we conclude that TRT is an effective tool for management of tinnitus, especially in patients with persistent, refractory tinnitus. This is seen with the significant improvement in not just severity of tinnitus but the QoL factors like sleep, anxiety and annoyance related negative associations are also positively improved. We also found no association between the severity and prognosis of outcomes with hearing loss of the individual. The limitations of this study are small study population and short duration of study.

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