

Efficacy of Intratympanic Dexamethasone Injection in Subjective Idiopathic Tinnitus- An Interventional Study

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ABSTRACT

Introduction: Tinnitus is a common and annoying symptom characterised by the perception of sound without any corresponding external stimulus. Subjective idiopathic tinnitus is a subjective form of tinnitus where the perceived sound originates from the auditory nervous system, without both aberrant aetiology and external stimuli. Intratympanic injection of steroid (Dexamethasone) is used for the treatment of subjective idiopathic tinnitus by introducing the drug through the tympanic membrane, resulting in reduced systemic toxicity and a higher perilymph steroid level.

Aim: To evaluate the efficacy of intratympanic dexamethasone injection in the treatment of subjective idiopathic tinnitus.

Materials and Methods: This prospective interventional study was carried out at Madurai Medical College, Madurai, Tamil Nadu, India, from March 2021 to March 2022. A total of 30 patients with subjective idiopathic tinnitus were subjected to

intratympanic dexamethasone injection, once per week for three weeks. Improvement in the symptom of tinnitus was assessed by means of subjective evaluation with the help of Tinnitus Handicap Inventory (THI) before and after one week, one month and three months of last injection. Data were statistically analysed using Student's paired t-test.

Results: The results of this study shows that, 53.33% of the population belonged to the age group of 31-40 years. There was 16 females and 14 males. There was a significant reduction in the mean grade of THI at one month and three months after the treatment. The mean THI score was significantly reduced from 50.067 before treatment to 35.733 in one month and 26.933 in three months after the treatment.

Conclusion: The intratympanic injection of dexamethasone was found to be effective in the treatment of subjective idiopathic tinnitus. Intratympanic treatment was demonstrated to improve tinnitus scores in the study population.

Keywords: Auditory disorder, Perception of sound, Steroid, Tympanic membrane

INTRODUCTION

The term "tinnitus" has been derived from the Latin word tinnire with a literary meaning "to ring" [1]. It is a phantom auditory perception due to an aberrant spontaneous activity, from an altered state of excitation or inhibition within the auditory system. With a prevalence of 6 to 17%, seen in any age and sex, it is one of the most common distressing problems, affecting the patient's lives to varying degrees [2]. Tinnitus is not a well-defined disease, but a symptom of many pathologies, because of otologic or non otologic causes. It may or may not be associated with hearing loss. Non otologic causes of subjective tinnitus may include neurologic, metabolic or psychogenic disorders. Objective tinnitus is usually due to vascular abnormalities of carotid artery or jugular venous systems, arteriovenous malformations, glomus tumours, palatal or tympanic myoclonus or eustachian tube dysfunction [3]. Subjective idiopathic tinnitus is defined as the experience of noises in the ears or head without both aberrant aetiology and external stimuli. Non otologic causes of subjective tinnitus may include neurologic, metabolic or psychogenic disorders. Several different options have been described for tinnitus treatment like tinnitus retraining, tinnitus masking, biofeedback therapy, and pharmacotherapy [3,4].

Intratympanic injection of steroids has been used as a treatment in various conditions like sudden sensorineural hearing loss and Meniere's disease [5]. Intratympanic injection of steroid (dexamethasone) is used for the treatment of subjective idiopathic tinnitus by introducing the drug through the tympanic membrane, resulting in reduced systemic toxicity and a higher perilymph steroid level. The proposed mechanism of action of intratympanic steroids are its anti-inflammatory action, increase in cochlear blood flow and evidence of steroid receptors in the inner ear [6].

Apart from the current available treatment options for tinnitus, like hearing aids with masking, tinnitus retraining therapy and oral medications, intratympanic injection with steroid is an emerging treatment option for idiopathic tinnitus [3,4]. There are a few studies done previously, by Yener HM et al, and Hoda E et al., which reported intratympanic steroid injection as an effective treatment of tinnitus [7,8]. Intratympanic route of steroid injection can be a safe and viable treatment and a better alternative to oral steroids in the treatment of subjective idiopathic tinnitus. Hence the present study, is aimed at evaluating the efficacy of intratympanic injection of dexamethasone as a safe treatment option in patients with subjective idiopathic tinnitus.

