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## Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden

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## 3 Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis

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### ABSTRACT

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**Background:** Sudden sensorineural hearing loss is a medical emergency characterized by sudden sensorineural hearing loss occurring within 72 hours with a hearing threshold decrease of at least 30 dB across three consecutive frequencies. The incidence ranges from 5–150 cases per 100,000 population annually and is likely underestimated because of underreporting. Systemic corticosteroids are currently considered first-line therapy; however, intratympanic corticosteroids are suggested to improve treatment outcomes.

**Objective:** To determine the effectiveness of combined systemic and intratympanic corticosteroids compared with systemic corticosteroids alone in patients with sudden sensorineural hearing loss based on pure tone average gain and adverse effects.

**Methods:** A systematic review and meta-analysis of randomized controlled trials was conducted using multiple electronic databases. Study quality was assessed using the Cochrane Risk of Bias 2.0 tool and the Scottish Intercollegiate Guidelines Network Methodology Checklist 2.

**Results:** Of 1,321 identified studies, four met the inclusion criteria. Meta-analysis demonstrated a mean difference of 8.10 dB (95% confidence interval: 0.61–15.59) with moderate heterogeneity, indicating significant hearing improvement in the combination therapy group.

**Conclusion:** Combined systemic and intratympanic corticosteroids provided greater hearing improvement with fewer adverse effects compared with systemic corticosteroids alone in patients with sudden sensorineural hearing loss.

### KEYWORDS:

SSNHL, systemic steroids, intratympanic steroids, combination therapy, pure tone average gain

### 1. INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is a medical emergency characterized by sudden sensorineural hearing loss occurring within  $\leq 72$  hours, with a hearing threshold decrease of at least 30 dB across three consecutive frequencies.<sup>1–3</sup> Most cases are unilateral, whereas bilateral cases account for only approximately 2%.<sup>4</sup> The incidence of SSNHL ranges from 5–150 cases per 100,000 population,

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with variations reported in countries such as the United States, Germany, and Japan.<sup>1,3,5,6</sup> The actual incidence may be higher because of under-reporting, delayed diagnosis, and spontaneous recovery.<sup>3,5,6</sup>

The etiology of SSNHL is predominantly idiopathic (approximately 90% of cases), although several causes such as infections, neoplastic disorders, autoimmune diseases, neurological disorders, and ototoxicity have also been identified.<sup>1,7</sup> Risk factors associated with SSNHL include depression, smoking, and alcohol consumption.<sup>2</sup> Common accompanying symptoms include tinnitus, vertigo, and aural fullness.<sup>4</sup> This condition is often diagnosed late because its symptoms may resemble other disorders, such as eustachian tube dysfunction and otitis media, potentially resulting in delayed treatment and reduced likelihood of hearing recovery.<sup>8</sup>

# Maria Jessica et al, Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis

According to the *Clinical Practice Guideline: Sudden Hearing Loss*, corticosteroids are one of the main therapies for SSNHL.<sup>9</sup> SSNHL may be administered systemically or intratympanically.<sup>10</sup> Systemic steroids are commonly used as first-line therapy because of their anti-inflammatory effects, whereas intratympanic steroids provide higher drug concentrations in the inner ear and may serve as an alternative for patients with contraindications to systemic steroid therapy.<sup>6,11,12</sup> In addition, intratympanic steroids may also be used as salvage therapy.<sup>12</sup> Combination therapy with systemic and intratympanic steroids has been reported to provide better hearing improvement compared with systemic steroids alone.<sup>13</sup>

However, studies regarding the effectiveness of SSNHL therapy remain inconsistent. Wen Xie et al. reported that combination therapy with systemic and intratympanic steroids did not provide significant differences in hearing recovery, whereas Al et al. demonstrated that intratympanic steroids were more effective than oral prednisone therapy.<sup>13,14</sup> Several studies and meta-analyses have also reported conflicting results regarding the superiority of combination therapy over systemic steroids alone.<sup>15</sup> Therefore, further research is needed to compare the effectiveness of combined intratympanic and systemic steroids in the management of SSNHL.

## II. MATERIAL AND METHODS

### Data Collection

Data collection was conducted through a literature search for Randomized Controlled Trial (RCT) studies based on the PICO framework presented in **Table 1**.

