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Original Research Article

Impact of patient adherence to oral versus intratympanic steroid protocols on hearing outcomes in sudden sensorineural hearing loss

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ABSTRACT

Background: Systemic and intratympanic steroids (ITS) are primary treatments for idiopathic sudden sensorineural hearing loss (SSNHL). While efficacy is known, real-world adherence to high-dose oral tapers and its impact on outcomes remains under-reported. We compared adherence rates between oral (OST) and ITS therapy and evaluated their correlation with hearing recovery.
Methods: This retrospective cohort study included 245 adults with unilateral SSNHL. Patients received a 14-day oral prednisolone taper (OST group) or four intratympanic Dexamethasone injections over two weeks (ITS group). OST adherence (defined as taking ≥80% of the prescribed dose) was assessed via refill records and patient diaries. ITS adherence required completing all injections. Multivariate logistic regression adjusted for baseline imbalances.
Results: Of the 245 patients, 138 received OST and 107 received ITS. The ITS group demonstrated significantly higher adherence (96.3%) versus the OST group (78.3%; $p<0.001$). OST non-adherence resulted mainly from hyperglycemia (30%), insomnia (25%), and gastrointestinal distress (20%). Adherent OST patients achieved a mean Pure Tone Average improvement of 24.5 dB, compared to 14.2 dB in non-adherent patients ($p=0.004$). Age >65 and diabetes history were independent predictors of poor OST adherence.
Conclusions: Adherence to high-dose oral steroids for SSNHL is suboptimal compared to intratympanic administration due to systemic side effects, significantly compromising hearing recovery. Intratympanic therapy may be the preferred primary modality for patients with non-adherence risk factors like diabetes or advanced age.

Keywords: Sudden sensorineural hearing loss, Steroids, Adherence, Intratympanic injection, Prednisolone, Compliance

INTRODUCTION

Idiopathic sudden sensorineural hearing loss (SSNHL) is a rapid-onset auditory deficit occurring over a period of fewer than 72 hours, affecting approximately 5 to 27 per 100,000 individuals annually.[1] It is an otologic emergency that requires prompt diagnosis and management to maximize the potential for hearing recovery. Despite decades of research, the precise etiology remains elusive in the majority of cases, with vascular occlusion, viral cochleitis, and autoimmune mechanisms proposed as primary pathophysiological pathways.[2]

The inner ear is a highly specialized, immunologically unique compartment protected by the blood-labyrinthine barrier (BLB). When this barrier is compromised by a viral insult or microvascular ischemia, a cascade of inflammatory cytokines leads to profound edema, hypoxia, and potential apoptosis of the delicate hair cells within the organ of Corti. Corticosteroids remain the only widely accepted pharmacological intervention due to their potent anti-inflammatory properties and their ability to upregulate ion transport systems in the stria vascularis, thereby restoring endolymphatic homeostasis. However, achieving therapeutic concentrations within the perilymph and endolymph is fundamentally challenged

by the BLB, necessitating either very high systemic doses or direct local application.

Current clinical practice guidelines, including the 2019 update by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF), strongly recommend corticosteroids as the initial therapy.[1] Treatment is typically administered via one of two routes: systemic (usually oral) high-dose corticosteroids or localized ITS injections. While both modalities have shown efficacy, the optimal route remains a subject of debate, as evidenced by various comparative clinical trials.[3,4] The classic oral regimen often involves high-dose prednisolone (e.g., 60 mg/day or 1 mg/kg/day) tapered over 10 to 14 days.[5] Conversely, ITS protocols generally involve 3 to 4 injections of dexamethasone or methylprednisolone administered over a similar timeframe.

Recent literature has focused heavily on the comparative efficacy of these two modalities. Several meta-analyses have suggested non-inferiority of ITS compared to oral steroids, with some indicating superior outcomes for ITS as a salvage therapy.[6-9] However, a critical epistemological gap exists in the current otologic literature: the distinction between efficacy and effectiveness. Efficacy describes how well a steroid protocol functions under the idealized, strictly monitored conditions of a randomized controlled trial (RCT). Effectiveness, conversely, describes how that same protocol performs in the chaotic reality of clinical practice.

