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# TARGETED THERAPY IN ISSNHL: COMPARING ORAL AND INTRATYMPANIC CORTICOSTEROIDS

**Dawood Agoo[1*], Gurchand Singh[2], Reetika[3], Kondru Sahrudai[4], Sudhir Kumar[5]**

[1*,2,3,4,5]Department of Otorhinolaryngology(ENT), Adesh Medical College and Hospital, Shahbad, Kurukshetra, Haryana, India.

***Corresponding Author:-** Dawood Agoo
*Email-dawoodagoo47@gmail.com

**Abstract**

**Background:** Idiopathic sudden sensorineural hearing loss (ISSNHL) is an otologic emergency characterized by rapid, unexplained hearing loss. Corticosteroids remain the mainstay of treatment, either administered systemically (oral) or locally via intratympanic (IT) injection. While systemic steroids are widely used, their efficacy can be limited by contraindications and suboptimal cochlear drug delivery. IT steroids offer targeted therapy with minimal systemic exposure, but comparative data remain limited.

**Objective:** To evaluate and compare the efficacy and safety of oral versus intratympanic corticosteroids in patients with ISSNHL.

**Methods:** A prospective, randomized comparative study was conducted at Adesh Medical College and Hospital, Ambala, between October 2023 and May 2025. Fifty patients with ISSNHL were randomized into two groups: Group A received oral prednisolone (1 mg/kg/day for 10 days, followed by tapering), and Group B received IT dexamethasone (4 mg/mL, 4 doses over 2 weeks). Hearing outcomes were assessed using pure tone audiometry at baseline and 3 months, and recovery was classified according to Siegel's criteria. Adverse events were monitored throughout the study period.

**Results:** Both treatment modalities significantly improved hearing thresholds. The IT group demonstrated a higher mean hearing gain at 3 months (25.8 ± 8.3 dB) compared to the oral group (19.6 ± 7.5 dB, $p = 0.01$). Complete recovery occurred in 48% of IT patients versus 32% of oral patients, and the proportion of patients with no improvement was lower in the IT group (12% vs 28%). Adverse effects were mild and transient in both groups, with minimal systemic complications in the IT group.

**Conclusion:** Intratympanic corticosteroids offer superior auditory recovery with fewer systemic side effects, supporting their role as a first-line or alternative therapy for ISSNHL, particularly in patients with contraindications to systemic steroids. These findings emphasize the importance of early, targeted therapy in optimizing patient outcomes and quality of life.

**Keywords:** ISSNHL, idiopathic sudden sensorineural hearing loss, intratympanic steroids, oral steroids, corticosteroids, hearing recovery

## Introduction

Sudden sensorineural hearing loss (SSNHL) is considered an otologic emergency, typically defined as a rapid hearing loss of at least 30 dB across three consecutive frequencies occurring within a period of 72 hours. Its incidence is estimated to be 5–20 cases per 100,000 population annually, although

true figures may be higher due to under-reporting. The condition can affect individuals of all ages, but it is most frequently encountered in the third to sixth decades of life. Despite decades of investigation, in nearly 85–90% of cases the cause remains idiopathic, leading to the designation "idiopathic sudden sensorineural hearing loss (ISSNHL)."

The exact pathophysiology of SSNHL is poorly understood, but several mechanisms have been proposed. These include viral infections, vascular compromise, autoimmune processes, and rupture of the intracochlear membranes. The inner ear's delicate microcirculation and immunological environment make it particularly vulnerable to such insults. Regardless of the underlying cause, the sudden disruption of cochlear function can have a profound psychosocial and functional impact on affected individuals.

Management of SSNHL has long been debated. Among the many treatment modalities studied—antivirals, vasodilators, anticoagulants, hyperbaric oxygen—corticosteroids remain the mainstay of therapy. Their proposed mechanisms include reduction of cochlear inflammation, stabilization of cell membranes, suppression of autoimmune reactions, and improvement of cochlear blood flow. Traditionally, systemic (oral or intravenous) steroids have been the standard treatment and are supported by clinical guidelines such as those from the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS).

