

# Effect of Intratympanic Steroid Injection in Patients of Idiopathic Tinnitus

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**Abstract:** **Background:** This study evaluates the effectiveness of intratympanic dexamethasone injections in alleviating tinnitus severity and improving hearing outcomes in patients with idiopathic tinnitus. **Methods:** A prospective observational study was conducted from June 2023 to December 2024 at the Department of Otorhinolaryngology, Gandhi Medical College & Hamidia Hospital, Bhopal. Seventy patients who met the inclusion criteria received two intratympanic dexamethasone injections at one-week intervals. Tinnitus severity and hearing thresholds were assessed pre- and 4 weeks post-treatment using the Tinnitus Handicap Inventory (THI) and Pure Tone Audiometry (PTA), respectively. **Results:** The mean THI score significantly reduced from  $44.89 \pm 18.16$  to  $35.11 \pm 16.94$  ( $p < 0.05$ ), with 67.1% of patients experiencing reduced tinnitus severity. Hearing thresholds improved significantly in both ears, with mean PTA decreasing from  $42.61 \pm 16.47$  to  $39.66 \pm 14.39$  dB in the right ear and  $38.9 \pm 17.77$  to  $36.62 \pm 15.46$  dB in the left ear ( $p < 0.05$ ). Complications were minimal (4.3%) and self-limiting. **Conclusion:** Intratympanic dexamethasone injection is a safe and effective modality for managing idiopathic tinnitus, leading to meaningful relief in symptoms and measurable hearing improvement. Larger, multicentric studies with long-term follow-up are warranted to validate these findings.

**Keywords:** Tinnitus, Intratympanic Injection, Dexamethasone, Idiopathic Tinnitus, Tinnitus Handicap Inventory, Sensorineural Hearing Loss

## 1. Introduction

Tinnitus refers to the sensation of hearing noise or ringing in the ears when there is no external sound present.<sup>[1]</sup> More than 740 million adults worldwide experience tinnitus, with over 120 million people regarding it as a significant health concern, according to a recent systematic review, which documented the significant contribution of tinnitus to the global burden of disease.<sup>[2]</sup> There are two types of tinnitus: subjective (audible to the affected person alone) and objective (audible to everyone in addition to the affected person). It can be loud or weak, pulsating (synchronous or asynchronous with the heartbeat), intermittent or constant, felt in one or both ears, or inside the brain, and it can appear at different pitches.<sup>[3,4]</sup>

Tinnitus is a chronic condition in most patients. The therapeutic goals are twofold: to lessen the intensity and to reduce its associated handicap.<sup>[5]</sup> Traditionally, tinnitus has been managed with a number of therapies, including sound therapy, cognitive-behavioral therapy (CBT), and various pharmaceutical medications such as antidepressants and anxiolytics.<sup>[6,7]</sup> Tinnitus retraining therapy (TRT) is a type of behavioral therapy that seeks to bypass or override abnormal auditory cortex neural connections. TRT entails facilitating habituation to the tinnitus signal through a combination of

retraining counseling and sound therapy with both broad band noise and environmental sounds.<sup>[8]</sup>

Intratympanic steroid injection has emerged as a promising therapy option, especially for acute sensorineural hearing loss, Meniere's disease, and other otologic diseases. Steroids' anti-inflammatory and immunosuppressive characteristics are thought to lower cochlear inflammation and improve hearing function, making them a potentially effective treatment for tinnitus. However, the efficacy of intratympanic treatment for tinnitus has not yet been established.<sup>[9,10]</sup> There have been conflicting results pertaining to the effects of intratympanic steroids on tinnitus.<sup>[11]</sup> Due to the common occurrence and often disabling impact of tinnitus, it is essential to identify an effective treatment for cases with no known cause.

With this background in mind, this study was designed to assess the efficacy of intratympanic steroid injection in patients with idiopathic tinnitus. The study's goal is to assess whether this strategy can provide significant relief from tinnitus symptoms while also improving overall quality of life for affected persons.

## 2. Methodology

The present study was conducted as a prospective observational study on patients with idiopathic Tinnitus

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attending the Otorhinolaryngology Department of Gandhi Medical College & Hamidia Hospital, Bhopal, Madhya Pradesh, during the study period of from June 2023 to December 2024. All patients with idiopathic Tinnitus (Bilateral or Unilateral) with or without hearing loss were included whereas participants with a history of middle ear surgery, head injury, or usage of ototoxic medications, with Chronic Suppurative Otitis Media, Perforated Tympanic Membrane, endolymphatic hydrops, otosclerosis and systemic diseases like hypertension and diabetes mellitus were excluded from the study.

