

Viability of Tinnitus Handicap Inventory in Management of Idiopathic Subjective Tinnitus

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ABSTRACT

Introduction

Idiopathic Subjective Tinnitus (IST) is an auditory condition perceived without an external stimulus and lacks identifiable cause which makes it very difficult to treat. The Tinnitus Handicap Inventory (THI) is a validated tool to assess the severity and impact of tinnitus which has been used extensively since it is practically free. This study evaluates the role of THI in monitoring treatment efficacy in IST.

Materials and Methods

A prospective observational study was conducted at a rural South Indian hospital involving 100 patients aged 21–60 years with IST of at least one year duration. Patients had audiometry to exclude objective causes. THI scores were recorded pre- and post-treatment (12 weeks) with Caroverine, Tocopherol, Levocarnitine, Tinnitus Retraining Therapy (TRT), and Cognitive Behavioral Therapy (CBT).

Results

The mean pre-treatment THI score was 44.92 (moderate), improving significantly to 15.78 (slight) post-treatment ($p < 0.01$). 64.87% overall symptom improvement was observed. Notably, the symptom of “desperation” improved by 98.71%, while “insecurity” improved by 16.36%. No patients worsened or dropped out during the study.

Conclusion

THI is a viable, practical tool for diagnosis, grading, and follow-up of IST. Caroverine is an ideal first line drug for the management of IST.

Keywords

Tinnitus Handicap Inventory; Idiopathic Subjective Tinnitus; Caroverine; Tinnitus Retraining Therapy

The term Tinnitus is derived from the Latin word tinnire which refers to a condition in which an individual experiences a ringing, buzzing or hissing auditory sensation in the absence of an external stimulus. It is usually a common symptom which has been cited in literature for about 150 years.¹

Most cases of tinnitus are subjective and has no antecedent cause, meaning the examiner cannot hear it. However, objective tinnitus can arise from organic causes and can be heard by the examiner. This makes it easier to treat an objective tinnitus as there is an identifiable cause to it.

The causes of Tinnitus can vary from causes in the external ear canal (wax, discharge, foreign body), middle ear (otitis media), inner ear (Meniere's disease), malignancies (Acoustic Neuroma), neurologic causes like Multiple Sclerosis, psychiatric illnesses like Depression and Anxiety among others.

Idiopathic Subjective Tinnitus (IST) is the most common form affecting adults and it is a diagnosis based on elimination of causes. It excludes all known causes like tinnitus associated pathology of the cochlea/nervous system or tinnitus that is susceptible to somatic modulation.²

Tinnitus Handicap Inventory (THI) is a tool which helps in analysis of the impact the disorder makes to the Quality of Life of the affected individual. It was first formulated in 1996 and has been in use ever since.³ It has 25 questions which assesses various symptoms which are associated with Tinnitus.

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The management of Tinnitus is usually complicated and the disorder is hard to treat. Since the etiology is still unclear, a lot of drugs have been used for the management of Tinnitus till date. A few examples are Gabapentin [Gamma-Aminobutyric Acid analogue], Fluoxetine [Selective Serotonin Reuptake Inhibitor], Acamprosate [N-methyl D-aspartate receptor antagonist] among others. Psychotherapy and auditory rehabilitation have also been used.

Caroverine acts as an antagonist of calcium and non-NMDA and NMDA glutamate receptors.⁴ Cochlear synaptic tinnitus arises from a synaptic disturbance of NMDA or non-NMDA receptors on the afferent dendrites of the spiral ganglion neurons. This antagonistic activity helps in alleviating the symptoms.

Tinnitus Retraining Therapy [TRT] forms a cornerstone in the management of the annoyance the sound causes in the individual. Masking a particular location of a sound in an environment can help in reducing the impact of the disorder.⁵

The aim of this study is to achieve an outreach in the community and reduce misdiagnosis which can be created in the absence of documentation of the intensity of symptoms. The THI can help in this scenario since it is practically free and can be used easily in both the educated and uneducated sections of the society.

