



## EFFECTIVENESS OF TINNITUS RETRAINING THERAPY IN THE TREATMENT OF TINNITUS

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**ABSTRACT**

Tinnitus is the perception of sound arising from neural activity, a common problem that may be associated with many conditions and drugs with no definitive treatment. A variety of treatment options abound as per literature reviews, one being Tinnitus Retraining Therapy (TRT). It includes comprehensive counseling and sound therapy. Its effectiveness in Tinnitus treatment compared to medical therapy alone is the subject of this study. 70 patients were selected from ENT OPD of Government Medical College and randomly assigned to one of the two groups, medical and medical with TRT. Internationally tested questionnaire tools were employed to assess symptoms and results in symptom improvement were statistically analyzed. Subjective improvement in symptoms was seen equally in both groups with no statistically significant difference in improvement between them. Thus TRT is concluded to be useful but does not add a treatment benefit over medical therapy alone.

**Summary**

- Tinnitus is perception of Ringing in the ears.
- Variety of treatments tried worldwide, none specific.
- Effectiveness of TRT with drugs over medical treatment alone studied here in 2 groups of patients.
- Results show equal improvement in symptoms in both groups but no significant difference with added TRT.
- Conclude that TRT is useful but not significantly effective.

**KEYWORDS :** Tinnitus , Tinnitus Retraining therapy , effectiveness.

**INTRODUCTION**

Tinnitus is referred to as "ringing in the ears" and it is defined as the perception of sound that result exclusively from activity within the nervous system without any corresponding mechanical, vibratory, activity within the cochlea and unrelated to external stimulation<sup>[1]</sup>. Two types tinnitus exist, objective and subjective. The purview of this study is solely subjective tinnitus. It is a common problem affecting many people around the world. Studies show that around 10 to 20 % of population around the world is affected by tinnitus and they seek help from an otologist<sup>[2,3,4]</sup>. The prevalence of tinnitus is expected to increase with age and noise exposure<sup>[5]</sup>. Tinnitus is associated with more than 300 diseases and 200 prescription and non prescription drugs. The most common cause proposed is subjective hearing loss and is then followed by vertigo, dizziness and hyperacusis<sup>[6]</sup>. According to Sanchez , 85 to 90% of the individuals with tinnitus present some level of hearing loss and only 4 to 8% present normal hearing sensitivity<sup>[7]</sup>. The treatment of tinnitus has varied down the ages and is yet to reach a Consensus. However the modern concept of tinnitus is that most forms of subjective tinnitus are attributable to changes in the CNS. Thus the concept of habituation therapy by counseling as well as Cognitive behavior modulation therapy have also developed over time along with drugs acting on the central nervous system and the neuronal pathways.

The clinical heterogeneity of tinnitus symptoms as also association with anxiety, depression, alcohol addiction and other factors have resulted in many different approaches to its treatment. A combination of therapies is more likely to benefit than single modality therapy. Here, we discuss the effectiveness of Tinnitus retraining therapy along with the standard medical/drug treatment followed in our institution as compared to medical therapy alone, in the treatment of tinnitus.

**Review Of Literature**

Like chronic pain, tinnitus is also referred to as a constant, aversive stimulation which can dominate the sufferer's thoughts and lifestyle, causing a significant interference with daily functioning<sup>[8,9,10]</sup>. Psychological reactions and negative associations can exacerbate the condition and in effect, amplify the perception of tinnitus resulting in subsequent anxiety, depression, and other somatic complaints<sup>[8,9,10,11]</sup>. Studies have found individuals with tinnitus were more socially withdrawn, reactive to stress, alienated, emotionally disturbed and less self-controlled. Studies also found significant correlation between severity of tinnitus with depression, anger and sleep disturbances<sup>[8,9,10,11,12,13]</sup>. A study on Indian population found a significant correlation between severity of tinnitus and depressive symptoms<sup>[14]</sup>. The study was conducted on 50 individuals with tinnitus and they found that scores of tinnitus handicap inventory strongly correlated with both state and trait anxiety levels which was assessed by state trait anxiety inventory and inventory of depressive symptomatology. Further they also found severity of tinnitus is not influenced by age, gender and hearing status of individual.

Several Tinnitus management programs such medical, surgical, hearing aids, tinnitus masking, Tinnitus Retraining Therapy, Cognitive Behavior Therapy, electrical stimulation, Complementary and Alternative Treatment methods like Music therapy have been proposed by various authors to treat tinnitus and its impact on daily life. The aim of most tinnitus management protocols is Habituation to the abnormal noise. However not a single tinnitus treatment approach can claim an unequivocal research evidence demonstrating consistent success for all case.