### Inclusion and Exclusion Criteria

The inclusion criteria were: (1) Randomized Controlled Trial (RCT) studies, (2) subjects diagnosed with sudden sensorineural hearing loss (SSNHL), (3) studies comparing systemic steroids with combined systemic and intratympanic steroids, (4) studies reporting Pure Tone Average (PTA), (5) studies published between 2022 and 2026, and (6) studies published in English.

The exclusion criteria were: (1) duplicate articles, (2) studies not relevant to the PICO framework, (3) review articles, (4) irrelevant studies, and (5) articles without full-text access.

### Search Strategy

The literature search was conducted online through ScienceDirect, Springer, Google Scholar, PubMed Central, PubMed, BMC, CORE, and ResearchGate. The keywords used in the search included “sudden sensorineural hearing loss” OR “SSNHL” OR “sudden deafness”, “intratympanic steroid” OR “intratympanic corticosteroid” OR “local steroid injection”, “systemic steroid” OR “oral steroid” OR “combination therapy”, and “hearing recovery” OR “hearing improvement” OR “pure tone average gain”.

**Table 1. PICO Framework of the Study**

<b>Population</b>	Patients with sudden sensorineural hearing loss.
<b>Intervention</b>	Systemic corticosteroid therapy.
<b>Comparison</b>	Combined intratympanic and systemic corticosteroid therapy.
<b>Outcome</b>	Pure Tone Average (PTA) gain

### Review Quality Assessment

Study quality assessment was performed using the Cochrane Risk of Bias 2.0 tool and the SIGN Methodology Checklist 2.

### Data Analysis

Data analysis was performed using Review Manager (RevMan) 5.4. Continuous data were analyzed using Mean Difference (MD) and 95% Confidence Interval (CI). Heterogeneity was assessed using the Chi<sup>2</sup> test and I<sup>2</sup> statistic, with either a fixed-effect model or random-effects model applied according to the heterogeneity results. A p-value <0.05 was considered statistically significant, and the results were presented in a forest plot.

## III. RESULTS

### PRISMA Flow Diagram of Study Selection

This systematic review and meta-analysis was conducted based on the PRISMA guidelines. Literature searches through ScienceDirect, Springer, Google Scholar, PubMed Central, PubMed, BMC, CORE, and ResearchGate identified 1,321 studies. After the screening process, 997 studies were excluded because of duplication, non-compliance with the PICO framework, and non-English language, leaving 324 studies for further review. During the full-text review stage, 310 studies were excluded because they were review articles or irrelevant to the study objectives. Among the remaining 14 studies, 10 articles were excluded because full-text access was unavailable. A total of four studies ultimately met the inclusion criteria and were included in this study. The study selection process is presented in **Figure 1**.

### Study Quality Assessment

Study quality assessment using the Cochrane Risk of Bias 2.0 tool showed that three studies were categorized as having some concerns and one study as low risk. Based on the SIGN (Scottish Intercollegiate Guidelines Network) Methodology Checklist 2, all studies were rated as acceptable (+). The quality assessment results are presented in **Figure 2**.

### Study Characteristics

Most studies were conducted in India and Hungary, with patient ages ranging from 23–67 years and hearing loss severity varying from mild to profound. In general, patients receiving combined systemic and intratympanic steroids demonstrated greater hearing improvement (PTA gain) compared with those receiving systemic steroids alone. Follow-up duration

