

Standardization of Outcome Measures for Intratympanic Steroid Treatment for Idiopathic Sudden Sensorineural Hearing Loss

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Objective: To identify variability in reported hearing outcomes for intratympanic (IT) steroid treatment of idiopathic sudden sensorineural hearing loss (ISSNHL) by comparing outcomes using the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) guideline with other published criteria.

Study Design: Retrospective chart review.

Setting: Tertiary otology practice.

Patients: Patients with ISSNHL treated with IT steroid between April 2003 and December 2020.

Interventions: IT steroid injection and audiometric evaluation.

Main Outcome Measures: 1) Rates of full, partial, or no recovery using the AAO-HNS guideline versus other reported criteria, and 2) correlation analyses of demographic and clinical variables with response to IT steroid.

Results: Using AAO-HNS reporting criteria, full recovery of the pure-tone average was noted in 25.68% of patients. Applying eight other published outcomes criteria to this patient cohort classified

full recovery in 14.87 to 40.54% of patients. Similarly, AAO-HNS criteria classified “no recovery” in 51.35% of our patients, whereas applying the other reported criteria showed an average rate of 62.16% no recovery and as high as 82.43% of patients without recovery. Younger age ($p = 0.003$; effect size, 0.924) and IT injection within a week of onset ($p < 0.001$; effect size, 1.099) positively correlated with full recovery. There was no impact of prior or concurrent oral steroids, or number of steroid injections on outcome.

Conclusion: Great variability exists in the literature for assessment of IT steroid outcomes in ISSNHL. Standard reporting of outcomes as per the AAO-HNS ISSNHL guideline is recommended to consistently characterize IT steroid efficacy and allow comparison across studies.

Key Words: Intratympanic—Outcomes—Steroids—Sudden hearing loss.

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INTRODUCTION

Idiopathic sudden sensorineural hearing loss (ISSNHL) accounts for 90% of sudden hearing loss cases and is defined as hearing loss developing within 72 hours with at least 30-dB threshold increase at three consecutive frequencies on pure-tone audiometry (1). The incidence of ISSNHL

in the United States is roughly 27 per 100,000, is slightly more likely to occur in men, and increases significantly with age (2). The widely accepted standard of treatment for ISSNHL is a tapering course of oral corticosteroid. This largely stems from an early study presented by Wilson et al. (3) in which data from two separately administered double-blinded randomized controlled trials using different corticosteroid regimens were combined and found an improved hearing recovery in patients receiving steroids compared with placebo (62% versus 31%, respectively). Corticosteroids are thought to improve ISSNHL by reducing inflammation and edema in the inner ear (4). As such, intratympanic (IT) corticosteroids have increased in popularity as a treatment modality for ISSNHL owing to the theoretical advantage of increased target site concentration and decreased systemic corticosteroid exposure (1,5).

Treatment outcomes after corticosteroids for ISSNHL differ by report with many reports using different definitions of hearing recovery. Sung et al. (6) showed *complete* hearing recovery rates between 55.6 and 58.3% using the commonly used Seigel's criteria (7). Koltsidopoulos et al. (8)

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found *significant* hearing recovery in 67.39% of patients using their own criterion. Other studies, using other criteria of response, have shown poorer outcomes. For example, Rauch et al. (9) reported a full recovery rate of 24.8%, whereas Battaglia et al. (10) and Vanwijck et al. (11) showed recovery rates of 29 and 31%, respectively.

The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) guideline acknowledges that the definitions of “recovery” in previous studies vary from any measurable improvement to full recovery of normal hearing (12). This lack of consistency makes it difficult to definitively assess hearing improvement and response to IT steroids in ISSNHL. For example, the definition of “full” recovery in one study could place an individual in upper or lower limits of “partial” recovery in another study. Thus, the need of a standardized model for the assessment of hearing recovery after treatment for ISSNHL is pertinent.

The AAO-HNS guideline recommends a standardized format for reporting hearing outcomes that includes 1) use of the unaffected ear as baseline for recovery comparison, 2) complete recovery requiring return to within 10-dB HL of the unaffected ear and recovery of word recognition score (WRS) to within 5 to 10% of the unaffected ear, 3) partial recovery defined in two ways based on whether the degree of initial hearing loss after ISSNHL rendered the ear nonserviceable or not, and 4) classification of no recovery as less than 10-dB improvement.

