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ORIGINAL RESEARCH

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Comparison between intratympanic injection of dexamethasone and methylprednisolone in idiopathic sudden sensorineural hearing loss: A randomized clinical trial

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Abstract

Objective: To compare the hearing outcomes of patients with idiopathic sudden sensorineural hearing loss after intratympanic (IT) injection of methylprednisolone and dexamethasone.

Study design: Randomized case-controlled clinical trial.

Methods: Seventy-five patients diagnosed with idiopathic sensorineural hearing loss were randomly divided into two groups based on therapy. Both groups received oral prednisolone (10 mg/kg; maximum of 60 mg) for 10 days without tapering and received IT injections two times a week for 2 weeks (four injections in total). One group received an IT injection of a 40 mg/mL solution of methylprednisolone, and the other one, 4 mg/mL dexamethasone. Three comparisons between the initial and third-month hearing tests were made to assess the degree of hearing change: (1) pure tone improvement in each individual tone (0.5, 1, 2, 3, and 4 kHz); (2) word-recognition score improvement; and (3) complete, partial, and no recovery of hearing calculated (as defined by American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guidelines).

Results: The study was completed with 69 of the 75 patients—34 in the methylprednisolone group and 35 in the dexamethasone group. The groups' differences in

Clinical trial number: IR.SBMU.RETECH.REC.1401.412.

frequency-specific hearing improvement were not statistically significant. There was no statistically significant difference in the word recognition score improvement between the two groups. Additionally, there was no discernible difference between the two groups' hearing recovery rates.

Conclusion: Methylprednisolone and dexamethasone IT injection therapy had similar hearing outcomes.

Level of evidence: 2.

KEYWORDS
dexamethasone, intratympanic injection, methylprednisolone, randomized controlled trial, steroid, sudden sensorineural hearing loss

1 | INTRODUCTION

A sensorineural hearing loss of 30 dB or more encompassing at least three contiguous audiometric frequencies that occurs in less than 3 days is referred to as sudden sensorineural hearing loss (SSNHL).[1] The reported annual incidence of SSNHL is 5–30 per 100,000 population.[2] Idiopathic sudden sensorineural hearing loss (ISSNHL) is defined as sudden sensorineural hearing loss with no identifiable cause despite adequate investigation.[3]

Three theories have been put forth to explain the pathophysiology of ISSNHL: viral cochleitis, vascular occlusion, and membrane breaks.[4] A review article indicates that acquired cardiovascular risk factors like heavy smoking and heavy alcohol consumption and also some inherited cardiovascular risk factors appeared to be associated with an increased risk of developing SSNHL.[5]

Several therapy regimens have been used to treat ISSNHL. The most used management options are observation, oral, intratympanic (IT), or a combination of oral/IT steroids and hyperbaric oxygen therapy.[6] Some studies have shown the significant effect of IT injection of corticosteroids for treating ISSNHL. The two most used glucocorticoids for IT injection therapy of ISSNHL are methylprednisolone and dexamethasone.[3,7]

In a systematic review, Plontke et al.[8] showed that studies differ in the dose of IT injection; most use a brief series of three to four injections spaced out over 7–14 days. The concentration of corticosteroids utilized in the randomized controlled trials typically ranged from 4 to 5 mg/mL for dexamethasone and mainly 40 mg/mL for methylprednisolone.[9]

Upon reviewing the literature, it appears that there is not enough research to compare IT methylprednisolone and dexamethasone therapy for ISSNHL. The purpose of this prospective, randomized study is to determine whether methylprednisolone or dexamethasone IT therapy is a superior treatment for ISSNHL patients.

2 | MATERIALS AND METHODS

2.1 | Setting

From 2022 to 2024, a prospective randomized controlled trial was conducted in three university-based tertiary care hospitals to examine the impact of IT therapy using methylprednisolone and dexamethasone on ISSNHL. Before starting the study, approval from the institutional review board (IRB code: IR.SBMU.RETECH.REC.1401.412) was secured. All participants provided informed consent and the research was done according to the Declaration of Helsinki ethical principles.