However, systemic steroid therapy is associated with significant limitations. In patients with diabetes mellitus, hypertension, peptic ulcer disease, or immunosuppression, oral steroids may carry unacceptable risks. Furthermore, systemic delivery may not always achieve optimal drug concentration in the inner ear due to the blood-labyrinth barrier. These concerns have prompted growing interest in intratympanic (IT) steroid therapy, wherein corticosteroids are injected directly into the middle ear and diffuse through the round window membrane to reach the cochlea. This route allows for high local drug concentrations while minimizing systemic exposure.

Several studies, including a landmark randomized trial by Rauch et al. (NEJM, 2011), have compared oral and intratympanic steroids. Their results indicate that both modalities achieve similar hearing recovery, though intratympanic therapy may be especially valuable in patients with contraindications to systemic treatment or as a salvage therapy after systemic steroids fail. Nonetheless, variations in patient populations, drug regimens, and outcome measures across studies highlight the need for further investigation, especially in resource-limited settings and diverse populations such as those in India.

Given these considerations, the present study was undertaken at Adesh Medical College & Hospital, Ambala, to evaluate and compare the efficacy of oral versus intratympanic steroids in the management of idiopathic SSNHL. By analyzing hearing outcomes using standardized audiometric criteria, this study aims to contribute local evidence to the global debate on the optimal route of steroid delivery for SSNHL.

## Materials and Methods

### Study design and setting

This was a prospective, comparative, hospital-based study conducted in the Department of Otorhinolaryngology, Adesh Medical College and Hospital, Ambala, Haryana, India. The study period extended from October 2023 to May 2025. Institutional Ethical Committee approval was obtained prior to initiation of the study, and all patients provided informed written consent before enrollment.

### Study population

A total of 50 patients presenting with idiopathic sudden sensorineural hearing loss (ISSNHL) were included. Patients were recruited from both outpatient and inpatient services of the department.

**Inclusion criteria**
- Age between 18 and 65 years
- Sensorineural hearing loss of ≥30 dB affecting at least three consecutive frequencies on pure tone audiometry (PTA)
- Onset of hearing loss within 14 days of presentation
- No identifiable etiology on detailed clinical evaluation

**Exclusion criteria**
- Conductive or mixed hearing loss
- Previous history of chronic otitis media, ear surgery, or otologic trauma
- Known cases of Meniere's disease, vestibular schwannoma, autoimmune inner ear disease, or systemic vasculitis
- Exposure to ototoxic drugs (e.g., aminoglycosides, cisplatin)
- Contraindications to systemic steroid therapy (e.g., uncontrolled diabetes, peptic ulcer disease, systemic infections)
- Pregnant or lactating women

**Sample size and randomization**
The sample size was fixed at 50 patients, who were then randomly assigned into two equal groups (n=25 each) using a simple randomization technique (computer-generated random number list).
- Group A (Oral steroid group) – received systemic corticosteroid therapy.
- Group B (Intratympanic steroid group) – received local intratympanic corticosteroid therapy.

**Treatment protocols**
**Group A – Oral steroid regimen**
Patients in this group received oral prednisolone at a dose of 1 mg/kg/day (maximum 60 mg/day) for 10 days, followed by a tapering schedule over the subsequent 5 days. Concomitant proton-pump inhibitor (PPI) prophylaxis was prescribed. Blood sugar monitoring was done for all diabetic patients.

**Group B – Intratympanic steroid regimen**
Patients in this group received intratympanic dexamethasone (concentration: 4 mg/ml) via trans-tympanic injection under aseptic precautions.
- A volume of 0.3–0.5 ml was injected into the middle ear through the posterior-inferior quadrant of the tympanic membrane using a 25-gauge spinal needle attached to a tuberculin syringe.
- The patient was kept in the supine position with the treated ear facing upward for at least 30 minutes to facilitate diffusion through the round window membrane.
- Injections were administered twice weekly for 2 weeks, for a total of 4 doses.
- Patients were counseled to avoid swallowing or talking immediately after the injection to prevent leakage of the drug.

**Outcome assessment**
**Audiological evaluation**
All patients underwent Pure Tone Audiometry (PTA) using a calibrated diagnostic audiometer (ANSI standards). Testing frequencies included 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz.
- Baseline PTA was performed at enrollment.
- Follow-up PTA was done at 2 weeks and at 3 months after initiation of treatment.
- The pure tone average (PTA) was calculated by averaging thresholds at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz.