While meta-analyses confirm the efficacy of high-dose oral steroids, they fundamentally fail to account for the "attrition of adherence." In a trial, a patient is a data point managed by a research coordinator; in the real world, a patient is an independent agent navigating the debilitating anxiety of sudden deafness alongside the metabolic toxicity of high-dose glucocorticoids. High-dose oral corticosteroids are associated with a constellation of adverse effects, including insomnia, mood lability, hyperglycemia, dyspepsia, and hypertension.[10] These side effects can be debilitating, potentially leading patients to self-discontinue or reduce their dosage without medical consultation. If a "gold-standard" therapy is chemically intolerable to 20% of the population, its theoretical superiority becomes clinically irrelevant.

Adherence to medication is a well-documented challenge in chronic conditions, yet it is frequently overlooked in acute otologic conditions. To date, there is a paucity of literature specifically examining adherence rates to the rigorous tapering schedules required for SSNHL and quantifying the audiometric "cost" of non-adherence. The objective of this study was to: compare adherence rates between patients treated with oral steroid therapy (OST) and those treated with primary ITS; identify clinical and demographic factors associated with non-adherence; and evaluate the impact of non-adherence on final audiometric outcomes. We hypothesized that adherence would be significantly lower in the OST group due to systemic side effects and that this would correlate with poorer hearing recovery.

METHODS

Study design and setting

This retrospective cohort study was conducted at the Department of Otorhinolaryngology and Head and Neck Surgery in a tertiary care teaching hospital in Bangalore. Medical records of patients who visited the ENT outpatient department between January 2021 and December 2024 for sudden hearing loss were taken for the study.

Inclusion criteria

Inclusion criteria were age ≥ 18 years, diagnosis of unilateral SSNHL, defined as a sensorineural hearing loss of ≥30 dB in at least three contiguous frequencies occurring within 72 hours, initiation of steroid treatment within 14 days of symptom onset; and minimum follow-up of 3 months post-treatment.

Exclusion criteria

Exclusion criteria included identifiable causes of hearing loss (e.g., vestibular schwannoma confirmed on MRI, Meniere's disease, ototoxicity, temporal bone trauma); fluctuating hearing loss, profound cognitive impairment preventing reliable history taking; or concurrent use of both oral and ITSs (combined therapy) as the primary treatment.

Treatment protocols

Patients were categorized into two groups based on the primary treatment modality. The choice of treatment was determined through shared decision-making between the clinician and patient. This discussion heavily weighed patient comorbidities (particularly diabetes mellitus and hypertension) and patient preference, which introduces an inherent selection bias into the cohorts.

OST group

Patients received oral prednisolone 1 mg/kg/day (maximum 60 mg) as a single morning dose for 7 days. This was followed by a 7-day taper, reducing the daily dose by approximately 10 mg every 1 to 2 days until completion (total 14 days).

ITS group

Patients received four injections of dexamethasone (10 mg/ml) into the middle ear, administered twice weekly for two weeks.

Adherence in OST group

Adherence was assessed using a composite of pharmacy refill records and physician documentation of patient reported compliance during follow-up visits. Adherence defined as consumption of ≥80% of prescribed total cumulative dose. "Non-adherence" defined as consumption of <80% of dose/early cessation (<10 days).

Adherence in ITS group

Adherence was defined as the completion of all 4 scheduled injection sessions. Patients who missed one or more sessions were classified as non-adherent.

Outcome measures

Hearing assessment included pure tone audiometry (PTA) calculated as the arithmetic mean of thresholds at 500, 1000, 2000, and 4000 Hz. Initial PTA: Measured at presentation. Final PTA: Measured at 3 months post-treatment. Hearing recovery: Assessment was based on Siegel's criteria:[11]

Complete recovery

Final hearing better than 25 dB.

Partial recovery

>15 dB gain and final hearing 25 to 45 dB.

Slight improvement

>15 dB gain and final hearing >45 dB.

No improvement

<15 dB gain or <75 dB final hearing.

Statistical analysis

Data were analyzed using SPSS version 28.0 (IBM Corp., Armonk, NY). Continuous variables were presented as mean±standard deviation (SD) and categorical variables as frequencies and percentages. Differences between groups were analyzed using the independent t-test or Mann-Whitney U test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables. A multivariate logistic regression analysis was performed to identify independent predictors of non-adherence, including age (>65 vs ≤65), diabetes mellitus (presence/absence), gender, and initial PTA severity as covariates. Effect sizes are reported as mean differences or odds ratios (OR) with 95% confidence intervals (CIs). Due to the exploratory and retrospective nature of this study, no formal correction for multiple comparisons (e.g., Bonferroni) was applied; therefore, secondary p-values should be interpreted as observational rather than definitive.