Materials and Methods

Source: From all Departments of a Rural Hospital in South India where any in-patient or out-patient complained of a ringing or buzzing sensation in the ears (unilateral or bilateral). Ethical committee clearance was obtained from the "RVM Institute Ethical Board" viz reference number RVM/22/94.

Sample Size: It was calculated with the formula $4pq/L^2$, wherein p was present prevalence [29.3%], q was 100-p and l was allowable error [5%]. Based on previous studies in similar populations, a sample size of 95 [closest round off value of 100] was taken.⁶

Statistical Analysis: All statistical analyses were performed using SPSS Statistics 19 for Windows (IBM Corp., Armonk, NY, USA). Samples were compared

and evaluated by means of a Paired T-Test. The confidence interval was set at 95% and 5% margin of error was given.

Inclusion criteria:

1. Idiopathic origin of Tinnitus.
2. Subjective Tinnitus.
3. Age group 21-60.
4. Individuals willing to follow up over 12 weeks with respect to pharmacological therapy and auditory rehabilitation.
5. Duration of symptoms of at least 1 year with no symptomatic relief.

Exclusion criteria:

1. Non-consenting individuals.
2. Presence of an antecedent cause of Tinnitus.
3. Individuals on long term medication causing Tinnitus which could not be stopped.⁷
4. Auditory hallucination misdiagnosed as tinnitus in the past and needing a psychiatric referral.
5. History of previous ear surgeries.

Method of assessment: All patients presenting with Tinnitus were considered for the study at first. Individuals meeting the strict inclusion and exclusion criteria went ahead and their data was documented after obtaining written informed consent. Any associated complaint which warranted further Radiological Evaluation via MRI or CT (viz. headache, vertigo, loss of consciousness), the investigation was done and such patients were re-evaluated by the concerned Department. A Neurological and Psychiatric examination was done to rule out evident causes.

In the presence of a local cause (Otitis Media/Labyrinthitis/Wax and Discharge of External ear Canal/Endolymphatic Hydrops/Vestibular Schwannoma/Tumors of Cerebellopontine Angle and other malignancies/Meniere's disease/Palatal Myoclonus/Semicircular Canal Dehiscence), the case was managed adequately and excluded from the study.

Each patient underwent a Pure Tone Audiometry

(PTA) and Impedance Audiometry (IA). They were included only if the findings of the Audiometry were normal.

At the end of this ordeal, the cases with Idiopathic Subjective Tinnitus made it to the final study irrespective of the duration of the symptom.

After obtaining informed consent from each patient, each patient filled out the THI proforma (Images 1 and 2) in the presence of the same researcher and a reliable relative by his/her side to prevent bias. Each question carried three options (viz. 0,2,4) and could make a score from 0-100. The severity was graded based on previous studies.⁸

Each patient was started on the following treatment protocol:

1 Tablet Caroverine 20 milligrams, two tablets a day after breakfast and dinner for 12 weeks.

1 Tablet Tocopherol 400 milligrams, one tablet a day after lunch for 12 weeks.

1 Tablet Levocarnitine 150 milligrams, one tablet a day after lunch for 12 weeks.

1 Tinnitus Retraining Therapy with White Noise on a daily basis for 4 hours per day.⁹

1 Cognitive Behavioural Therapy (CBT) to reach about 7-8 hours of sleep in the night without Pharmacotherapy.

The patient was monitored and the same THI (Figure 1 and 2) and was given at the end of 12 weeks. Any patient who did not improve as expected at the end of the study was evaluated further and kept on regular follow-up.

