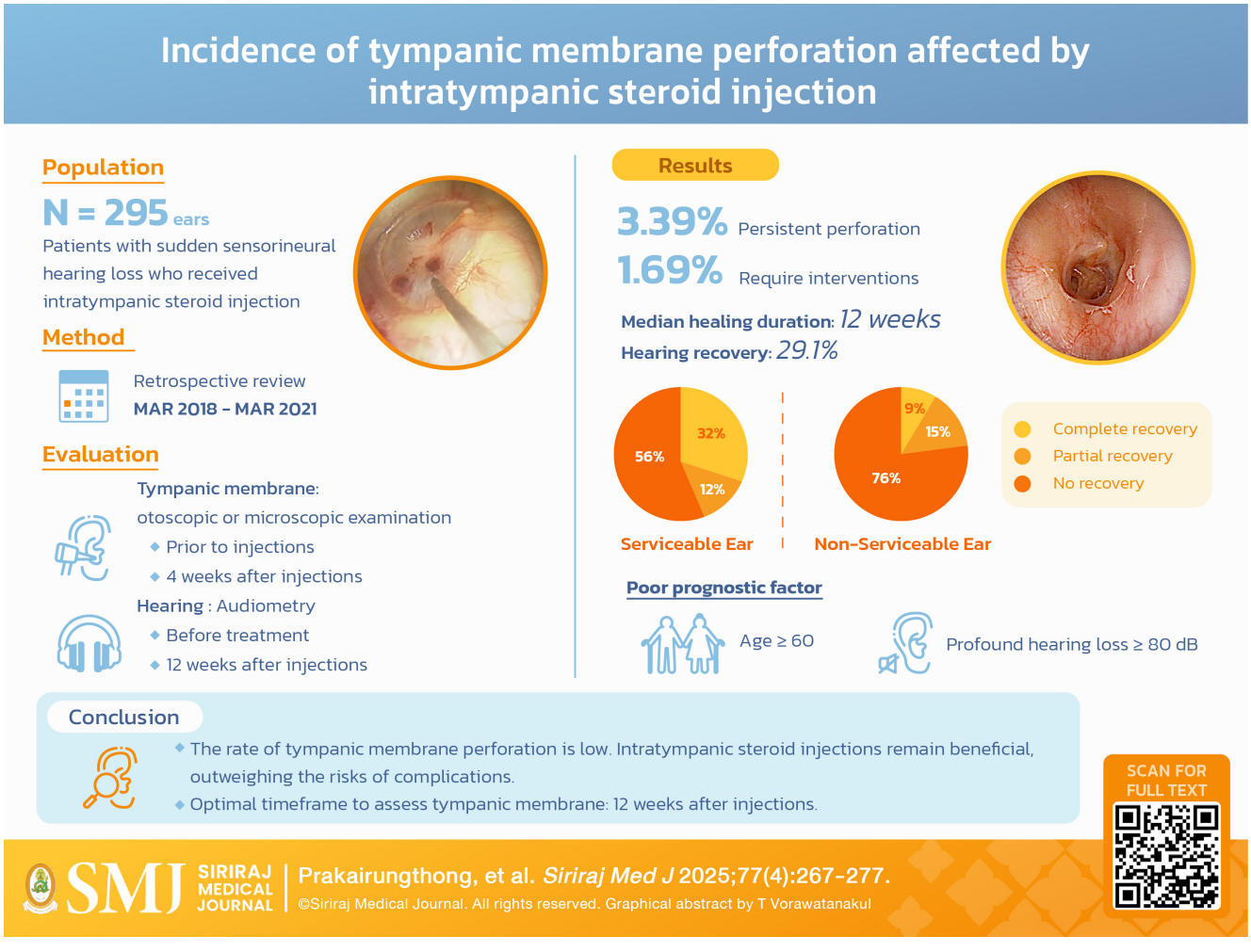
Incidence of Tympanic Membrane Perforation Affected by Intratympanic Steroid Injection: A Retrospective Review

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ABSTRACT

Objective: This study aims to determine the incidence of persistent tympanic membrane perforation following intratympanic steroid injection and to identify potential factors associated with delayed healing. Additionally, it aims to estimate the time required for perforation closure in prolonged cases to avoid unnecessary interventions.