In this study, we assessed our patient responses to IT steroid treatment consistent with the AAO-HNS guideline on threshold and compared those outcomes with other published criteria. The goal of using a single cohort with multiple outcomes criteria was to demonstrate the potential range of reported efficacy of IT steroids and to demonstrate the need for standardized outcome measures. In addition, we correlated demographic, therapeutic, and audiometric variables with level of recovery to identify factors impacting IT steroid response.

METHODS

Study Design and Patients

This project was approved under our department-wide OTO Clinomics outcomes assessment platform, which facilitates retrospective chart reviews of our entire health system (institutional review board number 1538127). Using procedure codes, we identified all patients treated in the tertiary otology practice with IT therapy between April 2003 and December 2020. Charts were reviewed for those treated with steroid, excluding those with other IT therapies such as gentamycin. Only patients treated for acute ISSNHL were included. That is, patients with recurrent episodes of SNHL, suspicion of cochlear hydrops or Menière disease, or retrocochlear pathology were excluded. Patients with complete threshold audiometry at presentation and after IT steroid treatment were analyzed for hearing response.

IT steroid was administered in the clinic using phenol topical anesthetic (Phenol Applicator Kit; Apdyne Medical, Denver, CO). A 25-gauge needle was used to puncture the posterior tympanic membrane and fill the middle ear with steroid. One provider typically made a second vent, but most subjects had only one myringotomy. Patients were instructed not to swallow and were left in a decubitus position with the affected ear up for 30 minutes. Injections were

repeated weekly until there was no change in the audiogram or no subjective change per patient report. All patients in this study received dexamethasone (between 10 and 24 mg/ml) except for two patients who received solumedrol (40 and 125 mg/ml). Most subjects were treated with commercial dexamethasone sodium phosphate injection solution (Mylan Institutional LLC, Rockford, IL).

Auditory and Hearing Recovery Assessment

Standard pure-tone audiometry was performed at the time of presentation for evaluation of hearing loss and after completion of steroid therapy. Although it is not explicitly defined, the AAO-HNS guideline suggests that threshold changes should be assessed using pure-tone average (PTA). As such, we used four-frequency PTA (e.g., 500, 1000, 2000, and 3000 Hz) for outcomes assessment because of its common clinical use. WRSs were obtained with recorded 25-word lists presented at least 45 dB above PTA or at maximal amplification for those with severe and profound losses.

Hearing recovery was assessed using the AAO-HNS guideline as well as applying the criteria used in eight other published studies on steroid treatment for ISSNHL (Table 1). The AAO-HNS criteria utilize both change in threshold and word recognition in assessing for complete, partial, and no recovery. Only three of the eight other studies incorporated speech recognition into their criteria. Therefore, for the purpose of comparison across studies, we did not utilize the word recognition criteria of the AAO-HNS guideline and assessed relative recovery based only on change in pure-tone threshold. We examined our patient speech outcomes in the 46 of 74 patients with full data and found that they largely co-segregated with changes in threshold, and thus, even without explicitly including WRS, our categorization of response to treatment is consistent with the AAO-HNS reporting criteria.

Statistical Analyses

For numeric versus categorical analyses (e.g., number of IT injections versus full recovery), one-way analysis of variance was used to assess for significant correlation. For categorical versus categorical analyses (e.g., affected ear versus full recovery), a χ^2 test of independence was used to determine correlation. Similarly, the χ^2 test was used to compare the results of applying the AAO-HNS outcomes guidelines on our cohort to the results obtained by applying each of the other reported outcome criteria. A significant correlation was noted if $p < 0.05$. Cramer's V was calculated to identify effect size for χ^2 analyses and η^2 for analyses of variance. All statistical tests were performed using R language (3.6.1).

RESULTS

There were 74 patients with ISSNHL meeting the inclusion criteria for assessment of hearing recovery after IT steroid (Table 2). The mean age was 56.1 ± 16.5 years, with 82.4% of patients being 40 years or older. There was a slightly male (56.8%) and right-sided (58.1%) preponderance. Just over half of patients were injected between 1 week and 1 month of hearing loss onset. Dexamethasone at 10 or 12 mg/ml was the most commonly used steroid (97.3%). About half of patients had a single injection (52.1%), with another 26% having two injections; the rest had more than two injections.

This cohort was used for two principal outcome measures: 1) to determine the rate and level of response to IT steroids for ISSNHL using the AAO-HNS guideline versus other reported criteria, and 2) to correlate clinical and treatment variables with response to IT steroid.