A large number of pharmacological agents have been used in the treatment of tinnitus, providing moderate relief of

symptoms and sometimes tinnitus suppression<sup>[15]</sup>. Acute tinnitus is always treated by drugs foremost being Corticosteroids, either systemic or intratympanic. Their effect is mainly anti-inflammatory and immunosuppressant. Nootropics like Piracetam refer to drugs that improve blood flow and oxygen consumption and its peripheral vascular effect has indicated its use for sudden deafness and tinnitus<sup>[16]</sup>. Local anaesthetic drugs like lidocaine can alleviate tinnitus but mechanism of action is still unknown<sup>[17]</sup>. Betahistine is a histamine analogue that induces vasodilatation and increased capillary permeability in ischaemic areas of the cochlea, leading to increased perfusion of the striavascularis<sup>[18]</sup>. Oxidative stress produces peroxides and Reactive oxidative species (ROS) that damage cochlear hair cells. High ROS levels in the blood were seen in patients with tinnitus<sup>[19]</sup>. Thus antioxidants and vitamins have been used from time immemorial as supplemental treatment in tinnitus. Ginkgo biloba is an extract from the leaves of ginkgotree and has antioxidant properties. Its two bioactive components flavonoids and terpenoids have neuroprotective properties and benefit cognitive function<sup>[20]</sup>. Traditionally used in tinnitus treatment, ginkgo biloba is a favourite in many treatment protocols. Negative emotions like depression, anxiety and other psychosomatic disturbances, under the control of the limbic system, are reported associated with tinnitus perception<sup>[21]</sup>. Depressed persons have a greater perception and lesser habituation of tinnitus. Hence the use of psychoactive drugs like Tricyclic antidepressants and Selective Serotonin Reuptake inhibitors in its treatment. Anticonvulsants have been used. Glutamate being the main excitatory neurotransmitter in the cochlea and CAP, glutamate receptor antagonists like caroverine have been used in tinnitus treatment. Hyperbaric Oxygen therapy (HBOT) has been tried based on the finding that inner ear tissue hypoxia is contributory to tinnitus pathogenesis.

A study was conducted in 2012 with the objectives of estimating the use of different tinnitus management programs (TMP) and document the current practices of audiologists in India<sup>[22]</sup>. The researchers developed a questionnaire on "tinnitus management survey" which was distributed to 150 institutions including medical colleges and speech and hearing clinic all over India. They found 54.28% of the institutes opted for tinnitus masking out of the various tinnitus management programs and 60% of the institutes were provided TMP with hearing aids. 71.42% of the institutes feel TMP is partially helpful to tinnitus sufferers.

Though the problem of tinnitus in India is as alarming or as severe as in western countries; there is dearth of studies in India related to tinnitus, its impact on individuals and its management. In this scenario the study focus is on to the effect of medications and tinnitus retraining therapy in individuals affected by tinnitus.

#### **Aim Of The Study:**

To Evaluate the effectiveness of tinnitus retraining therapy in tinnitus.

#### **Objectives:**

To determine the effectiveness of tinnitus retraining therapy in tinnitus as compared to medical treatment alone.

#### **Materials And Method**

It is a comparative single blind study carried out on a population suffering from subjective tinnitus selected from patients attending the ENT OPD. 70 subjects with subjective tinnitus were participated in the study. The subjects who satisfy the inclusion criteria randomly allotted into two groups using a randomization table obtained using the research randomization tool available on the internet. The groups were n Medical alone group and Medical with TRT group. The

Medical alone group of subjects were provided with medication alone for the management of tinnitus and for the Medical with TRT group, along with medication TRT training were given.

70 patients (aged between 18 to 80 years ) experiencing subjective tinnitus, with an average duration of tinnitus for 6 years ranging from 1 month to 30 years were selected for the study. Subjects with normal hearing and any type and degree of hearing loss, ranging from minimal to severe hearing loss were included in the study. Also the patient with persistent subjective post-operative tinnitus after surgery for intracranial lesions and with central tinnitus were participated in the study.