Materials and Methods: Data from patients who underwent intratympanic steroid injections were reviewed. The primary outcome was the incidence of tympanic membrane perforation lasting beyond four weeks post-injection. Secondary outcomes included identifying factors affecting healing duration and closure time in prolonged cases.

Results: Of 295 ears treated between March 2018 and March 2021, 3.39% (10/295) experienced persistent perforation at four weeks. Of these, 1.69% (5/295) required intervention, while the rest healed spontaneously. The median closure time was 12 weeks. All patients with persistent perforation were female. No statistically significant differences were found between groups. Hearing recovery was achieved in 29.1% (74/254) of patients with sudden sensorineural hearing loss. Younger age and non-profound hearing loss were favorable prognostic factors.

Conclusion: The incidence of perforation in this study is lower than that previously reported but consistent with other studies in the literature. Intratympanic steroid injections remain beneficial, outweighing the risks of complications.

Keywords: Tympanic membrane perforation; intratympanic steroid injection; sudden sensorineural hearing loss (Siriraj Med J 2025; 77: 267-277)

INTRODUCTION

Idiopathic sudden sensorineural hearing loss (ISSNHL) is a critical condition in otological practice, affecting individuals of all ages, with incidence rates increasing with age. Globally, ISSNHL affects 7 to 27 individuals per 100,000 population, though its incidence in Thailand remains undocumented.[1,2] Observations from our neuro-otology clinic between 2006 and 2008 revealed that 7.67% of patients were diagnosed with sudden sensorineural hearing loss (SSNHL).[3] While some cases were non-idiopathic, such as those associated with Meniere's disease, the management approach remains similar.

Systemic corticosteroid has long been the primary treatment for hearing loss, with oral corticosteroids being a common systemic approach.[4] However, systemic corticosteroid use is associated with adverse effects, including weight gain, sleep disturbances, gastrointestinal symptoms, and an increased risk of infection. Additionally, systemic steroids pose limitations for certain patient groups, such as those with uncontrolled diabetes mellitus or a history of peptic ulcer disease. As a result, local steroid application has emerged as an alternative approach.

The intratympanic administration of steroids was first introduced by *Itoh et al.* in 1991 for Meniere's disease, and later applied by *Silverstein et al.* in 1996 for ISSNHL.[5,6] This method allows higher concentrations of steroids to reach the inner ear, reducing systemic adverse effects. Numerous studies have since demonstrated its effectiveness in treating ISSNHL.[7-11] Intratympanic steroid injection, using steroids such as methylprednisolone and dexamethasone, has been used to treat various conditions, including Meniere's disease and labyrinthitis, serving as both first-line and salvage therapy.[12]

While generally safe, intratympanic injections can cause complications, including transient pain, dizziness, or tinnitus.[13] Persistent tympanic membrane perforation is the most concerning side effect, though studies report a low incidence of 1-2%.[14-16] However, a retrospective study in Thailand found a higher incidence rate of 7.18%, potentially due to differences in definition and criteria used.[17] This study aims to determine the incidence of tympanic membrane perforation at 4 weeks post-intratympanic steroid injection and to investigate potential risk factors, such as steroid type, needle gauge, and injection frequency, that may affect tympanic membrane perforation.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board (IRB), with approval code COA no. Si 218/2022.

Sample size

The sample size was calculated using an estimation for categorical outcome with the following formula.

$$n = \frac{z^2_{1-\frac{\alpha}{2}}\, p(1-p)}{d^2}$$

p = expected proportion in population based on literature review[16] = 0.0114
z = standard normal variate P values < 0.05
d = absolute error = 0.0126

The calculated sample size was 273. After adjusting for a 10% allowance for missing data, the final expected N was 300.