TABLE 1. American Academy of Otolaryngology–Head and Neck Surgery guideline for hearing recovery and other criteria previously used to determine intratympanic steroid efficacy

Published Criteria	Definition of Recovery
AAO-HNSF guideline (1)	Complete recovery: return to within 10 dB HL of the unaffected ear and recovery of WRS to within 5–10% of the unaffected ear Partial recovery: >50% WRS No recovery: improvement <10 dB HL
Siegel (7)	Complete recovery: final hearing better than 25 dB Partial recovery: improvement >15 dB; final hearing of 25–45 dB Slight improvement: improvement >15 dB; final hearing poorer than 45 dB No improvement: gain <15 dB; final hearing poorer than 75 dB
Rauch et al. (9)	Complete recovery: PTA <30 dB No recovery: hearing within 30–90 dB
Furuhashi et al. (13)	Complete recovery: final PTA ≤25 dB Marked recovery: PTA improvement >30 dB, marked recovery Slight recovery: 10 dB < PTA improvement < 30 dB No recovery: PTA improvement <10 dB
Battaglia et al. (10)	Full recovery: an improvement in PTA of 10–30 dB HL No recovery: 10 > HL improvement > 30
Vanwijck et al. (11)	Full recovery: a decrease in PTA ≥10 dB, an increase in WRS of 10% or more No recovery: a decrease in PTA of <10 dB, an WRS increase of <10%
Kwak et al. (14)	Complete recovery: return to within 10 dB HL of the unaffected ear and recovery of WRSs to within 5–10% of the unaffected ear Partial recovery: >50% WRS Slight recovery: improvement ≤10 dB HL or >10% (SDSs) without reaching serviceable hearing No recovery: improvement <10 dB HL
Chew and Md Daud (15)	Full recovery: improvement ≥15 dB in PTA No recovery: gain <15 dB in PTA
Koltsidopoulos et al. (8)	Full recovery: improvement >10 dB in PTA and 15% in SDS No recovery: improvement <10 dB in PTA and 15% in SDS

AAO-HNSF indicates American Academy of Otolaryngology–Head and Neck Surgery; dB HL, hearing level in decibels; PTA, pure-tone average (PTA); SDS, speech discrimination score; WRS, word recognition score.

Comparison of Outcomes Criteria

Using AAO-HNS outcomes guidelines for threshold change, 25.68% of patients demonstrated full recovery, 22.97% demonstrated partial recovery, and 51.35% demonstrated no recovery (Fig. 1). In contrast, full recovery would have been reported in as few as 14.86% if using the Siegel criteria to as many as 40.54% of patients if using the Vanwijck and Koltsidopoulos criteria. Similarly, no recovery would have been reported in an average of 62.16% of patients across all other criteria and as high as 82.43% of patients if the Rauch criteria were used.

Correlation analyses between the AAO-HNS guideline and the eight other published reports showed a statistically significant correlation with all criteria. Expectedly, the strongest correlations were to the criteria containing a partial recovery category, as opposed to the four reports in which recovery was noted only as full or none. Using effect size as a measure of strength of correlation, we found that the highest correlation was seen to the criteria used by Kwak et al. (14) ($p < 0.0001$; Cramer's $V = 2.83$) and the weakest correlation noted to the criteria reported by Rauch et al. (9) ($p < 0.0001$, Cramer's $V = 0.88$).

A commonly used assessment for hearing outcomes after medical or surgical intervention is to depict results using the recommendations of the Hearing Committee of the AAO-HNS (16). This requires measurement of both PTA and WRS. As noted in the Methods section, we used the AAO-HNS reporting criteria for threshold changes, without including WRS, because of lack of use of WRS among many other published criteria. However, there were 46 patients in our cohort with both pre- and post-PTA and WRS

for which we could depict standard AAO-HNS hearing changes with IT steroid (Fig. 2). Among these, 28 (60.9%) had an improvement of 10 dB or greater in PTA, and 20 (43.5%) had measurable improvement in both PTA and WRS. These rates of hearing change in the beneficial direction are comparable to the 48.7% of patients having either full or partial recovery using the AAO-HNS guideline criteria.

