

International Journal of Medical Science and Innovative Research (IJMSIR)

IJMSIR : A Medical Publication Hub Available Online at: www.ijmsir.com Volume – 7, Issue – 5, October – 2022 , Page No. : 145 – 150

A Novel Treatment Protocol for the Management of Tinnitus through Multimodality Brain Stimulation

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**Citation this Article:** Prajakta Patil, Abhijeet Shinde, Yash Huzurbazar, "A Novel Treatment Protocol for the Management of Tinnitus through Multimodality Brain Stimulation", IJMSIR- October - 2022, Vol - 7, Issue - 5, P. No. 145 - 150.

**Type of Publication:** Original Research Article **Conflicts of Interest:** Nil

## Abstract

**Background:** Tinnitus is a prevalent disorder affecting the quality of life of 0.5–3% of the population. We aimed to develop a novel treatment protocol for the management of tinnitus through multimodality brain stimulation.

**Method:** Present study included 33 adults of age ranged from 30-65years, with unilateral (31-subjects) and bilateral (2-subjects) chronic tinnitus with and/or without hearing loss independent of their etiology. Treatment protocol included 5 consecutive sessions with follow-up of 6 months. Each session was divided into 3 parts: • Pretreatment: a) Informed consent b) Pitch and loudness matching. • Treatment: Bimanual paper pen task with tinnitus masking for 30 minutes. • Post-treatment: a) Pitch and loudness matching b) Directive counseling and obtaining feedback. Paper-pen task was performed bimanually that included carrying out two different writing activities in different context. The level of difficulty of the activities was increased in successive sessions. Narrowband noise of a frequency same as that of tinnitus was presented at 10 dBSL of tinnitus for 30 minutes simultaneously in the ear with tinnitus.

**Results:** The perception of tinnitus was no longer present in 4 subjects while in remaining subjects it reduced to an intensity that its perception no longer troubled them without causing residual facilitation. Across the 33 subjects' intensity of tinnitus decreased by an extent of 45dBHL at an average. However, in few subjects, intensity of tinnitus also decreased by more than 45dBHL. The approach resulted in statistically significant reductions in TFI and THI scores. The results correlate with pre and post treatment score of THI that dropped from 90% to 0%.

**Conclusion:** The present study suggests that this novel treatment approach is cost effective, time saving and efficient to vanish the tinnitus or to reduce the intensity of tinnitus to a negligible level and thereby eliminating the negative reactions towards tinnitus.

**Keywords:** Tinnitus; Multimodality; Audiological; Tinnitus Functional Index; Tinnitus Handicap Inventory; Intensity

# Introduction

Tinnitus is defined as perception of sound which is involuntary, originates in the head or oversensitivity to external sound [1]. Prevalence estimates vary widely due to broad variations in study quality and construct definitions and range between 5 and 43% [2,3]. Multiple mechanisms may be responsible within one individual [4] such as over activity of auditory cortex [5]; involvement of autonomic nervous system and limbic system [6]. Writing with both hands simultaneously creates incoordination between both hands which could be due to hemispheric conflict. Brain asymmetry allows the 2 sides of brain to become specialized, increasing its processing capacity and avoiding situations of conflict where both sides of brain take charge [7].

The Tinnitus Handicap Inventory (THI; [8]) was developed to measure the impact of tinnitus on daily life. It has three subscales: functional, emotional, and catastrophic responses to the tinnitus. Both the overall questionnaire and the functional and emotional subscales show good internal consistency. However, a unifactorial structure was found in subsequent validation studies [9]. More recently, the Tinnitus Functional Index (TFI) was developed as a new measure of the severity and negative impact of tinnitus, both for use as a diagnostic tool and for measuring treatment-related changes in tinnitus [10]. The TFI is a multi-domain questionnaire, measuring tinnitus-related distress/severity as a function of predominantly psychological constructs, such as attention, worry, anxiety, depression as well as the more functional constructs such as hearing, social life, and activity level [11].

Tinnitus retraining therapy (TRT) is used as an effective treatment for tinnitus but followed by certain consequences such as residual inhibition and facilitation. The effect of TRT is not permanent since residual inhibition and facilitation occur after certain period of time. It takes 12-24 months for the individuals to get habituated to the negative reactions to tinnitus and its perception, which is a long-term process. Thus, there is a need to invent a treatment or management procedure supplementary to TRT that will reduce and/or eliminate the consequences of tinnitus and which will increase the efficacy and reduce the overall time duration required for treatment [12]. Hence the present study was undertaken to develop a novel treatment protocol for the management of tinnitus through multimodality brain stimulation.