Study population

A retrospective review was conducted on individuals who received intratympanic steroid injections at a tertiary care center from March 2018 to March 2021. Patients were identified using the International Classification of Diseases (ICD-10) code for "injection of tympanum" from the electronic database. Indications for steroid injections included ISSNHL, Meniere's disease, and labyrinthitis. Subjects with incomplete data, those lost to follow-up, tympanic membrane perforation at the injected or ventilation site before injection, and those who received gentamycin injections were excluded from the study.

Outcome assessment

The primary outcome was the percentage of persistent tympanic membrane perforations, defined as a perforation present at least 4 weeks after the last injection, confirmed through otoscopic or microscopic examination. The healing time in the protracted closure group was analyzed descriptively in weeks. Factors such as age, gender, diabetes mellitus, smoking, radiation exposure, type of steroid, number of injections, and prior systemic steroid use were considered as potential predictors. These factors were statistically analyzed to compare outcomes between the spontaneous tympanic membrane closure group and the perforation group.

Statistical analysis

The perforation rate was reported as a percentage, with comparisons between the normal and the perforation groups made using the Mann-Whitney U test and Fisher Exact test for continuous and categorical variables, respectively. A p-value <0.05 was considered statistically significant. Data collection and statistical analysis were conducted using SPSS version 22.

Procedure

After obtaining informed consent, the patient was positioned in the supine position with the head tilted toward the unaffected side. Local anesthesia with lidocaine was applied to the external ear canal. Under microscopic visualization, a ventilation hole was created at the anterosuperior portion of the tympanic membrane using a 25G needle tip. Subsequently, the steroid was then injected into the posteroinferior part of the drum, using the same 25G needle. Each injection administers 0.4-0.8 ml of steroid into the middle ear cavity. Patients were instructed to maintain in a lateral position for 30 minutes, without talking or swallowing. The injection was administered up to four times within a two-week period for one course. However, some subjects underwent fewer than four injections due to complications, but these patients were still included in the study. Hearing evaluations, including an audiogram, were conducted at initial diagnosis and repeated within 12 weeks after the last injection.

Operational definition

- Idiopathic sudden sensorineural hearing loss (ISSNHL) is defined as a hearing loss of ≥ 30 dB across at least three consecutive frequencies within a 72-hour period, following the clinical practice guidelines for sudden hearing loss published in 2019.[18]
- Recovery of SSNHL was assessed based on improvement in pure tone average (PTA; the mean hearing level at 500, 1,000, 2,000, and 4,000 Hz), and is categorized into three group according to the clinical practice guidelines[18]:
  - Complete recovery: PTA within 10 dB of the unaffected ear and WRS within 5-10% of the unaffected ear
  - Partial recovery: Defined based on hearing levels during the SSNHL episode.
    - Nonserviceable level: Return to serviceable hearing (PTA ≤ 50 dB and Word recognition score ≥ 50%)
    - Serviceable level: Improvement of PTA by ≥ 10-dB HL or WRS ≥ 10%
  - No Recovery: <10-dB HL improvement
- Persistent perforation is defined as a perforation present 4 weeks or more after the last injection, confirmed through otoscopic or microscopic examination.

RESULTS

A total of 320 subjects coded for the 'injection of tympanum' procedure, as per ICD-10 criteria, were initially recruited from the electronic database for this study. However, 42 subjects were excluded for various reasons: 27 had inadequate follow-up, 10 received injections with different medications, such as gentamicin, two were excluded due to incorrect ICD coding, and three had incomplete data. Ultimately, this left 278 subjects who met the study's inclusion criteria.

Among the 278 subjects, 15 received more than one course of injections. Of these, three subjects presented with bilateral SSNHL, resulting in steroid injections

administered in both ears. Additionally, one subject, with Meniere's disease, underwent three courses of steroid injections over the study period. Furthermore, 11 patients experienced fluctuating hearing loss, with 10 receiving two courses of injections, and 1 receiving three courses. In total, 295 ears from 278 subjects were included in the analysis.

