

## Role of Intratympanic Dexamethasone in The Management of Tinnitus- Our Experience

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### ABSTRACT

**Introduction:** This study attempts to see the role of weekly Intratympanic injection of Dexamethasone in the management of patients with idiopathic subjective tinnitus in a tertiary care hospital in Kolkata, West Bengal, India. Objective assessment was done by noting the change in Pure Tone Audiometry (PTA) & subjective analysis by Tinnitus Handicap Inventory (THI) score sequentially on Day 1, 4th week, 6th week, 8th week and 12th week.

**Methods:** 55 patients aged between 18 years to 65 years with idiopathic subjective tinnitus were enrolled in our study and 0.5 ml of intratympanic dexamethasone was administered in the respective ear under microscopic vision for 8 weeks. Changes in the THI & PTA were recorded on Day 1, week 4, week 6, week 8 & week 12 respectively.

**Results:** Based on PTA reports & THI, at the end of 12 weeks, improvement in symptoms was noted in 38 patients (69.09%), 12 patients (21.82%) did not show appreciable improvement over time, 2(3.64%) patients left the study midway due to lack of improvement in symptoms and 3(5.45%) patients were lost to follow-up. On comparing THI at Day 1 & week 12, a p-value of <0.0001 was obtained.

**Conclusion:** The p-value based on THI change from Day 1 to week 12 is <0.0001 which is statistically significant. An improvement in the grade of tinnitus based on THI & PTA was noted at week 12. Thus, we can conclude that Intratympanic Injection of Dexamethasone plays a pivotal role in managing idiopathic subjective tinnitus.

**Keywords:** Tinnitus, Intratympanic Dexamethasone; Tinnitus Handicap Inventory; Pure Tone Audiometry

## INTRODUCTION

Tinnitus has been defined as the conscious experience of a sound that originates in the head of the owner in the absence of any acoustic electrical or other external stimulation [1].

To simplify, Tinnitus is clinically manifested as a constant buzzing sound in the head or ear, that affects the patient both mentally and physically. The incidence of tinnitus has increased worldwide. Jarach et al. in their systematic review and meta-analysis recorded the annual incidence of tinnitus to be 1% with 14% of the adults experiencing any form of tinnitus and 2% of them experiencing a severe form of tinnitus [2]. Idiopathic tinnitus is often accompanied by sensorineural hearing loss. The most common site of origin of subjective tinnitus is in the cochlea [3].

Tinnitus is broadly classified into subjective & objective tinnitus. Subjective tinnitus is the perception of sound without any auditory stimulus. It is not associated with any physical noise and is audible only to the affected person. Objective tinnitus, on the other hand, is caused by a mechanical sound in the body. It is generated in the body and is conducted to the ear via body tissues. It is audible to anyone in addition to the affected person. Objective tinnitus, also known as somatic tinnitus, can be classified into pulsatile, muscular & spontaneous [1,3].

Scientists have been working worldwide to find a permanent cure for subjective idiopathic tinnitus. The most frequently used drugs which are approved for intratympanic injections are aminoglycoside antibiotics and steroids. Steroids, which have anti-inflammatory and electrolyte modifying effects, are one of the most popular agents used for intratympanic treatment of subjective idiopathic tinnitus [4].

Schuknecht [5], in the year 1956, was the first to use Intratympanic steroid injection as a method of treatment to relieve symptoms of Meniere's disease. Bird et al [6], in 2007, noted in their study that intratympanic use of dexamethasone resulted in a 1.270-fold increase in its perilymphatic concentration associated with a decline in its plasma concentration.

The therapeutic effect of intratympanic drugs is thought to occur by diffusion through round window, annular ligament of oval window, capillaries, or through the lymphatics of the inner ear. However, the effectiveness of the intratympanic steroid therapy for tinnitus has not yet been proven [4,7].

The aim of this study is to note the role of intratympanic injection of dexamethasone in the management of subjective idiopathic tinnitus by monitoring the change in score of Tinnitus Handicap Inventory (THI) & Pure Tone Audiogram (PTA) report.

## AIMS AND OBJECTIVES

1. To assess the type of tinnitus the patient has.
2. To assess the response to intratympanic injection of dexamethasone by monitoring change in THI score over 12 weeks.
3. To assess the response to intratympanic injection of dexamethasone by monitoring change in PTA report over 12 weeks.

## METHODOLOGY

An institution based prospective interventional observational study was done in the Department of Otorhinolaryngology at a tertiary care hospital in Kolkata, West

Bengal, India. A total of 55 patients were taken this study. All the patients have idiopathic subjective tinnitus.