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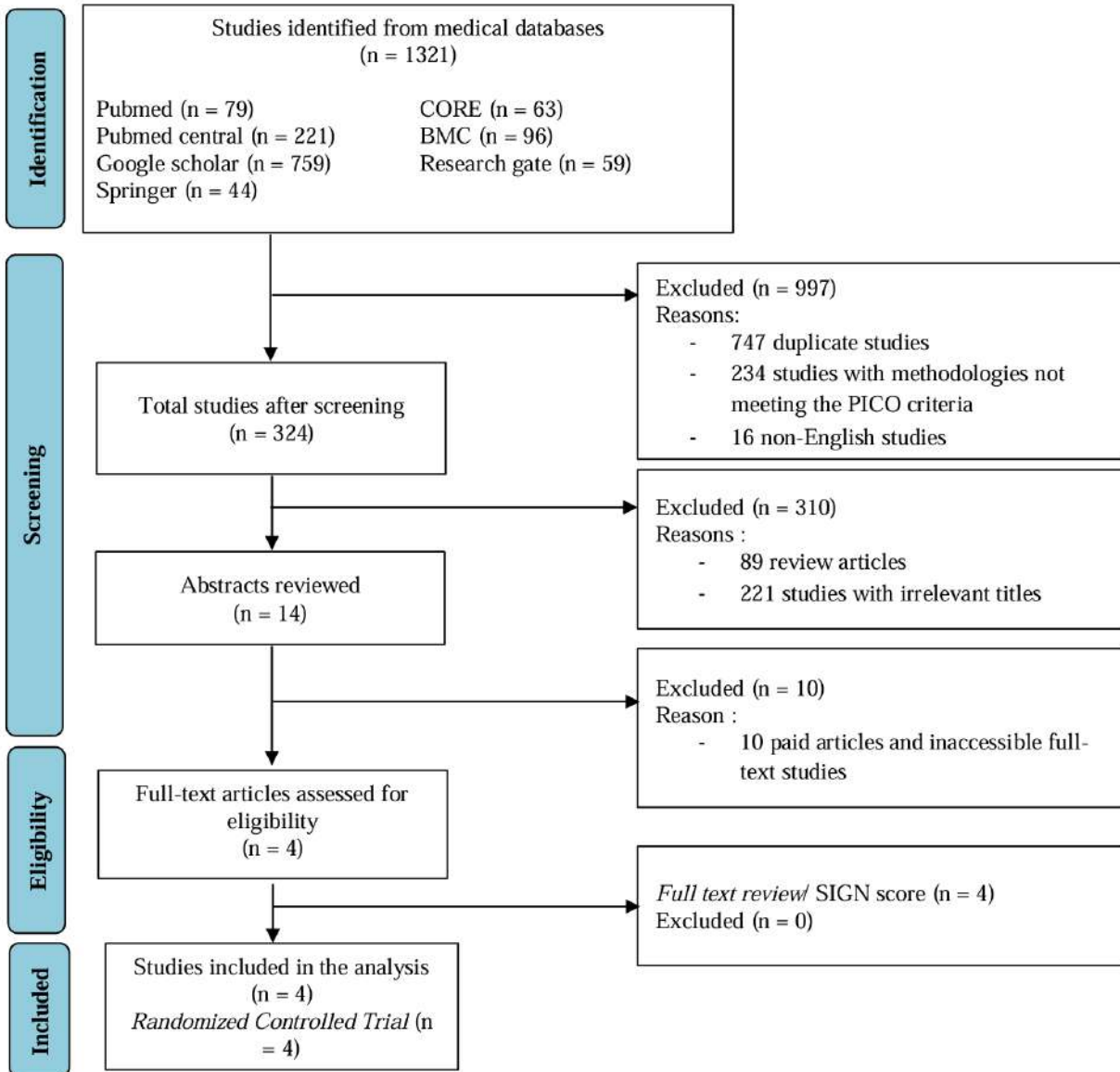
ranged from several days to 6 months. The study characteristics are presented in Table 2.

**Meta-Analysis Results of PTA Gain in Patients with SSNHL**

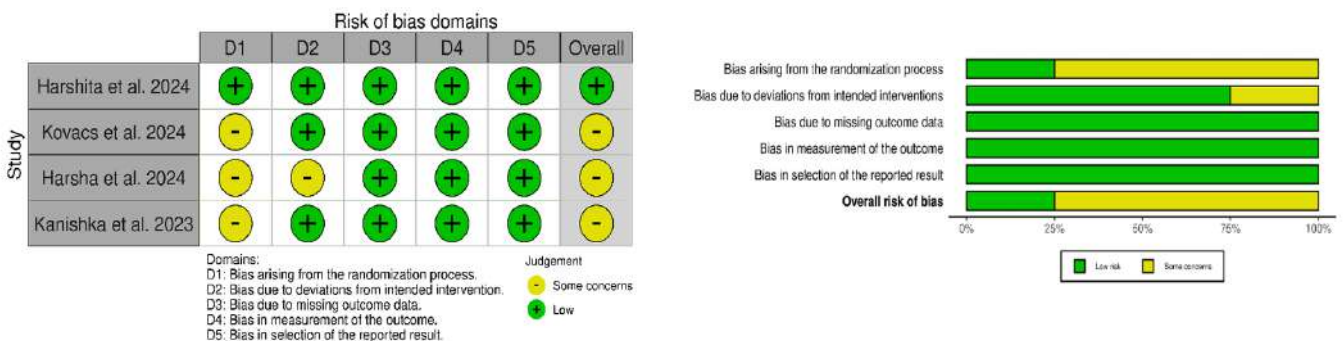
Meta-analysis of four studies demonstrated that combined intratympanic and systemic steroids provided greater hearing