RESULTS

Demographic characteristics

Out of 258 patients, a total of 245 patients met the inclusion criteria. 13 patients did not meet the inclusion criteria [Meniere's disease (n=5), lost to follow-up (n=4), presented >14 days from onset (n=2), received primary combined therapy (n=2)]. The OST group comprised 138 patients (56.3%), and the ITS group comprised 107 patients (43.7%). The mean age of the cohort was 52.4±14.1 years. Baseline characteristics, including initial PTA, time to treatment, and gender distribution, were comparable between the two groups (p>0.05). However, the ITS group had a significantly higher prevalence of diabetes mellitus (28.0% vs. 8.7%; p<0.001), reflecting the clinical preference for local therapy in diabetic patients (Table 1).

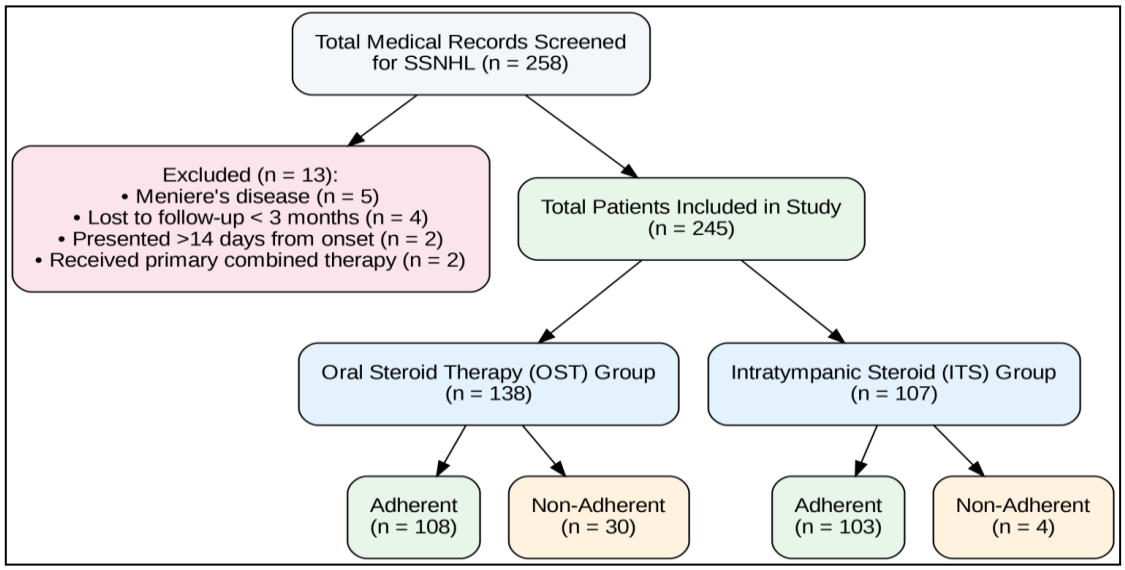

Figure 1: Flow diagram of patient selection, treatment allocation and adherence outcomes.

Table 1: Baseline characteristics of the study population.

Characteristic	OST group (n=138)	ITS group (n=107)	P value
Age (in years, mean±SD)	51.2±13.5	54.1±15.2	0.12
Male gender	72 (52.2%)	55 (51.4%)	0.98
Initial PTA (dB, mean±SD)	74.5±18.2	76.1±19.4	0.51
Time to treatment (days)	6.4±3.2	5.8±2.9	0.15
Diabetes mellitus	12 (8.7%)	30 (28.0%)	<0.001
Hypertension	34 (24.6%)	38 (35.5%)	0.06
Vertigo	41 (29.7%)	35 (32.7%)	0.64

Adherence rates

Significant disparities in adherence were observed between the two modalities. In the ITS group, 103 of 107 patients (96.3%) completed the full protocol. Conversely, only 108 of 138 patients (78.3%) in the OST group met the definition of adherence (Odds ratio [OR] for adherence in ITS vs. OST: 7.15; 95% CI: 2.43 to 21.01; p<0.001). Among the 30 non-adherent patients in the OST group, the mean duration of therapy before cessation was 5.4±2.1 days. The primary reasons cited for discontinuation were: Hyperglycemia/uncontrolled diabetes for 9 patients (30%), severe insomnia/psychiatric disturbance for 8 patients (26.7%), gastrointestinal intolerance (dyspepsia/gastritis) for 6 patients (20%), palpitations/elevated blood pressure for 4 patients (13.3%) and other/unknown 3 patients (10%).