Primarily, patients were explained about the study and a written consent from the subjects were taken. Subsequently, the Tinnitus Handicap Inventory (THI)<sup>[23]</sup> and visual analogue scale of tinnitus loudness, annoyance and effect on life<sup>[24]</sup> was administered to find out the severity of tinnitus. The THI has 25 items, and response choices are "no" (0 point), "sometimes" (2 points), points) and "yes" (4 points). The overall score ranges from 0 to 100. In order to validate THI, it was converted to local language by a language expert and a pilot study was carried out in 10 patients suffering with tinnitus and these subjects were excluded from the study. VAS scores are ratings on a scale from 0 to 10. The VAS score for loudness of tinnitus was assessed by asking the patient to rate the loudness of tinnitus during their waking hours over the last month (It was explained that 0 corresponds to no sound being heard and 10 is as loud as a gunfire). The VAS score for annoyance induced by the tinnitus was assessed by asking the patient to rate their subjective perception of annoyance on average during the last month (It was explained that 0 corresponds to no annoyance and 10 is the most annoying thing that can possibly happen). The VAS score for the impact of tinnitus on their life was assessed by asking the patient to rate the effect of tinnitus on their life during the last month (It was explained that 0 corresponds to no effect and 10 is as big as an earthquake)<sup>[25]</sup>. Then the cases were randomly assigned in the each group by simple random method. Proper history and clinical evaluation was done for each patient. Audiological and blood investigations given below were done to arrive at the correct diagnosis which is the protocol routinely followed in our department for cases of tinnitus

- Otoscopy
- Tuning fork test- Rinnie, Weber, and Absolute Bone Conduction Tests
- Pure tone audiometry
- Tinnitus matching test
- Immittance audiometry
- CT/MRI temporal bone(if indicated)
- Auditory brainstem response (ABR)(if indicated)
- Routine blood and Urine examination including LFT, RFT, RBS, TFT, serology, lipid profile.
- Chest X ray (as needed)
- ECG(as needed)

Later, the subjects were also referred for the cross consultation with neurology and psychiatry when indicated. Followed by the investigations and tests, both group of subjects were provided with one month of medication and review was done at 1, 3, and 6 months. The medications used were Betahistine hydrochloride 16 mg thrice daily, Ginkobiloba thrice daily Vit.B1, B6 B12 once daily and an anxiolytic at night if indicated. For the medical with TRT group, along with medication TRT also administered from the beginning and followed up as above. Audiologist provided TRT at 1 appointment in each month with a total of 6 sessions of 45 minutes duration. TRT involves a parallel use of retraining counseling with sound therapy. Retraining counseling acts to decrease the level of stimulation from the cortical areas of the brain to the limbic and autonomic nervous systems and to decrease the general level of activity within these two systems. During counseling, a

number of points are presented to the patient: (1) the perception of tinnitus results from a compensation occurring within the auditory system, (2) tinnitus is a problem because of the activation of emotional (limbic) and autonomic nervous systems, and (3) by using the plasticity of the nervous system, it is possible to retrain the brain to achieve habituation of tinnitus-induced reactions and tinnitus perception. Once the patient accepts these ideas as realistic and "making sense" to them, this puts tinnitus into the category of neutral stimuli, to which they may gradually habituate. Sound therapy provides significant help in the process of habituation by decreasing the strength of tinnitus-related neuronal activity within the auditory system and from the auditory system to the limbic and autonomic nervous systems. Specifically, sound therapy acts by providing the auditory system with constant, low level, neutral auditory signals to (1) decrease the contrast between tinnitus-related neuronal activity and background neuronal activity, (2) interfere with the detection of the tinnitus signal, and (3) decrease enhanced gain within the auditory pathways. Further, the THI and VAS will be administered in each group at the end of six months to find out the effectiveness of treatment in each group.

**RESULTS**

All data were analyzed using standard statistical methods (SPSS version 21) to reach the conclusion. An independent t test was used to find out the significance between pre and post treatment scores. The p value required for statistical significance was set at  $p < 0.005$ . Patients' age, gender, scores on THI and VAS scores for both groups were analysed. The demographic details of patients who participated in each group in terms of age is shown in Table 1. The mean and standard deviation of the pre and post assessment scores of THI, VAS loudness, VAS annoyance, VAS impact on life is given in Table 2. Table 3 shows a significant decline in post THI, VAS loudness, VAS annoyance, VAS impact on life scores for both the groups, indicating a decrease in the subjective tinnitus handicap.