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threshold improvement compared with systemic steroids alone, with a mean difference (MD) of 8.10 dB (95% CI:0.61–15.59; p=0.03). Moderate heterogeneity was observed among the studies (I<sup>2</sup>=58%; p=0.07). Overall, the forest plot demonstrated an effect direction favoring combination therapy. The meta-analysis results are presented in Figure 3.



**Figure 1. PRISMA Flow Diagram**



**Figure 2. Quality Assessment based on Cochrane Risk of Bias 2.0**

**Maria Jessica et al, Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis**
**Table 1. Study Characteristics**

Study	Country	SIGN	Age	Characteristic Sample	Intervention	Main Outcome	Follow-up
Harshita et al. 2024 <sup>18, 28</sup>	Bangalore, India	Acceptable (+)	SS group: 39.4 ± 10	SS group: Mild to profound hearing loss	SS group : Standard therapy with systemic steroids and intratympanic injection of 0.5 mL normal saline solution (placebo)	Mean Pure Tone Average (PTA) gain: - SS group: 19.8 ± 21.5 - CT group: 34.8 ± 14.2	Pure Tone Average (PTA) was reassessed on day 5, day 10, day 15, and 1 month after therapy
			CT group: 41.8 ± 10.8	CT group: Mild to profound hearing loss	CT group : Standard therapy with combined systemic steroids and intratympanic injection of 0.5 mL dexamethasone (4 mg/mL)	Mean PTA after 1 month improved: - SS group: 46.3 ± 14.2 - CT group: 29.5 ± 13.0	
Harsha et al. 2024 <sup>16</sup>	India	Acceptable (+)	SS group : 26.62	Mild - profound	SS group: Oral methylprednisolone at 4 mg/kg administered three times daily with a tapering dose over 4 weeks.	Mean hearing improvement (dB) after therapy: - ITS group: 13.96 ± 12.57 (23.33 dB) - CT group: 24.98 ± 10.76 (27.07 dB) - SS group: 12.95 ± 7.45 (15.51 dB)	-
			CT group: 29.77		CT group: Intratympanic dexamethasone (4 mg/mL, 0.2–0.3 mL weekly for 4 weeks) combined with oral methylprednisolone 4 mg/kg three times daily with tapering over 4 weeks.		
			ITS group : 37.69		ITS group: Intratympanic dexamethasone (4 mg/mL, 0.2–0.3 mL weekly for 4 weeks).		

**Abbreviations:** SS : systemic steroid; CT : combination therapy; ITS : intratympanic steroid

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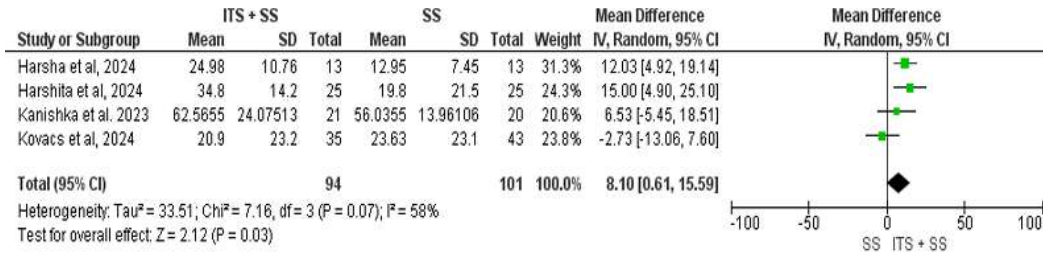
**Table 1. Study Characteristics (continued)**