MATERIALS AND METHODS

This was a prospective interventional study carried out at Madurai Medical College, Madurai, Tamil Nadu, India for a period of one year from March 2021-March 2022. Ethical Clearance was obtained from the Institutional Ethics Committee (EC/NEW/INST/2020/484).

Inclusion criteria: Patients between 15 to 50 years of age, with subjective idiopathic tinnitus refractory to medical treatment and gave informed consent were included in the study.

Exclusion criteria: Patients having otitis media, tympanic membrane perforation, pulsatile tinnitus and any other systemic diseases which are contraindicated for steroid injection were excluded from the study.

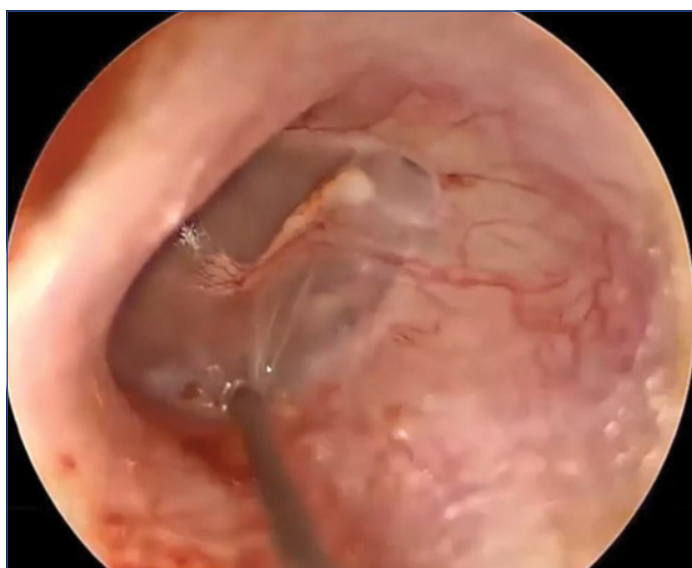
Sample size: All cases of subjective idiopathic tinnitus meeting the selection criteria who reported to the ENT department within the study duration (March 2021-March 2022) were included in the study by purposive sampling.

All cases underwent a detailed clinical examination which included otoscopic examination to ensure an intact tympanic membrane

and rule out any inflammatory diseases, tuning fork tests for clinical evaluation of hearing and otoscopic examination to confirm the otoscopic findings. Pure tone audiometry was done to confirm normal hearing and radiological investigations like High Resolution Computed Tomography (HRCT) Temporal bone was done to rule out other pathologies.

THI was administered to measure the impact of tinnitus on patient's life. THI is a set of 25 questions with the responses-Yes (4 points), sometimes (2 points) and No (0 points). The sum of all the responses is the THI score. With the THI score, patient's symptom were graded as Grade 1 to Grade 5 i.e., Grade 1: 0-16 (Slight), Grade 2:18-36 (Mild), Grade 3: 38-56 (Moderate), Grade 4: 58-76 (Severe), Grade 5: 78-100 (Catastrophic) [9].

After complete evaluation, the patient was given intratympanic injection of steroid by endoscopic method under local anaesthesia. The patient was placed in supine position with the head turned about 45° away from the surgeon. Topical anaesthesia of the external canal and tympanic membrane was administered using 10% lignocaine spray. Using a 2 mL syringe and a spinal needle of size 26 gauge, 0.5 mL of dexamethasone solution of dose 4 mg/mL was administered under direct vision using an endoscope in the posteroinferior quadrant of the tympanic membrane [Table/Fig-1]. The patient was asked to remain in the same position for about 20 minutes. A total of three injections were given, one injection per week for three weeks [5]. THI was again administered after first week, first month and three months of treatment.



[Table/Fig-1]: Intratympanic dexamethasone injection given in the posteroinferior quadrant of left tympanic membrane.