2.2 | Participants

Patients with ISSNHL were enrolled in this study. Patients were defined as those who experienced 30 dB or more idiopathic sensorineural hearing loss within 3 days or less, encompassing at least three contiguous audiometric frequencies. A thorough history and physical examination, audiological and vestibular tests, contrast-enhanced magnetic resonance imaging of the temporal bone and cerebellopontine angle were performed to rule out known causes of hearing loss. Table 1 displays the inclusion and exclusion criteria. Patients who chose not to participate and those who did not match the inclusion criteria were excluded from the study. Patients were randomly assigned to one of two groups (the methylprednisolone group and the dexamethasone group after providing informed written consent).

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria
1. Sensorineural hearing loss of 30 dB or more covering at least three contiguous audiometric frequencies, which occur within 3 days or fewer
2. No identifiable cause despite adequate investigation
3. Normal or near-normal hearing in the contralateral ear
4. Age between 18 and 60 years
5. No more than 10 days from the onset of disease
6. No history of previous treatment
7. No contraindication for the proposed therapy
8. Previous disease or surgery in the affected ear
Exclusion criteria
1. Any identified etiology during therapy
2. Pregnant or lactating women

2.3 | Randomization

The statistical program Stata 10.0 (Stata Corp., College Station, TX) was used to create the randomization sequence, which was stratified with a 1:1 allocation using random block sizes of 2, 4, and 6 in the center's research department, regardless of the participating researchers.

2.4 | Treatment groups

Both groups received oral prednisolone (10 mg/kg; maximum of 60 mg) for 10 days without tapering. Both groups received IT injections two times a week for 2 weeks (four injections in total). The methylprednisolone group was administered an IT injection of a 40 mg/mL solution. The dexamethasone group was given 4 mg/mL of injection.

2.5 | Outcomes

Word recognition score (WRS) and pure-tone audiogram were conducted prior to the treatment, and follow-ups were conducted in the second and third months (final outcome) thereafter. As the average of the thresholds at 0.5, 1, 2, and 3 kHz, the pure-tone average (PTA) was determined. PTA was used to determine the disease's severity. Mild hearing loss was defined as 40 dB or less, moderate hearing loss as 41–70 dB, severe hearing loss as 71–90 dB, and profound hearing loss as 91 dB or more. All measurements were done blinded and the performer was unaware of patient's treatment regimen.

Improvement in hearing was the main result, and it was compared in three ways between the two groups:

1. Pure tone improvement at 0.5, 1, 2, 3, and 4 kHz for each individual tone.
2. Improvements to WRS.
3. Based on comparisons between the two groups' initial and third-month hearing tests, there was full, partial, and no recovery of hearing. These were computed (Table 2) in accordance with the most recent AAOHNS clinical practice guideline.[3]

The audiologist and the author, who examined the treatment outcomes, were unaware of the treatment modality and the patient's group assignment.

2.6 | Statistics

Using the available research data from previous studies (Sung et al.[10] PTA improvement for IT injection of dexamethasone:32.79 ± 21.42 and Tong et al.[11] PTA improvement for IT injection of methylprednisolone), the sample size for each group was estimated to be 56 patients to be statistically significant at the 0.05 confidence level with 80% power. This would require 63 patients per group, or 126 patients in total, assuming more than a 10% dropout rate. We planned a 2 year recruitment period. For sample size estimation G*Power version 3.1.9.6 (Erdfelder, Faul, & Buchner) was used.[12] The software used for statistical analysis was SPSS 27.0 (SPSS Inc., Chicago, IL). At the confidence level of $p < .05$, significance was established, and standard deviations were provided as needed. GraphPad Prism 9.0 (GraphPad Software Inc., La Jolla, CA, USA) was used for making the figures.