Duration of study: October'2023 to April'2024

### INCLUSION CRITERIA:

- a) Age >18 Years & <65 Years
- b) All Patients Presenting with Subjective Tinnitus of duration 3 days to 1 year.
- c) Intact tympanic membrane.

### EXCLUSION CRITERIA:

- a) Age < 18 Years & > 65 Years
- b) Patients with active Inner Ear Diseases
- c) Psychiatric disorder associated auditory hallucination
- c) Tinnitus associated with Organic brain lesions like CP angle pathology
- d) Patients with H/O Pulsatile Objective Tinnitus.
- e) Tinnitus post trauma, injury
- f) Patients with conductive hearing loss due to middle ear disease and eustachian tube dysfunction.

All patients were subjected to Tuning fork examination and routine otoscopic evaluation to identify any middle ear (ME) or inner ear (IE) pathology. Whenever

indicated, High Resolution Computed Tomography scan of temporal bones was done to exclude ME pathology and Magnetic Resonance Imaging (MRI) with special

emphasis upon IE, Endolymphatic sac (ES) and Cerebello-pontine (CP) angles were done to exclude Endolymphatic Hydrops (EH) and CP angle pathology. After thorough clinico-radiological evaluation, patients were selected following strict above mentioned inclusion and exclusion criteria.

The selected patients on Day 1 of visit were assessed and provided with a Tinnitus Handicap Inventory and the score was noted. The questions were asked by rotational interneers of the Department of Otorhinolaryngology of the hospital to avoid observer bias. A Pure Tone Audiometry test was done to assess the degree of sensorineural hearing loss, if present. All other prior modes used for treating tinnitus in these patients were stopped. Before initiation of our treatment, a proper psychological evaluation of the enrolled patients was done. Weekly, Injection Dexamethasone was given via intra-tympanic route in the affected side under microscopic guidance for 8 weeks. The patients were provided with THI at 4 weeks, 6 weeks, 8 weeks & 12 weeks since Day 1 of Injection and the change in score was recorded. Pure Tone Audiometry was checked by the audiologist at 4,6,8 & 12 weeks since Day 1 of Injection Dexamethasone. Dose of 0.5 ml of 4mg/ml of Injection Dexamethasone was administered in the postero-inferior quadrant of the pars tensa. The procedure was performed in the minor Operation Theatre (OT) of the department under strict asepsis. The patient was made to lie supine with head tilted 45° to the opposite side. Topical Anaesthesia was achieved with 4% Xylocaine drop. A spinocan needle with insulin syringe was used to administer the drug to the patient. Post administration of drug, the patients were made to lie supine with the head

in neutral position for 15 minutes. The patients were specifically instructed not to swallow, which might result in immediate passage of the drug via tympanic end of pharyngo-tympanic tube. The THI & PTA were compared as mentioned before. At the end of 12 weeks, those patients who showed no improvement were reverted to their prior treatment plan for tinnitus.

#### TINNITUS HANDICAP INVENTORY:

TOTAL SCORE	INDICATION	GRADE
0-16	SLIGHT (ONLY HEARD IN QUIET ENVIRONMENTS)	1
18-36	MILD (EASILY MASKED BY ENVIRONMENTAL SOUNDS AND EASILY FORGOTTEN WITH ACTIVITIES )	2
38-56	MODERATE (NOTICED IN THE PRESENCE OF BACKGROUND NOISE, ALTHOUGH DAILY ACTIVITIES CAN STILL BE PERFORMED )	3
58-76	SEVERE (ALMOST ALWAYS HEARD, LEADS TO DISTURBED SLEEP PATTERNS AND CAN INTERFERE WITH DAILY ACTIVITIES )	4
78-100	CATASTROPHIC ( ALWAYS HEARD, DISTURBED SLEEP PATTERNS, DIFFICULTY WITH ANY ACTIVITIES )	5

It is a questionnaire comprising of 25 questions – each question having 3 options: Yes (a score of 4); Sometimes (a score of 2 ) and No ( a score of 0 ) . The total score is out of 100 [8].

The patients were given grades based on these scores on Day 1, 4th, 6th, 8th and 12th weeks from 1st day of visit and initiation of the intratympanic steroid injection.

#### STATISTICAL ANALYSIS:

The distribution of patients based on age group and sex were noted and tabulated in a bar diagram. The percentage of patients with unilateral and bilateral tinnitus was calculated. The percentage of patients showing response to treatment at the end of 12 weeks based on THI & PTA were calculated respectively. All the data were compiled using Microsoft Excel 2019 and MS Word and analyzed using standard statistical methods using SPSS 29 software.