Study	Country	SIGN	Age	Characteristic Sample	Intervention	Main Outcome	Follow-up
Kovacs <i>et al.</i> 2024 <sup>17</sup>	Hungaria	Acceptable (+)	CT group : 52.3	Mild to moderate, and severe to profound	CT group: Patients receiving standard therapy plus intratympanic dexamethasone (8 mg/mL) for 5 days.	Comparison of PTA change (PTA gain): - CT group: 20.9 dB (SD = 23.2; MR 37.89) - SS group: 23.63 dB (SD = 23.1; MR 40.81)	At day 3 and day 5, and during follow-up at 1, 3, and 6 months after treatment
			SS group : 54.3		SS (control) group: Patients received systemic steroids with intravenous methylprednisolone sodium succinate (250 mg for 3 days, followed by 125 mg for 2 days), then tapered oral methylprednisolone to 8 mg		
Kanishka <i>et al.</i> 2023 <sup>19</sup>	India	Acceptable (+)	Mean age: 41.97 years (range 23–67)	-	CT group: 21 patients received intratympanic dexamethasone (0.5 mL on days 1, 3, and 7) combined with oral prednisolone (1 mg/kg, max 60 mg/day) for 10 days, followed by tapering by 10 mg every 3 days.	CT group: - Mean PTA before treatment: 81.79 dB (85 ± 12.7) - Mean PTA after treatment: 32.62 dB (25.6 ± 11.3) - Mean hearing improvement: 62.56 ± 24.07 dB (SE 5.38)	Post-treatment PTA, SDS, and SRT assessments were performed 1 month after completion of treatment
					SS group: 20 patients received oral prednisolone 1 mg/kg/day for 10 days, followed by tapering by 10 mg every 3 days		

**Abbreviations:** SS : systemic steroid; CT : combination therapy; ITS : intratympanic steroid

12

**Maria Jessica et al, Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis**



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**Figure 3. Meta-Analysis Results of PTA Gain in Patients with Sudden Sensorineural Hearing Loss (SSNHL)**

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**IV. DISCUSSION**

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Most studies included in this review were comparative studies from India and Hungary evaluating the effectiveness of systemic steroids (SS), intratympanic steroids (ITS), and combination therapy (CT) in patients with mild to profound Sudden Sensorineural Hearing Loss. Participants were predominantly adults aged 23–67 years with symptom onset ≤2 weeks and hearing loss ≥30 dB across three consecutive frequencies. Interventions included oral or intravenous steroids, intratympanic injections, or combined regimens with varying doses and protocols. The primary outcome was hearing improvement measured by pure tone average (PTA) gain. All treatment groups demonstrated hearing improvement, with combination therapy generally showing greater PTA gain, although statistical significance was not consistently achieved. Follow-up duration ranged from several days to 6 months, with primary assessment commonly performed at 1 month post-treatment.

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random-effects model was applied due to substantial heterogeneity (I<sup>2</sup> ≥ 50%). Although the Chi-square test showed no statistically significant heterogeneity (Chi<sup>2</sup> = 7.16; p = 0.07), the Cochrane recommends prioritizing I<sup>2</sup>, as it better reflects the proportion of variability attributable to inter-study heterogeneity.<sup>20</sup> The study by Kovacs et al. showed findings that differed from most included studies. PTA4 improvement was slightly higher in the systemic steroid (SS) group than in the combination therapy (CT) group (23.63 dB vs. 20.9 dB). This discrepancy may be related to the unequal number of participants between groups, resulting in non-significant outcomes.

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**Hearing Loss by Goodman**

To facilitate interpretation of hearing loss severity, the degree of hearing loss in this review was described using the Goodman classification, with most included patients ranging from mild to profound hearing loss. Mild hearing loss (26–40 dB HL) indicates difficulty hearing soft sounds, whereas moderate hearing loss (41–55 dB HL) may interfere with understanding normal conversation. Moderately severe (56–70 dB HL) and severe hearing loss (71–90 dB HL) reflect progressively greater impairment in hearing speech

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and environmental sounds. Profound hearing loss (>90 dB HL) represents near-complete hearing dysfunction, in which patients may only perceive very loud sounds. The inclusion of patients with mild to profound hearing loss demonstrates that the studies evaluated SSNHL across a broad spectrum of disease severity, ranging from relatively limited auditory impairment to severe functional hearing disability.<sup>21</sup>