Demographic and Clinical Correlations With Hearing Recovery

Using the AAO-HNS criteria of full, partial, or no recovery, the response to IT steroid relative to demographic and clinical variables was assessed (Fig. 3). A younger age group ($p = 0.003$, Cramer's $V = 0.924$) and shorter interval until injection ($p < 0.001$, Cramer's $V = 1.099$) correlated with full hearing recovery (Table 3). Those younger than 40 years had a 61.5% rate of full recovery compared with those older than 65 years in which there was a 15.4% rate of full recovery. In fact, among all patients older than 40 years, the full recovery rate was only 18.0%. Affected side, concurrent or prior oral steroids, and number of injections had no correlation with outcome.

Level of hearing loss at presentation also correlated with recovery, and those having less hearing loss had a better chance of recovery ($p < 0.003$). The quartile with best hearing at presentation, a hearing loss not worse than 46.25-dB PTA, had a 52.63% rate of full recovery. Interestingly, this group had an “all-or-none” recovery pattern with no patient meeting the partial recovery criterion. Those with hearing worse than 46.25-dB PTA had less than 20% rate of full recovery. There may be an impact of age within these

TABLE 2. Clinical characteristics of 74^a patients treated with intratympanic steroid for idiopathic sudden sensorineural hearing loss

Age	
Mean ± standard deviation (yr)	56.1 ± 16.5
<40 yr, n (%)	13 (17.6)
40–65 yr, n (%)	35 (47.3)
>65 yr, n (%)	26 (35.1)
Sex, n (%)	
Male	42 (56.8)
Female	32 (43.2)
Affected side, n (%)	
Right	43 (58.1)
Left	31 (41.9)
Time to injection, n (%)	
<1 wk	18 (24.3)
>1 wk, <1 mo	40 (54.1)
>1 mo	16 (21.6)
Oral steroids, n (%)	
Yes	51 (70.0)
Prior ^b	41 (80.4)
Concurrent	10 (19.6)
No	22 (30.1)
Type of steroid, n (%)	
Dexamethasone	
10 mg/ml	36 (50)
12 mg/ml	26 (36.1)
24 mg/ml	2 (2.8)
≤5 mg/ml (range, 1–5 mg/ml)	6 (8.3)
Solumedrol (one at 40 mg and one at 125 mg/ml)	2 (2.7)
No. IT injections, n (%)	
1	38 (52.1)
2	19 (26.0)
3	11 (15.1)
>3	5 (6.8)

^aSome sections have 73 patients because of missing data.

^bStarted before IT steroid and not necessarily finishing oral steroids by the time of IT injection.

IT indicates intratympanic.

correlation data because those in the least quartile of hearing loss were also the youngest (mean, 49.5 yr), whereas those with the most hearing loss were the oldest (mean, 82.8 yr).

DISCUSSION

The purpose of this study was to understand the impact of outcomes guidelines on the perceived effectiveness of IT steroids. Our original intent was to apply the AAO-HNS guideline criteria to other studies to recalculate recovery rates and identify a better estimate of the efficacy of IT steroids for ISSNHL. However, almost all other studies publish group data, not individual patient data, thus preventing reassessment. As such, we used an internal cohort of 74 patients and applied eight different previously published criteria to define these differences. By using an internal cohort and having access to additional clinical data, we were also able to assess variables that predicted a favorable outcome.

If we focus on threshold, the AAO-HNS guideline defines full recovery as a return to within 10 dB of the unaffected ear. This entails the assumption that the unaffected ear was symmetric to the affected ear and represents a baseline of hearing. The only previous report to similarly use the unaffected ear was that by Kwak et al. (14). However, if the unaffected ear was in fact poorer than the affected ear, the bar for recovery is inadvertently lowered and those having partial recovery would be classified as full recovery. Without having previous audiometry, this scenario is possible in our cohort, and our finding of an overall 25.68% full recovery may be a slight overestimate of the effectiveness of IT steroids.