**Table 1**

	30- 45 yrs	46-60 yrs	>60 yrs	Total
Medical alone	7	16	12	35 subjects
Medical with TRT	7	13	15	35 subjects

**Table 2**

	N	Mean	Std. Deviation
THI (pre)	70	43.80	18.38
VAS loudness(pre)	70	5.74	1.69
VAS annoyance (pre)	70	5.84	1.60
VAS impact on life (pre)	70	5.57	1.73
THI (post)	58	27.67	17.21
VAS loudness (post)	58	3.43	2.23
VAS annoyance (post)	58	3.62	2.23
VAS impact on life (post)	58	3.41	2.21

**Decline In THI Scores After 6 Months**

The mean decline THI scores of Medical alone group was 30.50(SD=18.96) with p value 0.001. For Medical with TRT group mean decline in THI was 24.64(SD= 14.86) p value 0.001 which is also statistically significant. The mean decline in THI scores was 30.50(SD=18.96) for the medical alone group and 24.64(SD=14.86) for the Medical with TRT group. The difference in mean was not statistically significant with  $p > 0.005$

**Table 3**

Group		THI mean (SD)	VAS loudness mean (SD)	VAS annoyance mean (SD)	VAS effect on life mean (SD)
Medical alone	Pre	41.66 (17.81)	5.40 (1.79)	5.57 (1.85)	5.17 (1.80)

		30.50 (18.96)	3.87 (2.50)	3.87 (2.52)	3.63 (2.51)
	p value	0.001	0.001	0.001	0.001
Medical with TRT	Pre	47.32 (18.92)	6.21 (1.70)	6.00 (1.30)	6.34 (1.77)
	Post	24.64 (14.86)	2.96 (1.83)	3.36 (1.89)	3.18 (1.84)
	pvalue	0.001	0.001	0.001	0.001

**Decline In VAS Scores After 6 Months**

The VAS score for loudness, annoyance and effect on life improved significantly for the both groups. The mean decline for VAS loudness was 3.87(SD=2.50), VAS annoyance was 3.87(SD=2.52) and VAS effect on life was 3.63(SD=2.51) for Medical alone group which is statistically significant with p value 0.001. For Medical with TRT group also the mean decline in the VAS loudness 2.96(SD=1.83) VAS annoyance 3.36(SD=1.89) VAS impact on life 3.18 (SD= 1.84 ) is statistically significant with p value 0.001. But the difference in mean reduction in VAS loudness, VAS annoyance and VAS effect on life between the two groups is not statistically significant with  $p > 0.005$ .

**DISCUSSION**

Tinnitus Management protocols aim to habituate the patient to abnormal noise. However no single treatment modality has been found consistently effective. Here we studied the effectiveness of TRT in treating tinnitus symptoms compared to medical therapy alone. After analyzing our findings we find that of 70 patients enrolled in the study the majority fell into 46-60 yr age group(29) while close behind is the >60 group (27). This is expected. On randomization, more patients in Medical alone group fell in the 46-60 years group while in Medical with TRT group more fell in >60 age group.

Evaluating the Pre and Post-treatment values at the end of 6 months we see that Tinnitus handicap and VAS scores of Loudness, Annoyance and Effect on Life show Significant reduction after treatment in both groups. Thus there was significant improvement in patients' Quality of life with treatment though it is almost the same in both the groups i.e., with or without added TRT.

The difference in mean decline in scores in THI, VAS Loudness, Annoyance and effect on life between the two groups was seen to be minimal and a  $p > 0.005$  is not significant as seen in the analysis. The results point out that addition of TRT does not seem to give any added benefit in subjective improvement in Tinnitus symptoms. Though the armamentarium of drugs that may be used for Tinnitus management is huge, it usually narrows down to 2-3 drugs which vary according to Institutional and individual preferences. In this study we have used drugs which are easily available and used worldwide. We have found acceptable improvements with these drugs in Tinnitus symptoms in patients who have diligently followed advise over the years. Here we have employed these same medications.

**CONCLUSION**

Tinnitus retraining therapy targets the habituation of the patient to the perception of and reaction to tinnitus. Although it is one of the most promising habituation-based treatments, TRT has not yet sufficient scientific evidence supporting its efficacy in reducing tinnitus-related distress<sup>[26]</sup>. Our study too confirms this. We conclude that TRT, though useful, does not confer any additional Significant benefit over Medical therapy alone in the Management of Tinnitus.

The study is compliance with the ethical standards and approved by the ethical committee.