The demographic characteristics of the study population are summarized in Table 1. Females made up 63.1% of the subjects, with a median age of 58 years (range: 9 to 86 years). The median time from onset of hearing loss to treatment was 7 days (range: 1 to 60 days). At the onset of hearing loss, the median pure tone average (PTA) was 65 dB (range: 10 to 120 dB). The primary indication for intratympanic steroid injections was SSNHL, accounting for 86% of cases, while the remaining cases included Meniere's disease (13%) and labyrinthitis (1%).

TABLE 1. Demographic data.

Characteristic	Number of ears (%)
Age (years; min, max)	58 (9, 86)
Gender	
Male	109 (36.9)
Female	186 (63.1)
Diabetes mellitus	
DM	79 (26.8)
Non-DM	216 (73.2)
Side of affected ear	
Right	160 (54.2)
Left	135 (45.8)
Objective	
Primary	104 (35.3)
Salvage	191 (64.7)
Type of steroid	
Methylprednisolone	257 (87.1)
Dexamethasone	33 (11.2)
Both	5 (1.7)
Onset of hearing loss (days; min, max)	7 (1, 60)
PTA before treatment	
< 80 dB	193 (65.4)
≥ 80 dB	102 (34.6)

Abbreviations: DM, Diabetes mellitus; PTA, Pure tone average

At 4 weeks after the final injection , 10 subjects (3.39%) exhibited persistent tympanic membrane perforation. Of these, five cases (50%) achieved spontaneous closure, though the healing period extended beyond the 4-week cutoff, with a median healing time of 12 weeks (range: 6 to 50 weeks). The remaining five subjects required procedural intervention to close the perforation. Three of these subjects underwent office-based paper patch myringoplasty, one underwent tympanoplasty, and one subject, despite having a persistent perforation, declined any intervention.

All subjects in the persistent perforation group were female. Other factors did not show statistically significant differences between the spontaneous closure group and those with persistent perforation, as shown in Table 2. Ex-smokers who had abstained for more than 4 weeks were classified as non-smokers, as previous literature suggests that smoking cessation for at least four weeks improves wound healing.[19-21] None of the subjects in the perforation group had a history of radiation exposure to the head and neck region. Methylprednisolone was the most commonly used steroid in both the perforation group (80%) and the normal-healing group (87.4%). Although a full course of treatment generally involves four injections, eight subjects (2.8%) in the spontaneous closure group received fewer than four injections. No significant differences were observed between subjects who required procedural intervention for tympanic membrane perforation and those who did not, including those without perforation and those with delayed spontaneous closure, as shown in Table 3. Detailed data on subjects with perforations persisting beyond 4 weeks are presented in Table 4.

All subjects in the group requiring procedural intervention for perforation received four injections, with 90% having a history of systemic steroid use. Among these 10 cases, 8 (80%) received methylprednisolone injections, while two (20%) received dexamethasone. Both subjects who received dexamethasone had large perforations, measuring 20% and 30%, respectively. One notable case involved a 59-year-old female with no underlying disease, who presented with SSNHL and underwent tympanoplasty after receiving four doses of dexamethasone as salvage treatment. Her tympanic membrane perforation measured 20% at the injection site and did not close after 27 weeks of follow-up.

Hearing recovery rates were assessed in 254 subjects for whom SSNHL was the indication for intratympanic steroid injection. The overall recovery rate was 29.1% (74/254), with 14.6% (37/254) achieving complete recovery and 14.6% (37/254) partial recovery. The remaining 70.9%

TABLE 2. Comparison of potential factors associated with persistent TM perforation and spontaneous TM closure at 4 weeks after last injection.