Factors influencing adherence

Multivariate logistic regression was performed to identify predictors of non-adherence within the OST group. Age >65 years (Odds ratio [OR]: 3.4; 95% CI: 1.2-9.1; p=0.02) and a pre-existing diagnosis of diabetes (OR: 4.8; 95% CI: 1.5-15.2; p=0.008) were significant independent predictors of non-adherence. Gender and initial severity of hearing loss did not significantly predict adherence.

Hearing outcomes and adherence

When analyzing the OST group specifically, adherence had a measurable impact on audiometric outcomes. Adherent patients (n=108) achieved a mean PTA improvement of 24.5±12.1 dB (95% CI: 22.2 to 26.8), whereas non-adherent patients (n=30) achieved only 14.2±9.8 dB (95% CI: 10.5 to 17.9) (Mean difference: 10.3 dB; 95% CI: 6.0 to 14.6; p=0.004). Using Siegel's criteria for the total cohort:

Adherent OST

The 58.3% achieved complete or partial recovery.

Non-adherent OST

The 26.7% achieved complete or partial recovery (OR for recovery in adherent vs. non-adherent: 3.85; 95% CI: 1.57 to 9.41; p=0.002).

ITS group (Total)

The 54.2% achieved complete or partial recovery.

There was no statistically significant difference in recovery rates between the adherent OST patients and the ITS group (OR: 0.84; 95% CI: 0.49 to 1.45; p=0.54), suggesting that oral steroids are equally effective as ITS provided the patient can tolerate and complete the full course.

DISCUSSION

The management of SSNHL is a race against time, where the delivery of anti-inflammatory agents to the cochlea is paramount. While the debate over "Oral vs. Intratympanic" has dominated recent literature, our study highlights a critical, often ignored variable: the patient's ability to adhere to the prescribed regimen. Our findings demonstrate that while adherent patients derive similar benefits from both modalities, real-world adherence is significantly lower in the oral steroid group (78.3%) compared to the intratympanic group (96.3%), leading to poorer outcomes for the non-adherent cohort.

Metabolic implications of systemic therapy

Our findings crystallize a fundamental biological conflict in the management of SSNHL: the 'metabolic price' of hearing recovery. The inner ear is an immunologically privileged site, protected by the blood-labyrinthine barrier (BLB). To breach this barrier systemically requires supraphysiological steroid concentrations that can significantly disrupt glucose homeostasis and circadian rhythms. The 21.7% non-adherence rate observed in our OST cohort suggests that for nearly one in five patients, this metabolic price is too high to pay.

The burden of systemic steroids

The adverse event profile observed in our study-dominated by hyperglycemia, insomnia, and gastrointestinal distress-aligns with the broader literature on short-term high-dose steroid use. A recent scoping review by Achanta et al highlighted that adverse events in SSNHL steroid therapy are under-reported but significant, with hyperglycemia affecting up to 30% of patients.[10] Furthermore, the neuropsychiatric impact of

high-dose prednisolone cannot be overstated. SSNHL is inherently a psychologically traumatic event. When this baseline psychological distress is compounded by steroid-induced insomnia, mood lability, and chemical agitation, the patient's coping mechanisms can easily be overwhelmed. Older adults often have lower physiological reserve and polypharmacy, making them more susceptible to the hypertensive and psychotropic effects of steroids, which further compounds age as a known negative prognostic factor.[12,13]