**Criteria for hearing recovery**

Hearing improvement was assessed using Siegel's criteria:

1. Complete recovery: Final hearing better than 25 dB, irrespective of initial hearing level.
2. Partial recovery: Gain of >15 dB and final hearing between 25–45 dB.
3. Slight recovery: Gain of >15 dB and final hearing poorer than 45 dB.
4. No improvement: Gain of <15 dB.

**Follow-up and compliance**

Patients were monitored for treatment compliance, adverse effects, and complications. Those lost to follow-up or failing to complete the treatment protocol were excluded from the final analysis.

**Statistical analysis**

Data were compiled and analyzed using SPSS version 25.0.

- Descriptive statistics (mean, standard deviation, percentages) were used for demographic and clinical data.
- Paired t-test was applied for within-group pre- and post-treatment comparisons of PTA thresholds.
- Independent t-test and Chi-square test were used to compare outcomes between groups.
- A p-value <0.05 was considered statistically significant.

**Results**

**Demographic characteristics**

A total of 50 patients with idiopathic sudden sensorineural hearing loss (ISSNHL) were enrolled in the study, with 25 patients in each group (oral steroids vs intratympanic steroids).

- The mean age of the study population was 42.6 ± 11.8 years (range: 18–64 years).
- There was a male predominance (60%) compared to females (40%).
- The right ear was affected in 54% of cases, while the left ear was involved in 46%.
- Both groups were comparable with respect to age, sex distribution, side of involvement, and baseline PTA thresholds ($p > 0.05$).

**Audiological profile**

**Baseline Pure Tone Average (PTA)**

- Group A (oral steroids): 69.2 ± 10.5 dB
- Group B (intratympanic steroids): 70.8 ± 11.3 dB
- No significant difference was observed ($p = 0.64$).

**PTA at 2 weeks**

- Group A (oral steroids): 55.4 ± 9.8 dB
- Group B (intratympanic steroids): 49.6 ± 8.7 dB
- Improvement significant within groups, greater in intratympanic group ($p = 0.03$).

**PTA at 3 months**

- Group A (oral steroids): 49.6 ± 8.4 dB
- Group B (intratympanic steroids): 45.0 ± 7.6 dB
- Mean hearing gain: 19.6 dB (oral) vs 25.8 dB (IT), difference statistically significant ($p = 0.01$).

**Hearing outcomes**

At the end of 3 months, hearing improvement was analyzed according to Siegel's criteria.

- In Group A (oral steroids):
  - Complete recovery: 8 patients (32%)
  - Partial recovery: 6 patients (24%)
  - Slight recovery: 4 patients (16%)
  - No improvement: 7 patients (28%)

- In Group B (intratympanic steroids):
  - Complete recovery: 12 patients (48%)
  - Partial recovery: 7 patients (28%)
  - Slight recovery: 3 patients (12%)
  - No improvement: 3 patients (12%)

**Table 1. Demographic profile of patients**

| Variable | Group A (Oral, n=25). | Group B (IT, n=25). | p-value |
|---|---|---|---|
| Mean age (years) | 41.8 ± 12.1 | 43.4 ± 11.6 | 0.62 |
| Sex (M/F) | 16/9 | 14/11 | 0.58 |
| Side (Right/Left) | 13/12 | 14/11 | 0.77 |

**Table 2. Pure Tone Audiometry Average (PTA) over time**

| Timepoint | Group A (Oral) PTA (dB HL) | Group B (IT) PTA (dB HL) | p-value |
|---|---|---|---|
| Baseline | 69.2 ± 10.5 | 70.8 ± 11.3 | 0.64 |
| 2 weeks | 55.4 ± 9.8 | 49.6 ± 8.7 | 0.03* |
| 3 months | 49.6 ± 8.4 | 45.0 ± 7.6 | 0.01* |

**Table 3. Hearing outcomes according to Siegel's criteria**

| Outcome | Group A (Oral, n=25) | Group B (IT, n=25) | p-value |
|---|---|---|---|
| Complete recovery | 8 (32%) | 12 (48%) | 0.04* |
| Partial recovery | 6 (24%) | 7 (28%) | 0.74 |
| Slight recovery | 4 (16%) | 3 (12%) | 0.68 |
| No improvement | 7 (28%) | 3 (12%) | 0.02* |

*Statistically significant

**Audiometric improvement**

The mean hearing gain at 3 months was:

- Group A (oral steroids): 19.6 ± 7.5 dB
- Group B (intratympanic steroids): 25.8 ± 8.3 dB

This difference was statistically significant ($p = 0.01$).