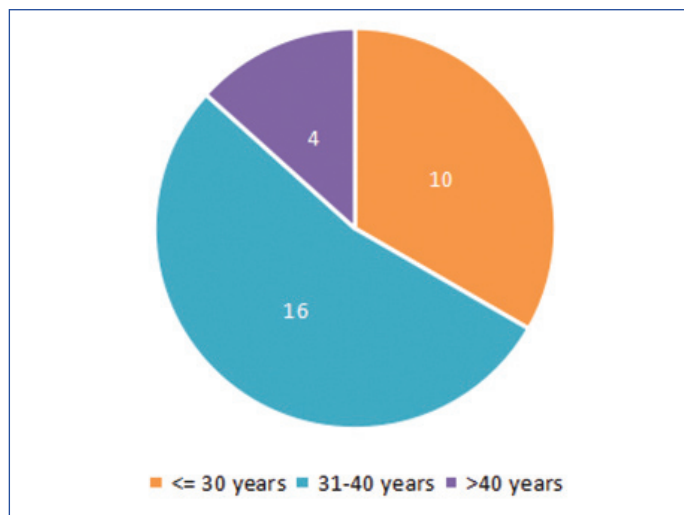
STATISTICAL ANALYSIS

Categorical variables were presented using frequencies and percentages. Data were statistically analysed using student's paired t-test. The p-value<0.05 was considered statistically significant. All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 11.0 for windows.

RESULTS

The study population had a total of 30 subjects aged between 15 and 50 years. Age distribution is shown in [Table/Fig-2]. Mean age in present study was 34.7±6.035 years. Gender distribution of the study population showed that 16 (53.33%), out of 30 patients were females.

Overall comparison of the mean values of THI scores before treatment and after one week, one month and three months of intratympanic therapy is as shown in [Table/Fig-3]. The mean THI score was significantly reduced from 50.067±16.942 before



[Table/Fig-2]: Age distribution of the study population.

treatment to 35.733±12.247 in one month and 26.933±11.335 in three months after the treatment. This reduction in THI scores was found to be significant [Table/Fig-3].

Time	Mean±standard deviation	p-value
Pretreatment	50.067±16.942	-
1 week after treatment	43.267±14.971	0.105
1 month after treatment	35.733±12.247	<0.001
3 months after treatment	26.933±11.335	<0.001

[Table/Fig-3]: Comparison of the mean values of THI scores before and after treatment. Student paired t-test was used. The p<0.05 considered significant

Comparing the values of grades of THI scores before treatment and after one week, one month and three months of intratympanic therapy showed that there was a statistically significant improvement in the grades of THI scores after the treatment. Before treatment maximum patients 15 (50%) were in grade 3 but one month after treatment maximum patients 17 (56.67%) were in grade 2 and three months after treatment maximum patients 19 (63.33%) were in grade 2, there was no patient in grade 4 and grade 5 after three months [Table/Fig-4].

Grades	Pretreatment	1 week after treatment	1 month after treatment	3 months after treatment
Grade 1	2 (6.67%)	2 (6.67%)	2 (6.67%)	7 (23.33%)
Grade 2	4 (13.33%)	8 (26.67%)	17 (56.67%)	19 (63.33%)
Grade 3	15 (50%)	15 (50%)	10 (33.33%)	4 (13.33%)
Grade 4	8 (26.67%)	5 (16.67%)	1 (3.33%)	0
Grade 5	1 (3.33%)	0	0	0
p-value		0.184	<0.001	<0.001

[Table/Fig-4]: Comparison of the mean values of THI grades before and after treatment. Student paired t test was used. The p<0.05 considered significant

DISCUSSION

Tinnitus is a global burden known to mankind since old age. It is not a disease but is a symptom of any possible underlying pathologies which may be of mild to even life-threatening forms. Each of the characteristics of tinnitus may signify an underlying pathology. In most of the cases, patients present to the hospitals or clinics with tinnitus only when it starts to bother or disturb them [7,8].

Keeping in mind the aetiological diagnosis and the goal of attaining a maximum symptomatic relief, different modalities can be considered in the treatment of tinnitus. In cases where the causes are treatable, specific medical or surgical mode of treatment should be adopted. In cases where the causes are non

treatable, symptomatic relief is aimed in the form of reducing the distress associated with tinnitus by decreasing its intensity and thus improving the quality of life.