Intratympanic therapy: the "guaranteed" delivery

The ITS group showed superior adherence (96.3%). This is intuitive; ITS places the burden of administration on the clinician rather than the patient. Once the patient arrives at the clinic, the drug is delivered. The few cases of non-adherence in the ITS group were due to logistical issues (unable to attend appointments) or pain intolerance, which is consistent with findings by Zhao et al. regarding the tolerability of ITS.[14] Crucially, our audiometric analysis revealed that when patients do adhere to oral steroids, their outcomes are statistically indistinguishable from ITS patients. This supports the "non-inferiority" conclusion of several meta-analyses.[6,8,9,14] However, the "intent-to-treat" reality is that a significant minority of oral patients will not complete the course, rendering the population-level efficacy of oral steroids lower than ITS in real-world settings. Furthermore, the 21.7% non-adherence rate observed in our OST cohort necessitates a re-evaluation of how otologists classify treatment outcomes. In routine practice, patients who fail to recover audiometrically are often documented as having 'refractory' or 'steroid-resistant' SSNHL. However, our findings suggest a significant proportion of these cases may actually represent 'silent treatment failure' due to undisclosed medication abandonment. Without aggressive verification of adherence-such as pharmacy refill audits or digital pill-tracking-clinicians cannot reliably distinguish between a biologically steroid-resistant cochlea and a metabolically intolerant patient. ITS effectively eliminates this diagnostic ambiguity.

Future directions in risk stratification

The era of 'one-size-fits-all' steroid protocols for SSNHL should be reconsidered. Our data supports a shift toward 'precision otology,' where the route of administration is phenotypically matched to the patient. Just as oncology selects chemotherapy based on tumor markers, otology must select steroid delivery based on 'metabolic markers.' A patient with a hemoglobin A1c >6.5% or a history of dyspepsia is not merely 'at risk' for oral steroid failure; they are genetically and physiologically ill-suited for it. In patients with marked metabolic comorbidities, intratympanic therapy may be considered a highly beneficial primary intervention rather than strictly a salvage option. The conventional 'oral first' approach may delay optimal treatment in patients destined to be non-adherent. I propose that future prospective research explore the development of an Oto-metabolic risk score (OMRS) to stratify SSNHL patients by adherence risk. Such a tool could weight factors including age ≥65 and diabetes-which our multivariate analysis identified as independent predictors of non-adherence-alongside markers like HbA1c and psychiatric history. Patients identified as high-risk could potentially be considered for primary ITS, pending prospective validation of this approach.

Risk stratification

Clinicians should proactively screen for risk factors of non-adherence (diabetes, history of gastritis, psychiatric history, advanced age) before prescribing oral steroids.

Early monitoring and the 'critical attrition window'

Our data reveals a highly specific 'critical attrition window' at approximately Day 5 of oral therapy, with the mean time to cessation being 5.4±2.1 days. This suggests that adverse effects compound rapidly over the first 72 to 96 hours, reaching an intolerable threshold just before the one-week mark. Therefore, the traditional model of reviewing a patient after the completion of a 14-day course may require modification. We propose the implementation of a mandatory 'day 4 telehealth toxicity check' for all patients initiated on OST. Identifying intolerance at this juncture allows the clinician to seamlessly transition the patient to salvage ITS before the crucial early therapeutic window for cochlear rescue permanently closes.

Primary ITS

For patients over 65 or those with metabolic comorbidities, primary ITS should be strongly considered not just to avoid side effects, but to ensure the therapeutic dose is actually received.

Limitations

This study has several limitations inherent to its retrospective design. First, the cohorts suffered from confounding by indication; the ITS group had a significantly higher prevalence of diabetes (28.0% vs. 8.7%), as clinicians preferentially recommended local therapy for these patients to avoid hyperglycemia. While multivariate analysis attempts to control for this, treatment selection bias remains a confounding factor. Future studies should employ propensity score matching to mitigate this. Second, there is an asymmetry in how adherence was measured. ITS adherence simply required clinic attendance, which is easily verifiable. OST adherence relied partially on self-reported patient diaries, which carries a known risk of recall bias and may have systematically overestimated true oral adherence. Finally, our data did not systematically capture how many non-adherent OST patients subsequently crossed over to

receive ITS as a salvage therapy. The inability to account for salvage therapy is a significant limitation, as it may bias the final audiometric outcomes of the non-adherent OST cohort.

CONCLUSION

Adherence to steroid protocols appears to be a critical factor in the recovery of hearing in SSNHL. While oral and ITSs offer comparable efficacy when fully completed, real-world adherence to high-dose oral regimens may be compromised by systemic side effects, particularly in older adults and those with metabolic comorbidities. Non-adherence to oral therapy is associated with poorer audiometric outcomes. Consequently, primary intratympanic therapy may be a beneficial consideration for patients with a high risk of steroid intolerance to ensure reliable drug delivery.

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