#### RESULTS

31 of the total 55 patients presenting with tinnitus were male and 24 were female. Among the 31 males, 1 was in the age group of 18-29 years, 4 in the age group of 30-41 years, 12 in the age group of 42-53 years, 14 in the age group 54-65 years. Among the 24 females, none were in the age group 18-29 years, 4 in the age group 30-41 years, 9 in the age group 42-53 years, 11 were in the age group 54-65 years. At the end of 12 weeks, 38(69.09%) patients showed an improvement in THI and PTA reports, 12(21.82%) patients showed no improvement, 2(3.64%) patients left the study and 3(5.45%) were lost to follow-up. It was noted that out of the 38 patients who showed an improvement, 23(60.53%) were male and 15(39.47%) were female patients. Further, it was noted that 23(74.2%) out of 31 male patients showed an improvement, 6 (19.35%) male patients did not show an improvement and 2 (6.45%) male patients left the study. If we study further, among the 23 males who showed an improvement, 1 patient was in the age group 18-29 years, 4 were in the age group 30-41 years, 10 were in the age group 42-53 years and 8 were in the age group 54-65 years. Among the 24 female patients, 15(62.5%) showed an improvement, 6(25%) did not show an improvement and 3(12.5%) of them left the study. Among the 15 females showing an

improvement, 3 were in the age group 30-41 years, 6 in the age group 42-53 years and 6 in the age group 54-65 years.

Among the 12 patients who showed no improvement at the end of the study, 4 (33.33%) were in the age group 42-53 years and 8 (66.67%) were in the age group 54-65 years.

Based on the duration of tinnitus, 38 patients had a duration of less than 6 months and all showed an improvement while 17 patients had tinnitus for six months or more. Among these 17 patients, 3 were lost to follow up, 2 left the study and 12 did not show any improvement.

At the beginning of the study, based on PTA, 2(3.64%) patients had a normal PTA, 20(36.36%) patients had mild sensorineural hearing loss (SNHL), 23(41.82%) patients had moderate SNHL & 10(18.18%) patients had severe SNHL. 0 patients had Grade 1 score, 21(38.18%) patients had Grade 2, 27(49.09%) patients had Grade 3 & 6(10.91%) patients had Grade 4 score based on THI on Day 1 of visit. The mean THI score was 2.709 and standard deviation was 0.658 on Day 1.

At the end of 4 weeks, based on PTA, 11(20%) patients had a normal PTA, 22(40%) patients had mild sensorineural hearing loss (SNHL), 15(27.27%) patients had moderate SNHL & 6(10.91%) patients had severe SNHL and 1(1.82%) patient was lost to follow-up. 14 (25.45%) patients had Grade 1 score, 21(38.18%) patients had Grade 2, 15(27.27%) patients had Grade 3, 4(7.27%) patients had Grade 4 score and 1(1.82%) was lost to follow-up based on THI on 4th week. The mean THI score was 2.167 and standard deviation was 0.906 on 4th week.

At the end of 6 weeks, based on PTA, 12(21.82%) patients had a normal PTA, 22(40%) patients had mild sensorineural hearing loss (SNHL), 14(25.45%) patients had moderate SNHL & 5(9.09%) patients had severe SNHL, 2(3.64%) were lost to follow-up. 19(34.55%) patients had Grade 1 score, 18(32.73%) patients had Grade 2, 14(25.45%) patients had Grade 3, 2(3.64%) patients had Grade 4 score and 2(3.64%) were lost to follow-up based on THI on 6th week. The mean THI score was 1.981 and standard deviation was 0.888 on 6th week.

At the end of 8 weeks, 13(23.64%) based on PTA, patients had a normal PTA, 20(36.64%) patients had mild sensorineural hearing loss (SNHL), 15(27.27%) patients had moderate SNHL & 2(3.64%) patients had severe SNHL, 2(3.64%) patients left the study and 3(5.45%) patients were lost to follow-up. 25 (45.45%) patients had Grade 1 score, 14(25.45%) patients had Grade 2, 11(20%) patients had Grade 3 & 0 patients had Grade 4 score, 3(5.45%) patients were lost to follow-up, 2(3.64%) patients left the study based on THI on 8th week. The mean THI score was 1.72 and standard deviation was 0.809 on 8th week.

At the end of 12 weeks, based on PTA, 15(27.27%) patients had a normal PTA, 19(34.55%) patients had mild sensorineural hearing loss (SNHL), 14(25.45%) patients had moderate SNHL & 2(3.64%) patients had severe SNHL, 2(3.64%) patients left the study and 3(5.45%) patients were lost to follow-up. 26(47.27%) patients had Grade 1 score, 12(21.82%) patients had Grade 2, 12(21.82%) patients had Grade 3 & 0 patients had Grade 4 score, 3(5.45%) patients were lost to follow-up, 2(3.64%) patients left the study based on THI on 12th week. The mean THI score was 1.72 and standard deviation was 0.834 on 12th week.