Tinnitus Handicap Inventory			
Instructions: The purpose of this questionnaire is to identify problems your tinnitus may be causing you. Check Yes , Sometimes , or No for each question. Do not skip a question.			
	Yes (4)	Sometimes (2)	No (0)
1F Because of your tinnitus is it difficult for you to concentrate?	☐	☐	☐
2F Does the loudness of your tinnitus make it difficult for you to hear people?	☐	☐	☐
3E Does your tinnitus make you angry?	☐	☐	☐
4F Does your tinnitus make you feel confused?	☐	☐	☐
5C Because of your tinnitus do you feel desperate?	☐	☐	☐
6E Do you complain a great deal about your tinnitus?	☐	☐	☐
7F Because of your tinnitus do you have trouble falling to sleep at night?	☐	☐	☐
8C Do you feel as though you cannot escape your tinnitus?	☐	☐	☐
9F Does your tinnitus interfere with your ability to enjoy social activities (such as going out to dinner, to the movies)?	☐	☐	☐
10E Because of your tinnitus do you feel frustrated?	☐	☐	☐
11C Because of your tinnitus do you feel that you have a terrible disease?	☐	☐	☐
12F Does your tinnitus make it difficult for you to enjoy life?	☐	☐	☐
13F Does your tinnitus interfere with your job or household responsibilities?	☐	☐	☐
14F Because of your tinnitus do you find that you are often irritable?	☐	☐	☐
15F Because of your tinnitus is it difficult for you to read?	☐	☐	☐
16E Does your tinnitus make you upset?	☐	☐	☐
17E Do you feel that your tinnitus problem has placed stress on your relationship with members of your family and friends?	☐	☐	☐
18F Do you find it difficult to focus your attention away from your tinnitus and on other things?	☐	☐	☐
19C Do you feel that you have no control over your tinnitus?	☐	☐	☐
20F Because of your tinnitus do you often feel tired?	☐	☐	☐
21E Because of your tinnitus do you feel depressed?	☐	☐	☐
22E Does your tinnitus make you feel anxious?	☐	☐	☐
23C Do you feel that you can no longer cope with your tinnitus?	☐	☐	☐
24F Does your tinnitus get worse when you are under stress?	☐	☐	☐
25E Does your tinnitus make you feel insecure?	☐	☐	☐
Total	_____	_____	_____

F denotes an item on the functional subscale; E, an item on the emotional subscale; and C, an item on the catastrophic response subscale.

Newman, C. W., Jacobson, G. P., & Spitzer, J. B. (1996). Development of the Tinnitus Handicap Inventory. *Archives of Otolaryngology—Head and Neck Surgery*, 122, 143–148.

Fig. 1. Questionnaire of Tinnitus Handicap

GRADE	SCORE	DESCRIPTION
1	0-16	Slight: Only heard in quiet environment, very easily masked. No interference with sleep or daily activities.
2	18-36	Mild: Easily masked by environmental sounds and easily forgotten with activities. May occasionally interfere with sleep but not daily activities.
3	38-56	Moderate: May be noticed, even in the presence of background or environmental noise, although daily activities may still be performed.
4	58-76	Severe: Almost always heard, rarely, if ever, masked. Leads to disturbed sleep pattern and can interfere with ability to carry out normal daily activities. Quiet activities affected adversely.
5	78-100	Catastrophic: Always heard, disturbed sleep patterns, difficulty with any activity.

Fig. 2. Grading of the severity of Tinnitus

Observations and Results

Table I : Age and Gender distribution

AGE GROUP	NUMBER (N=100)	
	MALE	FEMALE
21-30	6	8
31-40	13	21
41-50	11	18
51-60	8	15

As seen in Table I, the study had 38 male and 62 female participants. The most common age group affected was between 31 and 40.

As seen in Tables II and III, the improvement was clinically significant after 12 weeks as evidenced by a p-value of <0.05 . On the whole, the symptoms improved by 64.87%. A vast majority of patients improved from moderate and severe to slight and mild disturbance. None of the patients remained in or worsened to the catastrophic zone. The mean THI before the treatment was 44.82 (moderate) and the mean after treatment was 15.78 (slight).