**REFERENCES**

1. Jastreboff, P.J. (1995). Tinnitus as a phantom perception: theories and clinical

- implications. In: Vernon J, Moller AR, eds. *Mechanisms of Tinnitus*. Boston: Allyn & Bacon, 73-94
2. McFadden, D. (1982). Tinnitus: Facts, Theories, and Treatments. Washington, DC: *National Academy Press*.
  3. Coles, R.R.A. (1987). Epidemiology of tinnitus. In: Hazell JWP, ed. *Tinnitus*. Edinburgh: *Churchill Livingstone*, 46-70.
  4. Drukier, G.S. (1989). The prevalence and characteristics of tinnitus with profound sensori neural hearing impairment. *Am Ann Deaf* 134, 260-264.
  5. Jastreboff, P.J., Hazell, J.W. (1993). A neuro-physiological approach to tinnitus: clinical implications. *Br J Audiol*. 27(1), 7-17.
  6. Hiller, W., Goebel, G. (2006). Factors influencing tinnitus loudness and annoyance. *Arch Otolaryngol Head Neck Surg*. 132(12), 1323-30.
  7. Sanchez, L. (2004). The epidemiology of tinnitus. *J Aud Med*. 2(1), 8-17.
  8. Kirsch, C.A., Blanchard, E.B., Parnes, S.M. (1987). A multiple-baseline evaluation of the treatment of subjective tinnitus with relaxation training and biofeedback. *Biofeedback Self Regul*. 12(4), 295-312
  9. Scott, B., Lindberg, P, Lyttkens, L., Melin, L. (1985) Psychological treatment of tinnitus. An experimental group study. *Scand Audiol*. 14(4), 223-30.
  10. Sweetow, R.W. (1986) Cognitive aspects of tinnitus patient management. *Ear Hear*. 7(6), 390-396
  11. Lindberg, P, Scott, B., Melin, L., Lyttkens, L. (1987). Long-term effects of psychological treatment of tinnitus. *Scand Audiol*. 16(3), 167-72.
  12. Welch, D., Dawes, P.J. (2008) Personality and perception of tinnitus. *Ear Hear*. 29(5), 684-92
  13. Makar, S.K., Biswas, A., Shatapathy, P. (2014). The impact of tinnitus on sufferers in Indian population. *Indian J Otolaryngol Head Neck Surg*. 66(Suppl 1), 37-51.
  14. Aithal, V., Kumar, A., Mohan, K.M., Alex, J., Mahendra, M.H. (2013) The relationship of perceived severity of tinnitus with depression, anxiety, hearing status, age and gender in individuals with tinnitus. *International Tinnitus Journal* 18(1), 29-34.
  15. Langguth, B., Elgoyhen, A.B. (2012). Current pharmacological treatments for tinnitus. *Expert Opin Pharmacother* 13(17), 2495-509.
  16. Gutmann, R., Mees, K. (1995). Piracetam infusions in acute tinnitus and sudden deafness. *Fortschr Med*. 113(18), 288-90.
  17. Savastano, M. (2004). Lidocaine intradermal injection- a new approach in tinnitus therapy: preliminary report. *Adv Ther*. 21(1), 13-20.
  18. Dziadzola, J.K., Laurikainen, E.L., Rachel, J.D., et al. (1999). Betahistine increases vestibular blood flow. *Otolaryngol Head Neck Surg*. 120(3), 400-5.
  19. Savastano, M., Brescia, G., Marioni, G. (2007) Antioxidant therapy in idiopathic tinnitus: preliminary outcomes. *Arch Med Res*. 38(4), 456-9.
  20. Smith, J.V., Luo, Y. (2004). Studies on molecular mechanisms of Ginkgobiloba extract. *Appl Microbiol Biotechnol*. 64(4), 465-72.
  21. Jastreboff, P.J., Hazell, J. (2004). Tinnitus retraining therapy: implementing the neurophysiological model, 1<sup>st</sup> edn. Cambridge: Cambridge University Press.
  22. Makar, S.K., Kumar, S., Narayanan, P.S., Chattarjee (2012) . Status of the tinnitus management program in India-A Survey. *International Tinnitus Journal* 17(1), 54-60.
  23. Newman, C.W., Jacobson, G.P., Spitzer, J.B. (1996). Development of the Tinnitus Handicap Inventory. *Arch Otolaryngol Head Neck Surg*. 122(2), 143-8.
  24. Huskisson, E. (1983). Visual analogue scales. Pain measurement and assessment. New York: Raven Press.
  25. Aazh, H., Moore, C.J. (2016) Comparison between tinnitus retraining therapy and a simplified version in treatment of tinnitus in adults. *Aud Vest Res*. 25(1), 14-23.
  26. Phillips, J.S., McFerran, D. (2010). Tinnitus retraining therapy (TRT) for tinnitus. *Cochrane Database Syst Rev*. (3), CD007330.