TABLE 2 Hearing recovery classification.

1. Complete recovery: Return to within 10 dB HL of the unaffected ear and recovery of word recognition scores to within 5%–10% of the unaffected ear.
2. Partial recovery: Should be defined in two ways based on whether or not the degree of initial hearing loss after the event of SSNHL rendered the ear non-serviceable (based on the AAO–HNSF definition).
(a) For ears that were rendered non-serviceable by the episode of SSNHL, return to the serviceable hearing should be considered a significant improvement (partial recovery) and recovery to less than serviceable levels as "no recovery."
(b) For ears with SSNHL to hearing levels that are still in the serviceable range, a more than 10-dB HL improvement in pure-tone thresholds or an improvement in WRS of ≥10% should be considered partial recovery.
3. No recovery: Anything less than a 10-dB HL improvement should be classified as no recovery.

Note: Non-serviceable hearing: 50% speech discrimination score and 50 dB on pure tone average.
Abbreviations: AAO-HNSF, American Academy of Otolaryngology—Head and Neck Surgery Foundation; HL, hearing loss; SSNHL, sudden sensorineural hearing loss; WRS, word recognition scores.

3 | RESULTS

After recruitment time, we did not achieve the 126-patient recruitment goal. Ninety six patients were assessed for eligibility to enter the trial out of which 21 were excluded and 75 fulfilled all criteria and entered the study. Seventy five patients underwent randomization, with 37 assigned to the methylprednisolone group and 38 to the dexamethasone group. Six patients were lost to follow-up. In the end, there were 34 patients in the methylprednisolone group and 35 in the dexamethasone group who satisfied the inclusion and exclusion criteria, were monitored for at least 3 months following treatment, and were enrolled in statistical analysis (Figure 1: CONSORT diagram).

Table 3 summarizes the patient demographics and baseline audiologic data and demonstrates that the two groups were well-matched and did not differ significantly. Table 4 presents a comparison of the two groups' three-month hearing improvement following treatment. The two groups' hearing threshold improvements at