	Persistent TM perforation (N = 10) Number of ears (%)	Spontaneous TM closure (N = 285) Number of ears (%)	P value	OR (95%CI)
Age (years; min, max)	57.5 (42,77)	58 (9,86)	0.550	-
Gender				
Female	10 (100)	176 (61.8)	**0.015**	-
Male	0 (0)	109 (38.2)		
Diabetes mellitus				
DM	2 (20)	77 (27)	1.000	0.68
Non-DM	8 (80)	208 (73)		(0.14-3.25)
Smoking*				
Current smoker	0 (0)	4 (2.6)	1.000	-
Non-smoker or quit > 4 weeks	5 (100)	152 (97.4)		
Radiation (Head and neck)				
Yes	0 (0)	3 (1.1)	1.000	-
No	10 (100)	282 (98.9)		
Prior systemic steroid				
Yes	9 (90)	186 (65.3)	0.173	4.79
No	1 (10)	99 (34.7)		(0.60-38.36)
Type of steroid				
Dexamethasone	2 (20)	36 (12.6)	0.623	1.73
Methylprednisolone	8 (80)	249 (87.4)		(0.35-8.47)
Number of injections				
4 times	10 (100)	277 (97.2)	1.000	-
< 4 times	0 (0)	8 (2.8)		

*missing data 45.4%

Abbreviations: TM, Tympanic membrane; DM, Diabetes mellitus; OR, Odd ratio

(180/254) showed no recovery. Fig 1 illustrates a subgroup analysis of recovery rates, categorizing subjects into two groups based on initial hearing levels: serviceable and non-serviceable hearing. The serviceable hearing group had an overall recovery rate of 44% (29/66), with 32% (21/66) achieving complete recovery and 12% (8/66) achieving partial recovery. In contrast, the non-serviceable group had a complete recovery rate of 9% (16/188) and a partial recovery rate of 15% (29/188), with an overall recovery rate of 24% (45/188).

The mean improvement in pure tone average within 12 weeks after the last injection was 11.55 ± 20.57 dB. Factors potentially associated with hearing recovery are presented in Table 5. Age and initial hearing level were found to be significantly associated with hearing recovery. Subjects aged 60 years and older had a relative risk of non-recovery hearing of 1.30 (95% CI: 1.11 to 1.53) compared to younger subjects. Those with profound hearing loss at the onset had a higher risk of non-recovery, with a relative risk of 1.35 (95% CI: 1.17 to 1.57) compared to those with an initial PTA of less than 80 dB. Gender, underlying conditions such as diabetes mellitus, type of steroid used, the number of injections, and onset of hearing loss were not significantly associated with recovery.

TABLE 3. Comparison of potential factors associated with TM perforation in subjects undergoing the procedure and no procedure group.

	TM perforation underwent procedure (N = 5) Number of ears (%)	No procedure (N = 290) Number of ears (%)	P value	OR (95%CI)
Age (years; min, max)	59 (51,72)	58 (9,86)	0.621	-
Gender				
Female	5 (100)	181 (62.4)	0.162	-
Male	0 (0)	109 (37.6)		
Diabetes mellitus				
DM	1 (20)	78 (26.9)	1.000	0.68
Non-DM	4 (80)	212 (73.1)		(0.08-6.17)
Smoking*				
Current smoker	0 (0)	4 (2.5)	1.000	-
Non smoker or quit > 4 weeks	2 (100)	155 (97.5)		
Radiation (Head and neck)				
Yes	0 (0)	3 (1)	1.000	-
No	5 (100)	287 (99)		
Prior systemic steroid				
Yes	5 (100)	190 (65.5)	0.171	-
No	0 (0)	100 (34.5)		
Type of steroid				
Dexamethasone	2 (40)	36 (12.4)	0.126	4.70
Methylprednisolone	3 (60)	254 (87.6)		(0.76-29.12)
Number of injection				
4 times	5 (100)	282 (97.2)	1.000	-
< 4 times	0 (0)	8 (2.8)		

Abbreviations: TM, Tympanic membrane; DM, Diabetes mellitus

DISCUSSION

Steroid administration via intratympanic injection is an effective treatment for ISSNHL and other inner ear conditions such as Meniere's disease and labyrinthitis. However, this procedure can lead to complications, the most significant being tympanic membrane perforation. Previous studies including retrospective reviews, systematic reviews, and meta-analyses, have documented the rate of tympanic membrane perforation following intratympanic injections to range between 1.14% to 2.9%.[14-16]