The potential for the unaffected ear threshold to present an erroneous target may be why the seven other reports used threshold of the affected ear as the primary measure of efficacy. Some used an absolute change in threshold to demonstrate recovery, such as Vanwijck et al. (11) (an improvement of ≥10 dB), Koltisidopoulos et al. (8) (an improvement of >10 dB), Chew and Md Daud (15) (an improvement of ≥15 dB), and Battaglia et al. (10) (an improvement of 10–30 dB). A change of just 10 dB may be too low a bar to gauge recovery, and these standards may overestimate

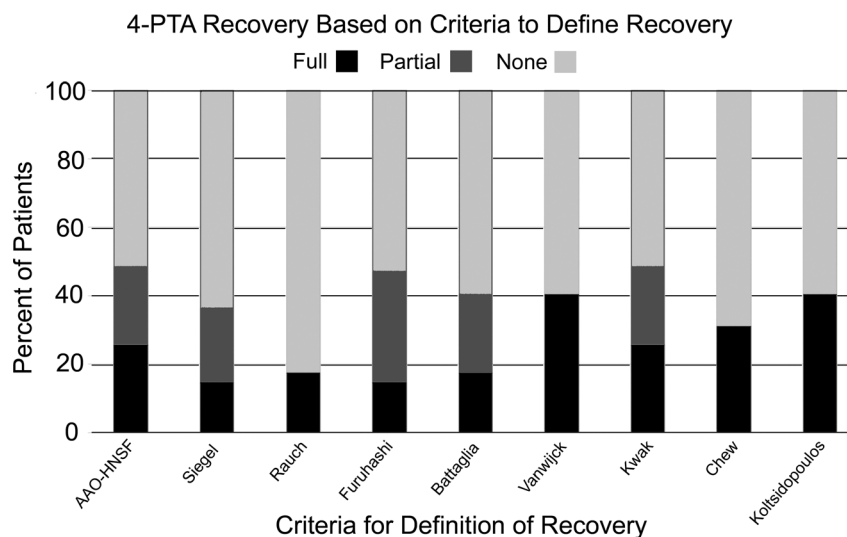


FIG. 1. Hearing recovery by reported outcome measure. We applied these nine reporting criteria to our cohort of 74 patients to determine rates of full, partial, or no recovery. There is great variability across criteria, but all measures demonstrate that at least 50% of patients have no recovery with intratympanic steroid.

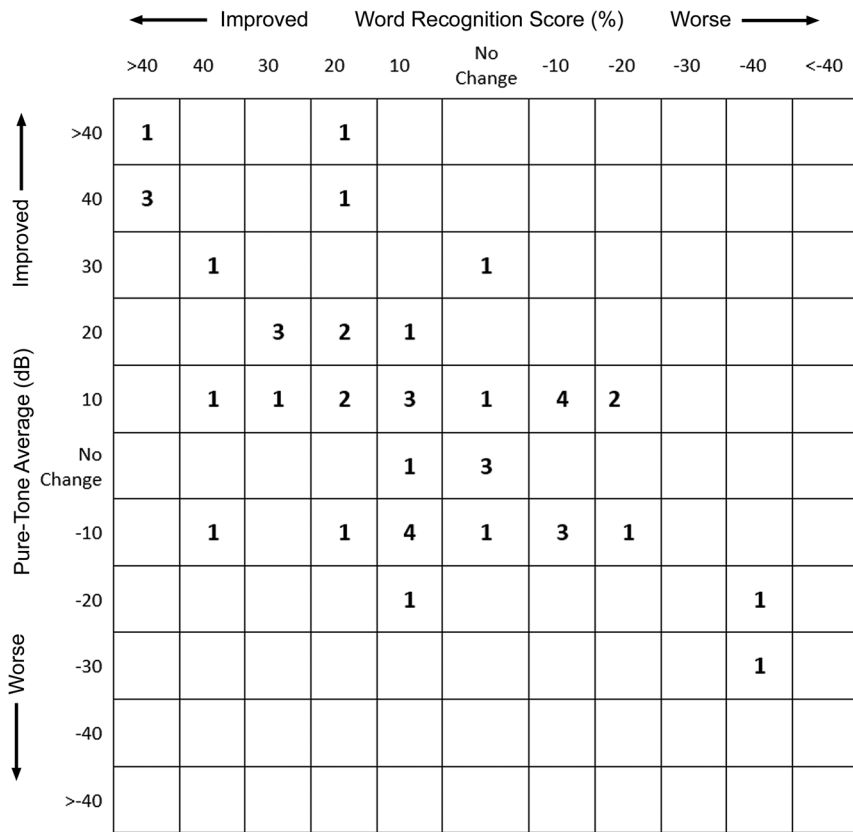


FIG. 2. Hearing response to intratympanic steroid for idiopathic sudden sensorineural hearing loss using standard reporting measures on 46 patients with complete threshold and word recognition data.

the efficacy of IT steroids. Indeed, three of these four criteria had the highest rates of recovery when applied to our cohort, as much as 40.54% full recovery.