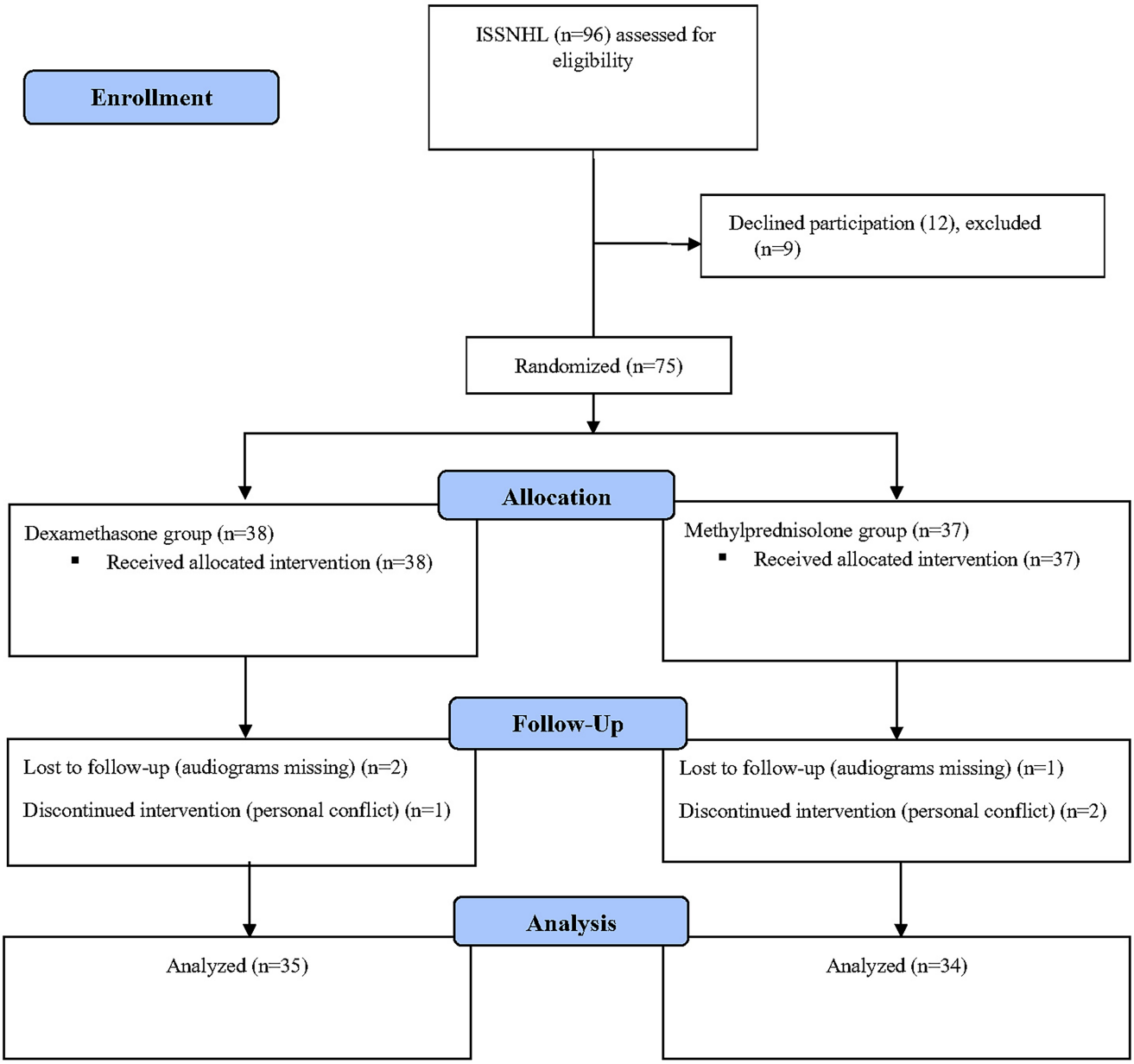

FIGURE 1 CONSORT diagram. ISSNHL, idiopathic sudden sensorineural hearing loss.

500, 1000, 2000, 3000, and 4000 Hz were comparable. Additionally, there was no statistically significant difference between the two groups' PTA and WRS improvements.

Figure 2 compares the two groups' 3-month post-treatment rates of hearing recovery. There were no significant differences in the hearing recovery rates between the two groups.

Each group's patients were also divided into patients with initial profound hearing loss and patients with initial hearing better than profound. A comparison of the hearing recovery rates in these customized groups (Figure 3) also revealed a statistically insignificant difference.

No serious problems or adverse effects were noted in any group.

4 | DISCUSSION

In this prospective, randomized study, we found that IT dexamethasone or methylprednisolone added to oral prednisolone has the same effect on hearing outcomes of patients with ISSNHL.

As its name implies, the etiology of idiopathic sudden sensorineural hearing loss is unknown. This seems to be the main reason why its treatment is still a matter of debate. Corticosteroids are the most popular treatment option, although their efficacy remains unclear.[3,8] Steroids can be administered systematically (orally or intravenously) and/or through IT injections.

Whether systemic steroids or IT corticosteroids are used alone or in combination is also a matter of wide controversy. Some clinicians

TABLE 3 Demographics and baseline audiologic features of patients in the two groups.