The present study was an interventional study carried out at Madurai Medical College involving 30 patients with complaints of tinnitus. Most of the study patients presented with tinnitus belonged to the age group of 31-40 years. In the study by Shetty S et al., the mean age was found to be 38.6 years [5]. The study by Sayoo C and Kumar S had 50% of their study sample in the age group of 21-40 years [10].

In this study, females showed a slight preponderance (53.3%) compared to males (46.7%) in the presentation of tinnitus. Working males may ignore their symptoms, while females tend to get more affected and annoyed by the symptom to a greater extent [11]. Psychological co-morbidities are also found more commonly among females, contributing to tinnitus [12]. Among the various types of tinnitus, in this study, those patients who had tinnitus which is subjective in nature were included.

THI questionnaire helped in evaluating the various characteristics of tinnitus [9]. This questionnaire helped to direct towards the diagnosis and also helps to assess the severity of tinnitus to decide on the modality of treatment to be considered. The severity of tinnitus was graded in the questionnaire based on the degree of tinnitus.

A step-wise treatment protocol was followed for treating the patients considering various factors like age, presence of co-morbidities etc. Specific causes were diagnosed and referred for specific treatment. The various classes of drugs tried in patients who were diagnosed to have subjective idiopathic tinnitus like labyrinthine sedatives like betahistine and cinnarizine, microvasodilators, antipsychotics including antidepressants and anti-anxiety drugs, neurotropics and antioxidants, antihistamines. Treatment of tinnitus currently includes hearing aids with masking, Tinnitus retraining therapy and oral medications which have limited efficacy. Hence, intratympanic treatment with steroid is an emerging treatment option for the idiopathic tinnitus. Patients who failed to respond to the above medical treatment were selected for intratympanic drug injection.

In this study, it was found that after completing three doses of intratympanic injection of dexamethasone, at the first follow-up that is one week after the treatment, there was no significant improvement in tinnitus. At the second follow-up that is one month after the last injection, there was a mild improvement in the tinnitus. At the third visit, that is three months after the last injection, there was statistically significant improvement in the tinnitus. This was similar to the study by Yener HM et al., which reported that the effect of intratympanic dexamethasone injection in tinnitus patients was statistically significant [7]. The study by Hoda E et al., reports that intratympanic dexamethasone injection is a simple and effective treatment where the tinnitus could be markedly decreased and easily tolerated [8]. Memari F and Hassannia F in their study done on 100 patients with Meniere's disease reported an improvement in tinnitus score from 40 before treatment to 31 after treatment and thus concluded that intratympanic steroid injection is an effective method in controlling tinnitus severity [13]. There are also a few studies that concluded that intratympanic injection of steroid and lidocaine was an effective treatment for idiopathic tinnitus [14,15].

The advantage of intratympanic steroid injection is that the adverse effects of the systemic administration of the drug can be avoided [16]. Local side-effects: may include injection site pain, dizziness, infection, persistent perforation of the membrane. In

this study, no significant side-effects were noted. The study by Moreno I and Belinchon A concluded that usage of high doses of intratympanic dexamethasone injection for a long time did not lead to any significant clinically worse hearing in humans [17]. Sufficient warming of the drug, the use of fine needles and appropriate local anaesthesia, a gentle rate of injection and avoidance of excessive volume of injection are the key factors for good local tolerance.

Limitations(s)

The sample size was small as many patients reporting with tinnitus did not satisfy the inclusion criteria.

CONCLUSION(S)

In the current study, the treatment efficacy of the intratympanic injection of dexamethasone on tinnitus severity was found to be statistically significant ($p < 0.001$). There was significant improvement in tinnitus at one month and three months after treatment. The patients in this study, experienced no side-effects after the treatment. Hence it is concluded that intratympanic injection of dexamethasone can be considered as a simple and effective method for controlling subjective idiopathic tinnitus. Due to its anti-inflammatory action and increase in cochlear blood flow, steroids are believed to alleviate tinnitus, thereby enabling the patient to cope more easily with the symptom and hence improving the quality of life. It is also recommended that future studies be done, with larger sample sizes and other tools to evaluate the efficacy of intratympanic steroid injection.

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