Patients who met the inclusion criteria were selected to participate in the study. Written informed consent was obtained from each participant in either English, or Hindi, depending on their preference. After their inclusion, baseline data for all participants were recorded in a semi-structured proforma, encompassing sociodemographic profiles.

All patients underwent a thorough ENT examination including Tuning Fork Test and Pure Tone Audiometry. Participants were given two intratympanic steroid injections with an interval of one week. Before intervention, each patient underwent Pure Tone Audiometry and completed the Tinnitus Handicap Inventory (THI) questionnaire. Follow-up was conducted 4 weeks after treatment to reassess both parameters. This follow-up session again involved a post intervention meticulous examination, Pure Tone Audiometry and administration of the THI questionnaire to evaluate treatment outcomes.<sup>[12]</sup>

During the follow-up, a thorough general medical examination was conducted, and any necessary interventions were implemented in adherence to established norms.

#### Details of procedure performed:

- 1) Patients were positioned supine with the head turned 45 degrees to other side and the ear to be treated facing upward.
- 2) Thorough microscopic examination of the ear was done.
- 3) Debris from external auditory canal was removed.
- 4) A cotton wick saturated with 4% xylocaine was placed in the external auditory canal and left in position for 5 minutes.
- 5) One milliliter of dexamethasone was loaded in 1 ml syringe and attached to a 26G needle.
- 6) The cotton wick was removed, and any residual xylocaine solution was aspirated.
- 7) The posteroinferior quadrant of tympanic membrane was focussed in microscope, for this aural speculum was used.
- 8) The needle was then introduced in the external auditory canal.
- 9) In all the patients 1 ml of dexamethasone was introduced into the middle ear through posteroinferior part of tympanic membrane.
- 10) The patient's head was maintained as such for 30 min to allow the drug to concentrate near the round window membrane.
- 11) The patients were instructed not to swallow their saliva to prevent escape of drug from Eustachian tube

#### Data Analysis

After the collection of data, it was entered in *MS Excel*. Data were analysed and interpreted to pursue defined objectives by using tables & graphs using IBM SPSS 20 software. The mean, standard deviation, and rate was used for descriptive analysis. Improvement in hearing outcome following steroid injection was assessed using Chi-squared test for categorical variables and paired-t test for continuous variables. The results were evaluated at the level of significance  $p < 0.05$ .

### 3. Results

The mean age of patients with idiopathic tinnitus was  $40.64 \pm 14.14$  years and the majority of patients belonged to age range of 41 to 50 years (30%). The male-to-female ratio was nearly equal at 1.01:1. About 45.7% cases presented with ringing sensation from right ear, 20% presented with ringing sensation from left ear and 34.3% cases presented with ringing sensation from bilateral ear. We observed reduced hearing in 82.9% cases and majority of patients presented with bilateral reduced hearing (42.9%). About 27.1% and 12.9% cases presented with reduced hearing from right and left ear respectively (Table 1).

In right ear, 24.3% ears had normal hearing pre-injection whereas 25.7% cases had mild SNHL, 30% had moderate SNHL and remaining 14.3% cases had moderately severe to profound hearing loss and 5.7% cases had mixed hearing loss. However, after intratympanic steroid injection, normal hearing was observed in 27.1% cases whereas 37.1% had mild SNHL, 20% had moderate SNHL. The severity of hearing loss reduced significantly in right ear post intratympanic steroid injection ( $p < 0.05$ ). Thus, hearing in right ear improved significantly as evidenced from mean PTA reduction from  $42.61 \pm 16.47$  at baseline to  $39.66 \pm 14.39$  dB after injection. In left ear, 40% ears had normal hearing pre-injection whereas 18.6% cases had mild SNHL, 25.7% had moderate SNHL and remaining 8.6% cases had moderately severe SNHL and 7.1% cases had mixed hearing loss. However, after intratympanic steroid injection, normal hearing was observed in 41.4% cases whereas 25.7% had mild SNHL, 20% had moderate SNHL. Thus, severity of SNHL reduced significantly after intratympanic steroid injections ( $p < 0.05$ ). The mean PTA in left ear before injection was  $38.9 \pm 17.77$  dB, which reduced significantly to  $36.62 \pm 15.46$  dB (Table 2).