	Methylprednisolone group ($n = 34$)	Dexamethasone group ($n = 35$)	p value
Mean age (years)	43.11 ± 14.35	48.86 ± 15.56	.53
Sex—male:female, *n*	18:16	20:15	.12
Vertigo	8 (23.5%)	6 (17.1%)	.4
Tinnitus	19 (55.9%)	16 (45.7%)	.6
Days from onset to treatment	4.81 ± 3.13	4.31 ± 2.55	.42
Severity of hearing loss, *n*			
Mild	1 (2.9%)	1 (2.9%)	.98
Moderate	7 (20.6%)	6 (17.1%)	
Severe	16 (47.1%)	17 (48.6%)	
Profound	10 (29.4%)	11 (31.4%)	
Hearing level in each frequency (dB)			
0.5 kHz	76.47 ± 23.37	79.86 ± 20.99	.43
1 kHz	85 ± 18.59	85 ± 21.28	.68
2 kHz	81.91 ± 22.33	82.71 ± 22.70	.967
3 kHz	82.79 ± 23.167	82.29 ± 22.92	.89
4 kHz	82.94 ± 24.47	82 ± 23.40	.81
PTA (dB)	81.54 ± 20.48	82.32 ± 41.46	1
WRS (%)	33.59 ± 41.46	26.71 ± 39.10	.184

Abbreviations: PTA, pure-tone average: average of the thresholds at 0.5, 1, 2, and 3 kHz; WRS, word recognition score.

TABLE 4 Hearing improvement 3 months after treatment in the two groups.

	Methylprednisolone group ($n = 34$) Mean (SD)	Dexamethasone group ($n = 35$) Mean (SD)	p value
Hearing improvement at each frequency (dB)			
0.5 kHz	33.38 ± 30.29	23.71 ± 29.24	.749
1 kHz	38.97 ± 30.30	25.29 ± 29.71	.736
2 kHz	33.68 ± 30.18	22 ± 26.85	.472
3 kHz	33.38 ± 28.49	18.71 ± 26.07	.480
4 kHz	31.47 ± 29.58	17.71 ± 26.19	.303
PTA improvement (dB)	35.34 ± 29.17	23.53 ± 27.58	.718
WRS improvement (%)	41 ± 42.61	33.49 ± 39.91	.228

Abbreviations: PTA, pure-tone average: average of the thresholds at 0.5, 1, 2, and 3 kHz; SD, standard deviation; WRS, word recognition score.

use IT corticosteroids alone or in conjunction with systemic corticosteroids at the onset of treatment. In contrast, others reserve IT injections as salvage therapy for patients who do not achieve satisfactory results from initial systemic therapy.

Kanotra et al., in prospective research, demonstrated that using IT corticosteroid alone is not superior to systemic administration.[9] Sialakis et al.,[13] in a systematic review and meta-analysis and Lai et al.,[14] in a meta-analysis, reached the same conclusion. On the other hand, in a prospective study, Tong et al. showed that IT injection of methylprednisolone yields better efficacy than systemic administration of methylprednisolone.[15] Similarly, in a retrospective study, Jiang et al. reported the same outcome.[16]

Some studies demonstrate that adding IT corticosteroid to systemic corticosteroid therapy yields better results than using either treatment alone.[13,17] However, Aliyeva et al.[18] found that this combination did not offer additional benefits compared to systemic corticosteroids alone in treating severe and profound SSNHL.

It appears that the two most commonly used corticosteroids for IT injection in ISSNHL are dexamethasone and methylprednisolone.[3,8,14] Protocol and dosages of IT injections vary widely in the literature. Some centers use a dexamethasone solution of 4 mg/mL[9,17,19,20] while others opt for 5 mg/mL.[10,16] Some centers use a solution of 40 mg/mL methylprednisolone[11,16,21] and some 20 mg/mL.[19] The intervals for IT injections also differ significantly between studies: some administer daily injections,[18] others every other day,[11] twice weekly[9] or weekly,[16] with the total number of injections ranging from three to six.