**Hearing Recovery by Modified Siegel Criteria**

According to Siegel’s criteria, hearing recovery is classified into complete, partial, slight, and no recovery based on post-treatment hearing threshold and degree of hearing improvement.<sup>22</sup> In the study by Harsha et al., mean hearing improvement was greater in the combination therapy group than in the systemic steroid group (27.07 dB vs. 15.51 dB), indicating slight-to-partial recovery. Kovacs et al. reported complete recovery in 17.1% and 16.2% of patients, partial recovery in 22.8% and 16.2%, slight improvement in 5.7% and 16.2%, and no improvement in 28.8% and 41.8% of patients in each group, respectively, with no significant difference between groups (p = 0.524). In the study by Kanishka et al., complete recovery was achieved in 76.1% of patients receiving combination therapy compared with 45% in the oral steroid group, while partial recovery occurred in 14.4% and 40% of patients, respectively. Overall, most patients achieved partial to complete recovery, particularly in the combination therapy groups.

**Adverse Effect**

According to Achanta et al., adverse effects varied according to the route of steroid administration. Systemic steroids were associated with hyperglycemia, hypertension, gastrointestinal disturbances, and sleep or mood disorders, with sleep disturbances reported in up to 44.6% of patients. Intratympanic steroid (ITS) therapy mainly caused local adverse effects, including otalgia (6.1–54.3%), dizziness (5.5–27.1%), and occasional tympanic membrane perforation.<sup>23</sup>

In the combination therapy group, both systemic and local adverse effects were observed. Sleep disturbances and gastrointestinal complaints occurred in 73.1% and 48.1% of patients, respectively, while otalgia and dizziness were reported in 3.8–13.5% and 8.1–28.3% of patients.<sup>23</sup> These findings were supported by Harshita et al. and Kovács et al.,

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## Maria Jessica et al, Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis

who also reported local complications related to ITS procedures.

### Guidelines

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According to the American Academy of Otolaryngology–Head and Neck Surgery guideline, management of Sudden Sensorineural Hearing Loss includes confirmation of diagnosis with audiometry and exclusion of other causes, such as retrocochlear disorders. Corticosteroids are recommended as first-line therapy within 2 weeks of symptom onset, while intratympanic steroids may be considered as salvage therapy in patients with incomplete recovery. Other therapies, including antivirals, vasodilators, and thrombolytics, are not routinely recommended because of limited evidence of benefit.<sup>9</sup>

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### Strengths and limitations of the included studies

The study by Harsha et al. demonstrated better hearing improvement with combination therapy, particularly in severe hearing loss, and also evaluated prognostic factors such as hearing loss severity and affected frequencies. However, evidence supporting systemic steroids as monotherapy remained limited, and potential sources of bias were not clearly addressed.

Harshita et al. conducted a prospective randomized study comparing three treatment modalities, providing comprehensive clinical data. Nevertheless, the study was limited by a small sample size, short follow-up duration, and outcome assessment based solely on audiometry.

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The study by Kovács et al. used multiple recovery criteria, including Siegel, Kanzaki, and modified Siegel classifications, with a randomized controlled design comparing systemic and combination therapies. Its limitations included small and unequal sample sizes, imbalance in baseline characteristics, incomplete follow-up, lack of placebo control, and reliance solely on pure tone audiometry outcomes.

Kanishka et al. reported better hearing recovery and higher rates of normal hearing in the combination therapy group.

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However, the differences were not statistically significant, likely due to the limited sample size.

### V. CONCLUSION AND RECOMMENDATION

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In conclusion, the addition of intratympanic steroids to systemic steroid therapy demonstrated statistically significant superior hearing improvement compared with systemic steroids alone in patients with Sudden Sensorineural Hearing Loss. Based on the Modified Siegel criteria, combination therapy was associated with better hearing recovery outcomes. Furthermore, combination therapy showed a more favorable adverse effect profile than systemic steroid therapy alone, suggesting that it may be an effective and relatively safe treatment option for SSNHL.

Further studies with more homogeneous designs and standardized outcome assessments, such as uniform pure tone average (PTA) measurements or consistent clinical recovery criteria, are needed to improve comparability and strengthen future meta-analyses. Increased public awareness regarding the early symptoms of Sudden Sensorineural Hearing Loss is also important, as prompt medical evaluation and treatment within the first 72 hours may improve hearing recovery outcomes. In addition, academic institutions should continue to support evidence-based research and methodological training related to SSNHL management, particularly regarding the role of intratympanic steroids as adjunctive therapy.

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# Maria Jessica et al, Effectiveness of Intratympanic Steroids as Adjunctive Therapy in Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-Analysis

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