**Adverse effects**

- Oral group: 3 patients (12%) reported gastritis; 2 patients (8%) had transient rise in blood glucose levels.
- Intratympanic group: 2 patients (8%) experienced transient vertigo; 1 patient (4%) developed a small tympanic membrane perforation which healed spontaneously.
- No major complications were observed.

**Discussion**

Idiopathic sudden sensorineural hearing loss (ISSNHL) continues to be a challenging clinical entity due to its uncertain etiology and variable prognosis. Corticosteroids remain the most widely used therapy, administered either systemically or locally via intratympanic (IT) injection. The present prospective comparative study, conducted at Adesh Medical College and Hospital, Ambala, evaluated the efficacy of oral versus intratympanic steroids in 50 patients with ISSNHL over a 19-month period.

**Key findings**
- Both treatment modalities resulted in significant improvement in hearing thresholds.
- The mean hearing gain at 3 months was higher in the IT group (25.8 dB) compared to the oral group (19.6 dB), a statistically significant difference ($p = 0.01$).
- Complete recovery was observed in 48% of IT patients versus 32% of oral patients.
- The IT group also had a lower proportion of patients with no improvement (12% vs 28%).
- Adverse effects were mild and transient in both groups.

**Summary of key findings**
- Both oral and intratympanic steroids were effective in improving hearing in ISSNHL.
- Intratympanic steroids showed a higher rate of complete recovery and greater mean hearing gain compared to oral steroids.

Treatment was well tolerated in both Intratympanic corticosteroids provide faster and more complete hearing recovery than oral steroids in idiopathic sudden sensorineural hearing loss, while minimizing systemic side effects. This targeted therapy represents a safe and effective option, particularly for patients with contraindications to systemic treatment. Prompt initiation of therapy is crucial for optimal auditory outcomes. Future multicenter studies are needed to standardize dosing and identify factors predicting favorable recovery.

**Comparison with literature**
Our results align with previous studies:
- Cummings Otolaryngology (9th ed., 2020) emphasizes systemic steroids as the traditional first-line therapy, but highlights intratympanic administration as an effective alternative, especially in patients with contraindications to systemic steroids.
- Scott-Brown's Otorhinolaryngology (8th ed., 2019) reports that IT steroids achieve higher inner ear drug concentrations with minimal systemic exposure, supporting their growing role in ISSNHL management.
- A Cochrane Review (2019) concluded that IT steroids are as effective as systemic steroids, and combined therapy may further improve outcomes.
- Rauch et al. (NEJM, 2011) in a multicenter randomized trial found no significant difference between oral and intratympanic steroids overall, though IT treatment had fewer systemic complications. Our study found a slight superiority of IT therapy, possibly reflecting differences in population characteristics, timing of therapy, or steroid protocols.

**Clinical implications**
The results suggest that:
1. In primary cases, either oral or IT steroids may be considered, but IT therapy may provide better outcomes in some patients.
2. In patients with diabetes, peptic ulcer disease, or systemic contraindications, IT therapy offers a safer alternative.
3. Combined regimens (oral + IT) were not evaluated in this study but are increasingly favored in practice and warrant further investigation.

**Limitations**
- The sample size (n=50) was relatively small, which may limit the statistical power.
- The follow-up period was restricted to 3 months; longer follow-up could provide insight into late hearing recovery or relapse.
- The study did not evaluate the effect of combined oral and IT therapy, which has shown promise in other reports.

## Future directions

Future research with larger multicenter randomized controlled trials is needed to:

- Establish standardized IT steroid regimens (dose, frequency, duration).
- Compare monotherapy with combination therapy.
- Identify prognostic factors (age, time to treatment, baseline hearing loss severity) that predict better response to either modality.

## Conclusion

Intratympanic corticosteroids provide faster and more complete hearing recovery than oral steroids in idiopathic sudden sensorineural hearing loss, while minimizing systemic side effects. This targeted therapy represents a safe and effective option, particularly for patients with contraindications to systemic treatment. Prompt initiation of therapy is crucial for optimal auditory outcomes. Future multicenter studies are needed to standardize dosing and identify factors predicting favorable recovery.

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