Based on PTA reports & THI, at the end of 12 weeks, improvement in symptoms was noted in 38 patients (69.09%), 12(21.82%) patients showed no improvement over time, 3(5.45%) patients were lost to follow-up and 2(3.64%) patients left the study.

Based on the mean and standard deviation values THI scores of Day 1 & Week 12, a difference of -0.989 was obtained, a standard error of 0.143, 95% Confidence Interval of -1.2728 to -0.7052 and a p value of <0.0001 was obtained.

## DISCUSSION

The word tinnitus is derived from the Greek word 'tinnire' meaning 'to ring'. Positron emission tomography (PET) scanning and functional magnetic resonance imaging (fMRI) studies indicate that a loss of cochlear input to neurons in the central auditory system (such as occurs in cochlear hair cell damage or a lesion of the vestibulocochlear nerve) can result in abnormal neural activity in the auditory cortex [15]. This leads to the perception of tinnitus. There is a loss of suppression of the neural feedback loops which help tune and reinforce auditory memory in the central auditory cortex and disruption of this feedback loop leads to the disinhibition of normal synapses and the creation of uncontrolled alternative neural synapses which lead to the abnormal auditory perception of tinnitus [16].

On an average, we receive three-hundred (300) patients daily in the outdoor unit of the Department of Otorhinolaryngology of our hospital. Based on the records, roughly 15 patients present daily with complaints of tinnitus. Thereby, the annual prevalence of tinnitus in our hospital was noted to be 5%. Beukes et al. in their study related to the impact of COVID-19 and the pandemic on tinnitus, noted the pooled prevalence of tinnitus to be 8% [14].

The effect of intratympanic steroids on steroids is not a well-established finding. But the prevalence of tinnitus and the mental agony associated with it urged us to do this detailed prospective interventional study.

In our study, 31 patients (56.36%) were male & 24 patients (43.64%) out of 50 were female. Based on PTA reports & THI, at the end of 12 weeks, improvement in symptoms was noted in 38 patients (69.09%), 12(21.82%) patients showed no improvement over time, 3(5.45%) patients were lost to follow-up and 2(3.64%) patients left the study. Based on the mean and standard deviation values THI scores of Day 1 & Week 12, a difference of -0.989 was obtained, a standard error of 0.143, 95% Confidence Interval of -1.2728 to -0.7052 and a p value of <0.0001 was obtained. In a study done by Haydar Murat Yener et al. [9], they found that the effect of the intratympanic injection of dexamethasone on the efficacy of treatment of tinnitus severity was statistically significant.

Araújo MFS et al [10], conducted a study and concluded that there was no advantage in intratympanic injections of dexamethasone over saline solution in the treatment of severe, disabling tinnitus.

Chanmiki Sayoo et al [11], concluded that after receiving several number of injections, 24 patients (60%) reported complete disappearance of tinnitus, 10 of them (25%) still had residual tinnitus but comparatively less severe and 6 (15%) of them reported no improvement.

Silverstein H et al. [12-16], in their preliminary study, concluded that intratympanic steroids may affect the symptoms of hearing loss and tinnitus in patients with various inner ear problems.

In this study, an improvement can be clearly noted in the change in symptoms of tinnitus after administration of Intratympanic injection of Dexamethasone.

In this study, it was noted that patients in the older age group, showed less response to treatment than those in the younger age group. Attanasio *et al.* [17] in their study concluded that ‘the age, delay and pre-PTA may be considered factors influencing therapeutic success in intra-tympanic steroid therapy’.

In this study, among the 12 patients who did not show any improvement at the end of the study, equal number of male and females (six each) failed to show improvement.

Among those who failed to show improvement, the duration of tinnitus was six (6) months or more.

Oh *et al.* [18] in their study concluded that short duration of tinnitus, no immediate exposure to noise were favourable prognostic factors in the management of acute subjective tinnitus with intratympanic steroid injection.

## CONCLUSION

This study indicates that a significant improvement can be obtained in treating patients with idiopathic subjective tinnitus by administering intratympanic dexamethasone on a weekly basis. A p-value of <0.05 based on change in scores of THI from Day 1 to Week 12 further establishes this correlation. We can conclude that there is a pivotal role of Intratympanic Injection of Dexamethasone in the management of Idiopathic Subjective Tinnitus in this given study.

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