In Thailand, a study by *Limviriyakul et al.* using a retrospective chart review at a tertiary care hospital and reported a perforation rate of 7.18%, significantly higher than rates observed in international studies.[17] This discrepancy may be attributed to differences in criteria for defining persistent perforation or the type of steroid used. In our current study, the incidence of persistent tympanic membrane perforation was 3.39% across 295 ears, which is lower than Limviriyakul's findings but more closely aligns with rates reported in international literature.[14-17]

Several factors could explain the lower perforation rate observed in this study. First, intratympanic steroid injections have been increasingly used in our clinical setting over the past few years, and the sample size for this study was calculated to adequately evaluate the rate of tympanic membrane perforation. Secondly, Limviriyakul's study did not specify the timeframe for evaluating tympanic

TABLE 4. Details of subjects with persistent perforation more than 4 weeks after last injection.

	Age (years)	Sex	Risk	Disease	Prior steroid	Injection Count (times)	Steroid type	Size	Site	Duration (weeks)	Procedure
1	54	F	None	SSNHL	Yes	4	Methylpred	pinpoint	Injected	23	Paper patch
2	51	F	None	SSNHL	Yes	4	Methylpred	pinpoint	Injected	12	No
3	77	F	DM (HbA1C = 6)	SSNHL	Yes	4	Methylpred	pinpoint	Ventilation	16	No
4	59	F	None	SSNHL	Yes	4	Dexa	20%	Injected	27	T-plasty
5	73	F	None	SSNHL	No	4	Methylpred	pinpoint	Injected	12	No
6	51	F	None	SSNHL	Yes	4	Dexa	30%	Injected	9	Paper patch
7	72	F	DM (HbA1C = 8.1)	SSNHL	Yes	4	Methylpred	20%	Injected	*	Follow up
8	56	F	None	Meniere	Yes	4	Methylpred	pinpoint	Ventilation	50	No
9	42	F	None	SSNHL	Yes	4	Methylpred	10%	Injected	6	No
10	67	F	None	Meniere	Yes	4	Methylpred	pinpoint	Injected	7	Paper patch

Abbreviations: F, Female; DM, Diabetes mellitus; SSNHL, Sudden sensorineural hearing loss; Methlypred, Methylprednisolone; Dexa, Dexamethasone

*Subject with persistent perforation refused intervention

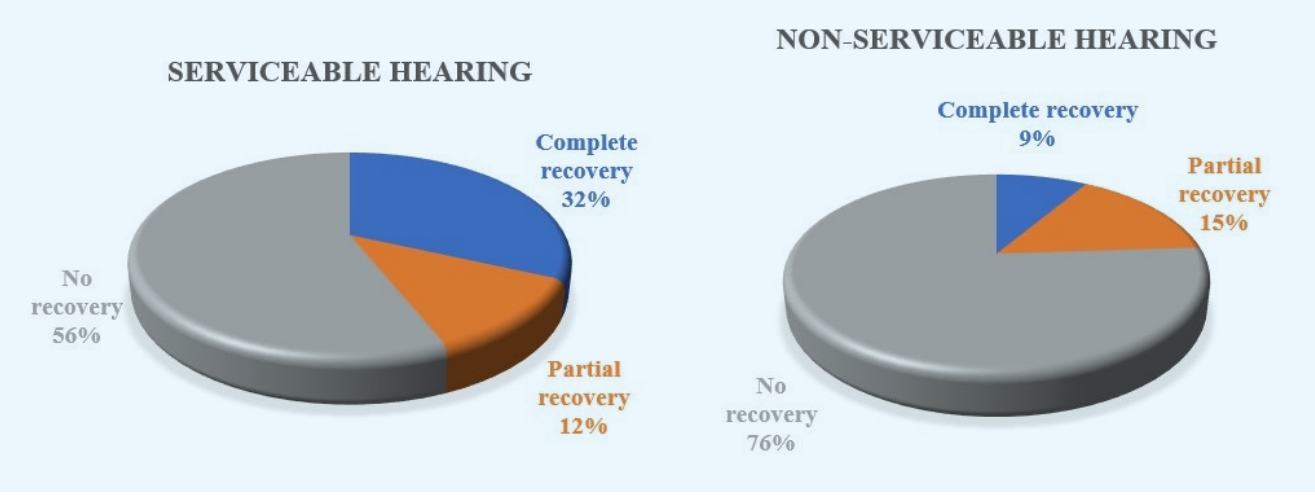


Fig 1. Recovery rates in initial serviceable hearing vs non-serviceable hearing group.