The impact of IT injection interval on therapeutic benefit remains a subject of debate. A study in Korea found a statistically significant difference in the complete hearing recovery rates and audiometric

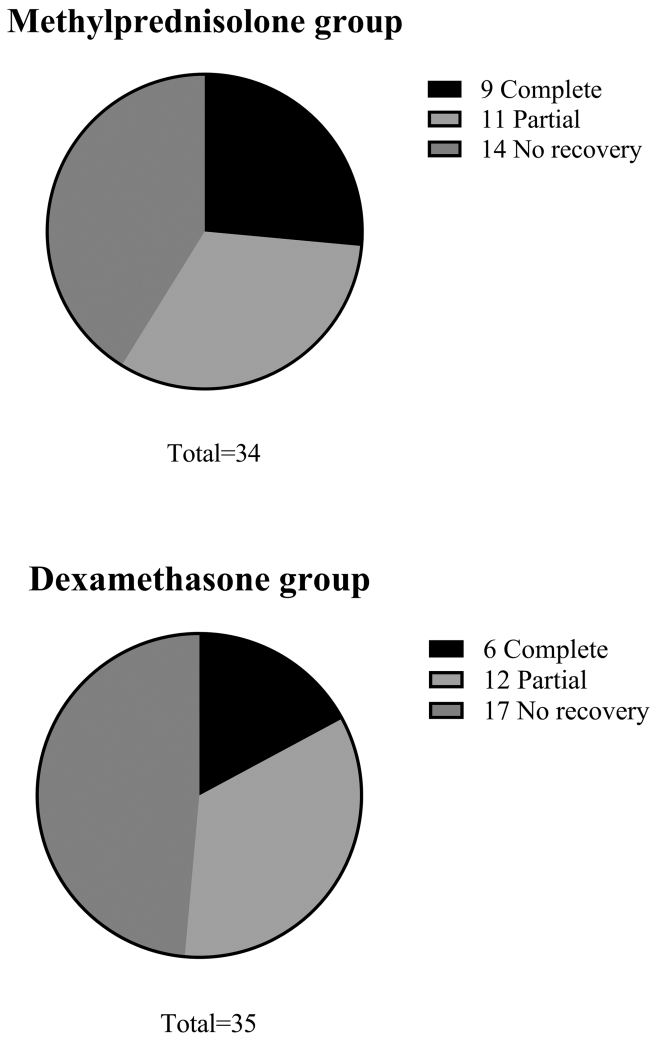

FIGURE 2 Recovery (defined in Table 2) results of patients in the two groups. *p* value for comparing the dexamethasone and methylprednisolone groups' recovery (Chi-square test) = .63.

results (PTA) between a group receiving daily dexamethasone injections and another group with a 4-day interval between injections.[15] Conversely, another study in Korea by Sung et al. found no significant differences in hearing outcomes or recovery rates with dexamethasone administered daily or at 2–3 day intervals.[10]

As discussed earlier, there is no consensus on the optimal treatment protocol. Some studies have favored IT corticosteroids over systemic administration,[15,16] others have found no significant difference between the two approaches,[9,13,14] while some suggest that combining IT corticosteroids with oral treatment provides additional benefit.[13,17]

In light of these findings, we adopted a combined therapy approach in our prospective study to maximize potential treatment benefits for our patients. All patients received oral corticosteroids, with one group additionally receiving IT methylprednisolone and the other IT dexamethasone. It is important to note, however, that the concurrent use of oral corticosteroids may influence the outcomes we aim to attribute to IT corticosteroids.

Tarkan et al.,[19] in a retrospective research without using systemic steroids, compared IT methylprednisolone and dexamethasone and found no superiorities between the two. In contrast to their study and ours, Jiang et al.[16] in a retrospective study showed that IT methylprednisolone resulted in a better hearing improvement than IT dexamethasone. Our protocol involved IT injections twice a week for two weeks (four injections total) using a 40 mg/mL solution of methylprednisolone or a 4 mg/mL solution of dexamethasone. Tarkan et al.[19] used 20 mg/mL methylprednisolone or 4 mg/mL dexamethasone for 5 consecutive days for each group, while Jiang et al.[16] used 5 mg/mL dexamethasone or 40 mg/mL methylprednisolone three times, 1 day apart. The varying dosages, frequencies, and intervals in these studies may contribute to the differing results in these three studies and highlight the need for more similar protocols for comparison.