Other studies used final PTA of the affected ear as a measure of full recovery, such as Siegel (7) and Furuhashi et al. (13) (better than 25 dB), and Rauch et al. (9) (better than 30 dB). These studies assume that that affected ear had borderline or normal hearing before insult. This may therefore set too high a bar for recovery and underestimate the true rate of recovery to baseline. Expectedly, these three studies had the lowest rates of full recovery when applied to our cohort, as low as 14.86%.

Several demographic and clinical factors correlated with full recovery after IT steroid. These included age, level of hearing loss, and time to injection. Younger patients in our cohort had a significantly higher likelihood of achieving recovery, and patients younger than 40 years showed significantly higher recovery rates than those older than 40 years. Similarly, Lee et al. (15), using Siegel's criteria, showed age to be a significant factor and found that the recovery rate was significantly higher in patients younger than 60 years (71.4%). Our study noted worse hearing at presentation in older patients. The impact of age on hearing recovery with IT steroids may thus be partially explained by concurrent presbycusis or other age-related coexisting comorbidities (cardiovascular disease and diabetes) that impact hearing in older populations.

We identified that those with worse hearing at presentation had poorer prognosis for full recovery. This suggests that recovery rates decrease with increasing levels of hearing severity, which is consistent with previous reports. Lee et al. (17) showed hearing recovery of 83.0% in those with less hearing loss but 42.9% in those with profound hearing loss. Similarly, Tiong (18) found that patients with moderately severe initial hearing loss had favorable recovery rates of 86.3%.

As noted earlier, there was a correlation between age and level of hearing loss, which confounds these univariate findings. Specifically, those in the quartile with the least hearing loss were much younger (49.5 years) than the quartile with the most hearing loss (82.8 years). The relationship between these variables raises questions as to whether the mechanism of hearing loss may be different between younger and older patients, thus impacting the degree of hearing loss, or the chance for recovery.

Two common theories for the etiology of ISSNHL include vascular versus viral causes. In a study conducted by Yildiz and Zer Toros (18), it was found that mean platelet volume and neutrophil-to-lymphocyte ratio were significantly higher in patients with ISSNHL compared with healthy controls. In recent years, increased mean platelet volume and neutrophil-to-lymphocyte ratio have been associated with an increased risk of microvascular thrombotic events and inflammation in comorbid conditions such as diabetes mellitus