After intratympanic steroid injection, we observed significant improvement in tinnitus severity and found very mild tinnitus in 10%, mild tinnitus in 58.6% and moderate tinnitus in 17.1% cases. Mean THI score at baseline was  $44.89 \pm 18.16$ , which reduced significantly to  $35.11 \pm 16.94$  and the mean reduction in THI score post-injection was  $9.77 \pm 4.15$  ( $p < 0.05$ ) (Figure 1).

Out of 33 cases with mild THI score, we observed improvement in 21.2% cases. However, out of 17 cases with moderate THI score, improvement post intratympanic injection was noted in 88.2% cases. About 66.7% and 60% cases with severe and catastrophic THI score improved post intratympanic injection to moderate and severe THI score respectively (Table 3).

Complications occurred in 4.3% of cases following intratympanic steroid injections. We found otitis externa, otomycosis and pin point perforation in 1.4% cases each, which got resolved later (Figure 2).

#### 4. Discussions

As tinnitus is often chronic, the primary aim of treatment is to reduce its intensity and lessen its associated impact.<sup>[5]</sup> Tinnitus care, particularly idiopathic tinnitus, remains difficult due to its obscure cause and a lack of generally effective treatments. Tinnitus retraining treatment, masking-equipped hearing aids, and oral medicines are currently the successful methods to treat tinnitus.<sup>[11]</sup>

In this study, intratympanic steroid injections were effective in enhancing hearing and decreasing the severity of hearing loss compared to pre-injection levels in both the right and left ears ( $p < 0.05$ ). The mean PTA decreased from  $42.61 \pm 16.47$  and  $38.9 \pm 17.77$  dB at baseline to  $39.66 \pm 14.39$  dB and  $36.62 \pm 15.46$  dB after injection in right and left ear respectively, indicating a substantial improvement in hearing. In the study conducted by Yener et al, mean PTA in right ear was  $23.7 \pm 19.06$  dB before treatment, which reduced to  $22.7 \pm 18.11$  dB after treatment whereas mean PTA in left ear increased from  $26.27 \pm 27.76$  dB to  $27.43 \pm 29.88$  dB after treatment. However, the observed difference in PTA post treatment as compared to pretreatment values was statistically insignificant ( $p > 0.05$ ).<sup>[11]</sup> Our study findings were supported by the findings of Mokhatrish et al, in which, the authors observed mild, moderate, moderately severe and severe hearing loss in 25.42%, 25.42%, 18.65% and 30.51% cases respectively before treatment, whereas hearing was normal in 47.46% cases following treatment ( $p < 0.05$ ).<sup>[13]</sup>

Severity of tinnitus was assessed using Tinnitus Handicap Inventory score. In the present study, mean THI score at baseline was  $44.89 \pm 18.16$ , which significantly reduced to  $35.11 \pm 16.94$  following intratympanic steroid injection. At baseline, 47.1% cases had mild tinnitus, 24.3% had moderate tinnitus, 21.4% had severe tinnitus and 7.1% cases had catastrophic tinnitus, whereas after intratympanic steroid injection, we found very mild tinnitus in 10%, mild tinnitus in 58.6%, moderate tinnitus in 17.1%, severe tinnitus in 11.4% and catastrophic tinnitus in 2.9% cases ( $p < 0.05$ ). We found improvement in THI score in 21.2% cases with mild tinnitus, 88.1% cases with moderate tinnitus, 66.7% cases with severe tinnitus and 60% cases with catastrophic tinnitus. Similarly, in a study conducted by Mokhatrish et al, 32.2% patients exhibited complete recovery; 39.0% showed a decline in THI scores, 5.0% showed no change, and 23.8% showed increase in THI score. Tinnitus significantly improved in the light handicap group, remained unchanged in the mild to moderate handicap groups, and significantly increased in the severe to catastrophic groups.<sup>[13]</sup> Additionally, Shetty et al found that mean THI score at baseline was  $40.44 \pm 9.76$ , which reduced significantly to  $36.76 \pm 8.47$  at 1 month and  $34.33 \pm 8.31$  at 3 months following treatment ( $p < 0.01$ ).<sup>[14]</sup>