The average duration of Tinnitus for all patients in the study was 9.3 ± 2.5 years. Among the 100 patients taken in the study, 78% of them were exposed to loud sounds at their workplace (factory workers, street hawkers and drivers) for at least a duration of 5 years ($p < 0.05$).

Table II : Paired Samples Correlations for THI before and after 12 weeks of treatment

	PAIRED DIFFERENCES					T	SIG.	CORRE- LATION
	MEAN	STANDARD DEVIATION	STANDARD ERROR MEAN	95% CONFIDENCE INTERVAL OF THE DIFFERENCE				
				LOWER	UPPER			
Before vs After	29.14	17.42	1.74	25.68	32.60	16.73	0.01	0.462

Table III : Paired Sample Statistics for THI before and after 12 weeks of treatment

	MEAN	N	STANDARD DEVIATION	STANDARD ERROR OF MEAN
Before	44.92	100	19.41	1.94
After	15.78	100	11.67	1.17

The symptom which improved the most was the feeling of desperation because of the tinnitus (98.71% better after treatment). The symptom which improved the least was the feeling of insecurity (16.36% better after treatment). 17 of the 25 symptoms improved by at least 50% post the treatment.

None of the patients dropped out of the study in the middle for further medical or surgical needs.

Discussion

Since the management of Tinnitus of any form is highly difficult, a lot of methods have been used for the same over a number of years. The most commonly used methods include Tinnitus Retraining Therapy,¹⁰ Customized Music Therapy (CMT),¹¹ NMDA receptor antagonists,¹² Hearing Aids,¹³ Brain Stimulation¹⁴ among others.

A study conducted by Roberts et al in 2010 concluded that increasing age, and Sensorineural hearing loss are the most common risk factors for Tinnitus. They also said that with an increase in professional noise and excess stimulation of the cochlea during leisure times, the prevalence of tinnitus is expected to rise.¹⁵

In a study conducted in 2021 by Ledesma et al, it was seen that the average THI was 36 in the study group and 32 in the control group. The average age of presentation of the patient to the study was 52 years.¹⁶ This did not correlate well with our study as the average age of presentation was 34 years and the average THI was 45. This discrepancy can be attributed to our study group which included only Idiopathic Subjective type of Tinnitus and probably the etiology which had exposure to sounds at the work place.

Our study correlated well with Biswas et al's study in

2023 wherein they said that environmental influences that damage the auditory system such as the exposure to loud noise can also trigger tinnitus.¹⁷ Our study also included participants who had some sort of exposure to loud sounds at workplace for at least a duration of 5 years.

In 2024, Dash et al reported that the THI improved by 53.3% post the use of monotherapy Caroverine for 90 days in cases of Tinnitus.¹⁸ This correlated well with our study wherein the symptoms improved by 64.8% after the same study period. The slight betterment can be because of the addition of Levocarnitine, Tocopherol and TRT.

In 2020, Gos et al reported that THI is a reliable uni dimensional scale to evaluate tinnitus severity. The dimensionality of THI was evaluated by them using several models of Confirmatory Factor Analysis and an Item Response Theory approach and it proved to be apt as a first use tool.¹⁹ The same holds good in our study since use of complicated testing mechanisms are not always freely available in all rural setups.

A study by Dehkordi et al in 2015 said that in cases of improper management or non-treatment of IST, it can cause increase in neuroticism and decrease in extraversion.²⁰ As this is a rare entity and diagnosis can also be difficult, management should be prompt and quick so as to prevent personality changes.

Conclusion

Idiopathic Subjective Tinnitus is a difficult diagnosis as it is done by exclusion which requires immense knowledge and resources from the side of the physician and patience from the side of the patient. Once the diagnosis is made, management is fairly straightforward but needs adequate monitoring. This can be achieved by the Tinnitus Handicap

Inventory which is easy to use and has good validity. Caroverine is easily procurable and does not have any toxicity which makes it a good first line drug for the management of Idiopathic Subjective Tinnitus.

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