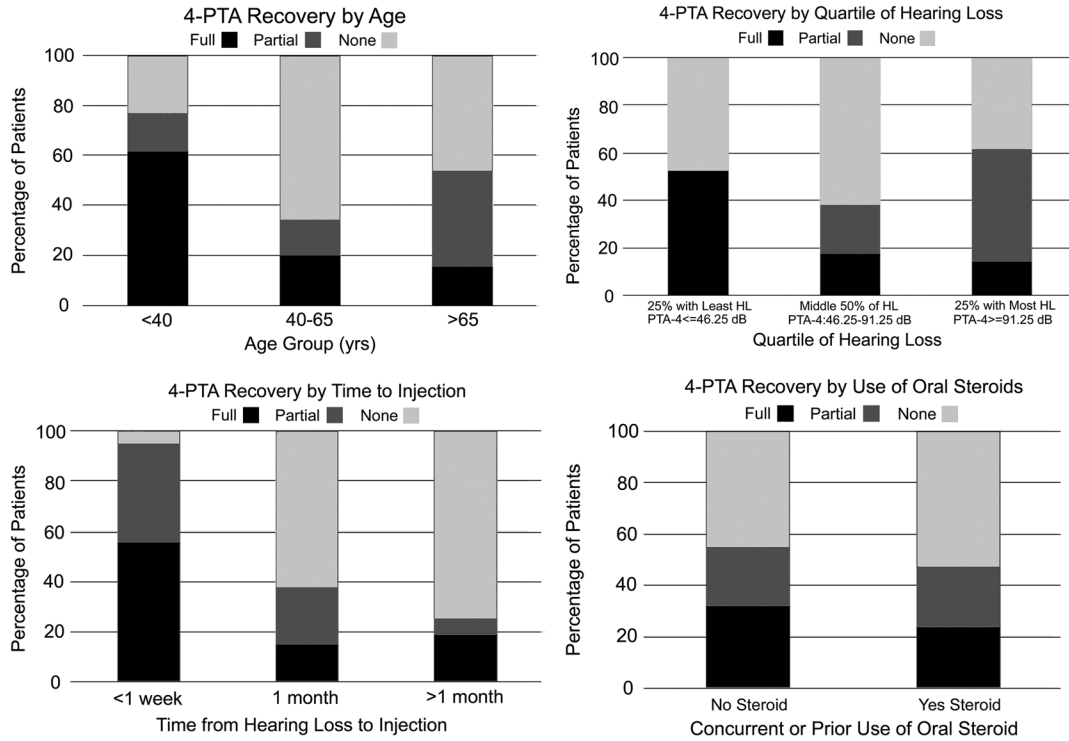


FIG. 3. Hearing recovery to intratympanic steroid relative to patient age, degree of hearing loss, time to intratympanic injection, and exposure to oral steroid. Younger age, less hearing loss, and less than 1 week until injection demonstrated significant rates of hearing improvement.

and hypertension (20,21). Older patients presenting with conditions such as diabetes mellitus or hypertension are at increased risks for impaired cochlear blood perfusion and microvascular damage, which have been implicated as inciting events for ISSNHL (22). Thus, it can be speculated that the increased degree of hearing loss and lower rates of recovery seen in older patients can be attributed to the higher degree of susceptibility to vascular insults.

Alternatively, when assessing the potential role of viral infection leading to ISSNHL, Wilson et al. (23) found a significant relationship between higher rates of ISSNHL and increased seroconversion to mumps, rubeola, influenza B, and varicella zoster. When considering viral infection as a potential cause for ISSNHL, it can be speculated that the younger patients in our study who presented with less hearing loss and had higher recovery rates are less likely to have

underlying vascular risk factors and may thus have had a viral etiology to their hearing loss.

An inverse correlation was noted between time to injection and hearing recovery. Patients who received IT steroid injection within 1 week of diagnosis of ISSNHL had a significantly more likelihood of achieving recovery. Similarly, Chen et al. (22) showed that the number of days before the onset of treatment between the overall recovery group (6.70 ± 5.96) and the no-recovery group (10.21 ± 8.85) was shorter. Although some patients with ISSNHL recover without treatment, watchful waiting may miss this therapeutic window.

A vast majority of our patients were treated with IT dexamethasone, and thus, our analysis did not find a significant correlation between steroid type and hearing outcomes. When comparing the benefits of IT dexamethasone versus IT methylprednisolone, Tarkan et al. (24), using the Furuhashi criteria, did not find a significant difference between therapeutic success rates (methylprednisolone, 62.5%; dexamethasone, 54.6%). Our current report, using predominantly IT dexamethasone, did not show results that disparate from other reports suggesting that dexamethasone is an acceptable option.

We noted no difference in outcome between those receiving only IT steroids and those with either concurrent or prior oral steroids. Similarly, Ashtiani et al. (25) showed no significant difference in response to treatment with respect to patients in an IT group (71.9%), systemic group (60%), or combination group (68.6%). Consistent results among three treatment groups were also found by Bae et al. (16).

TABLE 3. Correlation of clinical and demographic characteristics and full hearing recovery

	<i>p</i>	Effect Size ^a
Categorical variables (χ^2)		
Affected ear (L/R)	0.9490	0.087
Age range: <40, 40–65, >65 yr	0.0033	0.924
Time to injection: <1 wk, within 1 mo, >1 mo	0.0002	1.099
Oral steroids: concurrent or prior	0.8189	0.289
Continuous variables (ANOVA)		
Age (yr)	0.1550	0.051
No. IT injections	0.0912	0.065

Values in bold are significant at $p < .05$.
^aEffect size: Cramer's V for χ^2 analyses; η^2 for ANOVA.
 ANOVA indicates analysis of variance; L/R, left/right.

Some limitations to our study include that many of our patients were initially evaluated elsewhere, which limited the early IT injection group. In addition, our study only included patients who received both pretreatment and posttreatment audiograms, excluding some patients who subjectively may have noted full recovery. Our study was conducted at a single institution, which limits the size of the study population yet ensured that we analyzed consistent and complete audiometric data.

CONCLUSION

The wide range of reported outcomes with IT steroid for ISSNHL reflects variable outcome measures, which prevents accurate representation of the efficacy of this treatment. Standard reporting of outcomes as per the AAO-HNS SSSNHL guideline is recommended to consistently characterize IT steroid efficacy and allow comparison across studies.

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