Intratympanic steroid injection is an invasive technique, which makes it clinically burdensome. Although it is recognized that complications such as middle ear

inflammation, eardrum perforation, and hearing loss are uncommon following intratympanic steroid injections, physicians find treatment of these complications to be more challenging.<sup>[1]</sup> In the present study, out of 70 cases with idiopathic tinnitus, complications following intratympanic steroid injections were seen in 4.3% cases, with otitis externa, otomycosis and pin point perforation (resolved later) in 1.4% cases each. The use of an IT route to treat tinnitus has two benefits: first, it allows for a direct passage through the oval window membrane, resulting in high perilymph levels; second, it prevents the negative effects of systemic medication administration.<sup>[14]</sup>

Liu et al observed increasing tinnitus in 5.4% cases following ITI, temporary vertigo in 16.9% and post-injection vertigo in 1.8%.<sup>[15]</sup> On the other hand, Hu et al, the rates of otalgia, vertigo, and chronic eardrum perforation were observed in 47.2%, 4.1%, and 4.9%, respectively following ITI.<sup>[16]</sup> Yener et al documented no complications following intratympanic steroid injection in their study.<sup>[11]</sup>

The present study had certain limitations. The sample size of the study was small and the study was conducted as a unicentric study, thus the population may be homogenous, limiting the generalizability of study findings. Only efficacy of intratympanic steroid injection was assessed, lack of comparison group is another limitation. Patients were followed up till only 4 weeks, thus long term outcome and recurrence rate could not be observed.

#### 5. Conclusion

Based upon the findings of present study, intratympanic steroid injection appears to be a safe, effective, and minimally invasive treatment modality for idiopathic tinnitus, particularly in patients with moderate to severe symptoms. While not curative, it offers meaningful symptom relief and improved functional outcomes when given early. As intratympanic steroid injection is effective in improving the hearing outcome as well as reducing the severity of tinnitus and intratympanic injection is devoid of systemic side effects and thus should be considered a first-line treatment for management of idiopathic tinnitus. Large multicentric study including larger sample size with long term follow up is recommended to assess the long term efficacy of intratympanic injection in treatment of idiopathic tinnitus.

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**Table 1:** Distribution of patients according to baseline variables

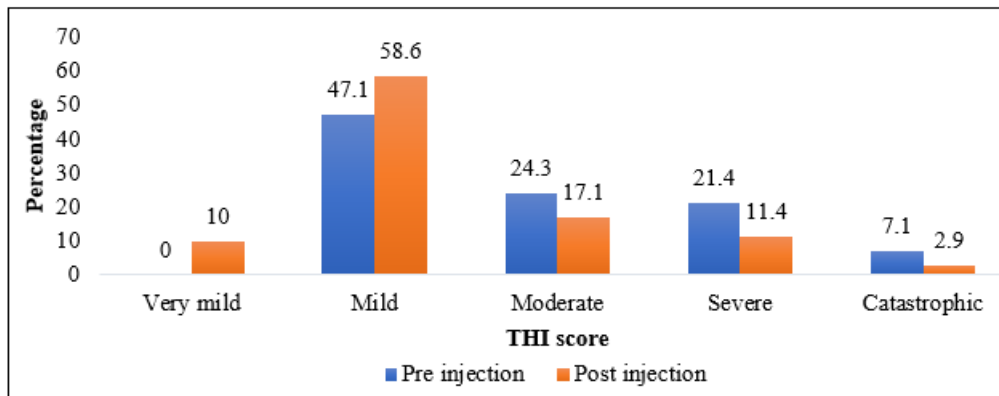
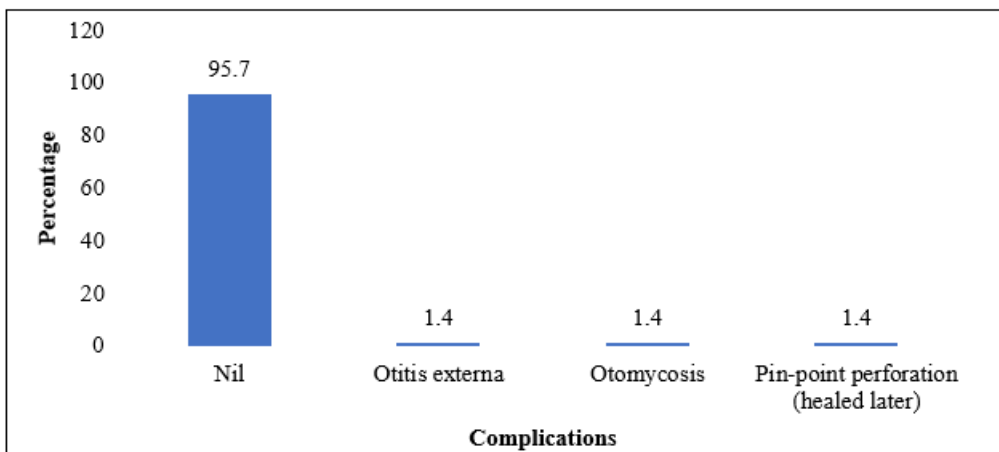
| Baseline variables |               | Frequency (n=70) | Percentage |
|--------------------|---------------|------------------|------------|
| Age (years)        | ≤20           | 4                | 5.7        |
|                    | 21-30         | 19               | 27.1       |
|                    | 31-40         | 12               | 17.1       |
|                    | 41-50         | 21               | 30.0       |
|                    | 51-60         | 7                | 10.0       |
|                    | >60           | 7                | 10.0       |
| Gender             | Male          | 36               | 51.4       |
|                    | Female        | 34               | 48.6       |
| Ringing Sensation  | Right ear     | 32               | 45.7       |
|                    | Left Ear      | 14               | 20.0       |
|                    | Bilateral Ear | 24               | 34.3       |
| Reduced hearing    | Absent        | 12               | 17.1       |
|                    | Right ear     | 19               | 27.1       |
|                    | Left Ear      | 9                | 12.9       |
|                    | Bilateral Ear | 30               | 42.9       |