The present controlled study aimed to compare hearing outcomes in ISSNHL patients treated with IT dexamethasone and methylprednisolone.

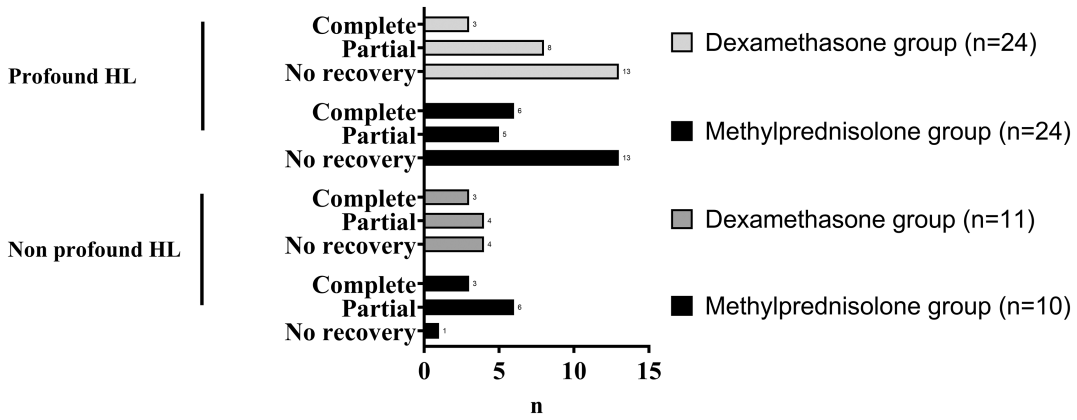

FIGURE 3 Recovery results of patients with and without Initial profound hearing loss. *p* value for comparing methylprednisolone and dexamethasone groups' recovery in profound HL = 0.34 and for non-profound HL = 0.43. HL, hearing loss.

As shown in Table 3, there was no significant difference between the two groups before treatment, indicating they were well-matched. Table 4 and Figure 2 suggest that neither drug—at least with our studied protocol—has a superior therapeutic effect. Additionally, no complications or adverse effects were observed in either group, further supporting the lack of a clear superior treatment regimen.

In a retrospective study Wen et al.[22] found that a higher initial hearing loss indicated a poorer prognosis with only 29.8% of their patients showing some hearing recovery. In our study, 11 patients in the methylprednisolone group (45.8%) and 11 patients in the dexamethasone group (45.8%) with initial profound hearing loss had either complete or partial hearing recovery. As methylprednisolone and dexamethasone groups' recovery in profound hearing loss and non-profound hearing loss were statistically insignificant, it can be concluded that the two IT treatments were equally effective in treating ISSNHL (Figure 3).

The non-significant difference between the two IT drugs in our study, combined with the variability in findings across studies in the literature, highlights why there is still no consensus on the optimal treatment protocol for idiopathic sudden sensorineural hearing loss. This underscores the need for future studies with larger sample sizes and consideration of the rate of spontaneous recovery.

There are some limitations in our study, the major one is its small sample size, which may limit the certainty of its conclusions. This limitation could be found in most studies concerning ISSNHL therapy due to the low incidence of the condition, especially when inclusion and exclusion criteria are strictly applied.[9,10,15,16,21,23–25] Despite this limitation, the prospective randomized design of this study ensures that its data remain valuable for future systematic reviews and meta-analyses. We did not assess quality of life (QoL), functional hearing outcomes, or patient satisfaction with therapy in our study. However, we believe these could be valuable and interesting aspects to explore in future research.

5 | CONCLUSION

Similar improvements in hearing were observed in ISSNHL patients treated with IT therapy using either methylprednisolone or dexamethasone.

CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

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