# **Materials and Method**

The present study included 33 adults of age range between 30-65years with unilateral (31 subjects) and bilateral (2 subjects) chronic tinnitus with and/or without hearing loss independent of their etiology. Out of these, two subjects had normal hearing sensitivity and bilateral tinnitus while the others had bilateral mild to moderately severe sensorineural hearing loss and unilateral tinnitus. Audiological test battery was administered in order to ascertain the type and degree of hearing loss and the characteristics of their tinnitus. Tinnitus Handicap Inventory [8] and Tinnitus Functional Index [10] was administered before and after the treatment sessions to record the subject's self-report about tinnitus.

The Treatment protocol included 5 consecutive sessions with follow-up of 6 months with each session of 90 minutes was divided into 3 parts:

- Pre-treatment: a) Informed consent c) Pitch and loudness matching (20 mins)
- Treatment: Bimanual paper pen task with tinnitus masking (30 mins)
- Post-treatment: a) Pitch and loudness matching b)
  Directive counselling and obtaining feedback (40 mins)

Session description: Pitch and loudness matching was done pre and post session by presenting the pure tone and/or NBN in the ear contralateral to tinnitus. Then the subjects were instructed to perform bimanual paper pen tasks for 30 minutes while narrow band noise of a frequency same as that of tinnitus was presented at 10 dBSL of tinnitus for 30 minutes simultaneously in the ear with tinnitus. Paperpen task was to be performed bimanually that included carrying out two different writing activities of different context by using both hands simultaneously. (For ex: Writing given numbers in the form of words using left hand while drawing rectangles using right hand.) The level of difficulty of the activities was increased in successive sessions. (e.g., by Writing the names of local train stations y left hand while simultaneously solving a basic mathematical problem by right hand)

Directive counselling was focused on:

- 1) Rationale of treatment
- 2) The subconscious mind and the vicious cycle of tinnitus
- 3) Attention, diversion, and ignorance from tinnitus
- Precautions to be taken to avoid relapse and follow up
- 5) Clearing subject's doubts (if any)

Treatment program was conducted for 5 consecutive sessions, subsequent to which each subject is kept on a follow-up for a period of 6 months to eliminate the possibility of residual inhibition.

## **Statistical Analysis**

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) software, version 25 (IBM Corp., Armonk, NY, USA). Values for continuous variables are presented as mean  $\pm$  standard deviation. The mean score of TFI and THI were

compared using the paired sample t-test. Differences with

p<0.05 were considered statistically significant.

# Results

A total of 33 adults' patients were enrolled in the study. Most of the patients were in the age group of 51-60 years (48.48%) with male predominance (75.75%), (Table 1). The mean age of patients was  $57\pm11.3$  years, ranged from 30-65 years.

Parameters		No.	of	Percentage
		patients		
Age	30-39	02		6.06
group	40-49	10		30.30
	50-59	16		48.48
	≥60	05		15.15
Gender	Male	25		75.75
	Females	08		24.24

Table 1: Demographic profile of the patients

The perception of tinnitus was no longer present in 4 subjects while in remaining subjects it reduced to an intensity that its perception no longer troubled them without causing residual facilitation. The negative reactions (e.g., stress, anxiety, frustration, irritation) to the tinnitus were decreased in all subjects. Across the 33 subjects the intensity of tinnitus decreased by an extent of 45dBHL at an average. However, in few subjects, intensity of tinnitus also decreased by more than 45dBHL. The approach resulted in statistically significant reductions in Tinnitus Functional Index and Tinnitus Handicap Inventory scores, (Table 2). The results correlate with pre and post treatment score of Tinnitus Handicap Inventory that dropped from 90% to 0%.