**Table 2:** Impact of intratympanic steroid injection on hearing assessment on Pure tone audiometry

| PTA hearing assessment |                         | Pre-injection (n=70) |      | Post-injection (n=70) |      | P value      |
|------------------------|-------------------------|----------------------|------|-----------------------|------|--------------|
|                        |                         | n                    | %    | n                     | %    |              |
| Right ear              | Normal                  | 17                   | 24.3 | 19                    | 27.1 | <b>0.001</b> |
|                        | Mild SNHL               | 18                   | 25.7 | 26                    | 37.1 |              |
|                        | Moderate SNHL           | 21                   | 30.0 | 14                    | 20.0 |              |
|                        | Moderately severe SNHL  | 6                    | 8.6  | 7                     | 10.0 |              |
|                        | Severe to profound SNHL | 4                    | 5.7  | 0                     | 0    |              |
|                        | Mixed hearing loss      | 4                    | 5.7  | 4                     | 5.7  |              |
|                        | Mean±SD                 | 42.61±16.47          |      | 39.66±14.39           |      | <b>0.001</b> |
| Left Hearing           | Normal                  | 28                   | 40.0 | 29                    | 41.4 | <b>0.001</b> |
|                        | Mild SNHL               | 13                   | 18.6 | 18                    | 25.7 |              |
|                        | Moderate SNHL           | 18                   | 25.7 | 14                    | 20.0 |              |
|                        | Moderately severe SNHL  | 6                    | 8.6  | 4                     | 5.7  |              |
|                        | Severe to profound SNHL | 0                    | 0    | 0                     | 0    |              |
|                        | Mixed hearing loss      | 5                    | 7.1  | 5                     | 7.1  |              |
|                        | Mean±SD                 | 38.9±17.77           |      | 36.62±15.46           |      | <b>0.001</b> |

**Table 3:** Changes in the severity of THI score post intratympanic steroid injection

| THI SCORE severity | Pre-injection (n=70) | Post-injection (n=70) |    |      |
|--------------------|----------------------|-----------------------|----|------|
|                    | n                    | Severity              | n  | %    |
| Mild               | 33                   | Very mild             | 7  | 21.2 |
|                    |                      | Mild                  | 26 | 78.8 |
| Moderate           | 17                   | Mild                  | 15 | 88.2 |
|                    |                      | Moderate              | 2  | 11.8 |
| Severe             | 15                   | Moderate              | 10 | 66.7 |
|                    |                      | Severe                | 5  | 33.3 |
| Catastrophic       | 5                    | Severe                | 3  | 60   |
|                    |                      | Catastrophic          | 2  | 40   |

**Figure 1:** Impact of intratympanic steroid injection on severity of tinnitus**Figure 2:** Complications of intratympanic steroid injections