Table 2: TFI and THI scores evaluated at the first visit

TFI and THI scores		Pre-treatment	Post-	P value
			treatment	
Overall TFI		45.0±22.7	30.8±16.1	0.005
TFI	Auditory	14.33±26.30	10.6±10.3	0.075
subscale	Sleep	10.12±8.5	5.80±6.2	0.005
scores	Cognitive	12.11±7.4	10.12±6.1	0.253
	Quality of	13.11±13.2	10.8±7.2	0.197
	life			
	Intrusive	17.4±6.9	10.5±5.1	< 0.001
	Relaxation	12.7±8.7	9.2±6.8	0.121
	Sense of	19.11±7.2	11.2±5.7	< 0.001
	control			
Overall THI		38.2±22.8	23.6±17.2	< 0.001

and 6 months after the start of treatment

# Discussion

Brain mapping (qEEG) studies report that there is multiple parallel overlapping of subnetworks in the nonauditory areas of the brain which exhibits abnormal, constant, and spontaneous neural activity involved in the perception of tinnitus with each subnetwork and area reflecting specific aspect of tinnitus percept. The paper pen task and directive counselling are designed and delivered respectively in a way that is assumed to induce normal, rhythmically constant, and premediated neural activity and mask the abnormal, constant, and spontaneous neural activity in the above-mentioned subnetworks and the specific non auditory area. Counselling was focused on breaking the vicious cycle causing and maintaining the presence of tinnitus. Diverting auditory attention alone is not sufficient to reduce the severity of tinnitus and prevent its relapse. Conscious awareness of tinnitus can be suppressed when individuals engage in cognitively demanding tasks particularly of non-auditory nature such as the paper pen task used in the present study. To carry out this task selective, divided, sustained, simultaneous and split attention act cumulatively.

Bimanual paper pen task represents a top-down activity.

Top-down processing refers to how our brain makes use of information that has already been brought into the brain by one or more of the sensory systems [13]. Topdown modulation underlies our ability to selectively attend to relevant stimuli and to ignore irrelevant stimuli [14]. In the present study, the bimanual paper-pen task represents top-down activity that underlies brain's ability to selectively attend to the bimanual written activity as a relevant stimulus and to ignore tinnitus that is the irrelevant stimuli.

Mechanism underlying tinnitus suppression by task involvement may include inhibition of auditory regions by top-down structures [15]. There are different simultaneous ongoing processes in the brain during the treatment procedure that may contribute to achieving the aim. The possible explanations in reduction of the perception of tinnitus using this novel approach can be as follows:

- The paper pen task is considered to be the relevant stimulus on which the brain is made to focus by ignoring the irrelevant tinnitus contributing to the spontaneous habituation of tinnitus.
- 2) fMRI Studies report that there is excess and abnormal neural firing in specific areas of brain in individuals with tinnitus. The paper pen task has been designed in such a way that it increases the communication between the right and left hemispheres of brain which increases the relevant neural activity in certain areas of the brain. These include supplementary motor area, dorsal lateral prefrontal lobe, orbitofrontal cortex, auditory cortex, and insula. This increased relevant neural activity is hypothesized to be regulating the abnormal neural firing thus helping in resolving tinnitus. fMRI studies while administering the explained treatment session

the present study will help to explain the proposed hypotheses.

- 3) Increase in the relevant neural activity in these areas hypothesized to be masking the abnormally increased irrelevant neural activity causing tinnitus at central level, thus suppressing the centres that are responsible for generation of tinnitus.
- 4) Directive counselling has been provided to the subjects considering every domain of their background. Counselling was focused on comprehending the sequential events: the auditory cortex analyses the stimuli, the hippocampus identifies the stimuli, and then the amygdala determines how important the stimuli is, and whether or not neurotransmitters need to be released. Focused counselling helped in breaking the vicious cycle maintaining the presence of tinnitus.
- 5) Feldmann (1971) has investigated a type of residual inhibitory effect produced by very short duration masking sounds [16]. Hence, NBN presented to the test ear at 10dBSL of tinnitus for 30 minutes efficiently masks the tinnitus. This combined effect of intensity and duration of masking noise overcomes the residual inhibition and helps in permanent habituation to the perception of tinnitus

# Conclusions

The present study suggests that this novel treatment approach is cost effective, time saving and efficient to vanish the tinnitus or to reduce the intensity of tinnitus to a negligible level and thereby eliminating the negative reactions towards tinnitus. The approach reduces the duration of a complete treatment program from 24 months to 4 weeks or even less. fMRI studies conducted during the treatment sessions will help in monitoring the changes in neural activity within the brain providing rationale for the success of this approach.  McFadden D. Tinnitus: Facts, Theories, and Treatments. Washington, DC: National Academy Press: Washington, D.C.1982;13(3):150.

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