TABLE 5. Comparison of potential factors associated with recovery vs. non-recovery groups

	Non-recovery (N = 180) Number of ears (%)	Recovery (N = 74) Number of ears (%)	P value	Relative risk (95% CI)
Age				
≥ 60 years	99 (80.5)	24 (19.5)	**0.001**	**1.30**
< 60 years	81 (61.8)	50 (38.2)		**(1.11 to 1.53)**
Gender				
Female	111 (68.9)	50 (31.1)	0.375	0.93
Male	69 (74.2)	24 (25.8)		(0.79 to 1.09)
Underlying disease				
Yes	110 (75.3)	36 (24.7)	0.068	1.16
No	70 (64.8)	38 (35.2)		(0.98 to 1.37)
Diabetes mellitus				
DM	54 (74)	19 (26)	0.489	1.06
Non-DM	126 (69.6)	55 (30.4)		(0.90 to 1.26)
Type of steroid				
Dexamethasone	19 (70.4)	8 (29.6)	0.952	0.99
Methylprednisolone	161 (70.9)	66 (29.1)		(0.77 to 1.28)
Objective				
Salvage	119 (69.6)	52 (30.4)	0.521	0.95
Primary	61 (73.5)	22 (26.5)		(0.80 to 1.11)
Number of injections				
4 times	175 (70.9)	72 (29.1)	1.000	0.99
< 4 times	5 (71.4)	2 (28.6)		(0.62 to 1.60)
Onset of hearing loss*				
>14 days	42 (79.2)	11 (20.8)	0.112	1.17
≤ 14 days	134 (68)	63 (32)		(0.99 to 1.38)
PTA before injection				
≥ 80 dB	82 (84.5)	15 (15.5)	**<0.001**	**1.35**
< 80 dB	98 (62.4)	59 (37.6)		**(1.17 to 1.57)**

*missing data 1.6%

Abbreviations: DM, Diabetes mellitus; PTA, Pure tone average

membrane status post-injection, whereas this study assigned a clear 4-week post-injection evaluation period. In the literature, timeframes for evaluating persistent tympanic membrane perforations vary, ranging from 4 to 12 weeks.[14,16] In this study, the evaluation was set at 4 weeks or later after the last injection, based on findings from *Simani et al.'s* systemic review, which indicated that most perforations would heal within this period.[16] However, our observations indicated a median healing time of 12 weeks, with three subjects initially categorized as having persistent perforations eventually experiencing spontaneous healing within 12 weeks. This suggests that a 12-week evaluation period may be more appropriate for assessing persistent perforation in clinical practice.

Among the 10 subjects in the perforation group, five required procedural intervention to close the perforation, resulting in an incidence rate of 1.69% for persistent tympanic membrane perforations requiring a procedure.

However, two of these patients underwent interventions at 7- and 9-weeks post-injection, and it is possible that their perforations might have healed spontaneously with a longer observation period. Predictors of persistent perforation are divided into two categories: host-related factors affecting immune status and wound healing, and procedure-related factors. The first category included diabetes mellitus, smoking, radiation exposure, and HIV infection, while the second group involved variables such as prior steroid usage, number of injections, and type of steroid. These factors were analyzed by comparing the persistent perforation group with the spontaneous closure group, as well as the procedural and non-procedural groups.

In the first group of factors, gender was the only variable that showed a statistically significant difference between the persistent perforation group and the spontaneous closure group. This finding contradicts other studies, which found no association between gender and perforation healing.[22-24] This discrepancy is likely coincidental and not clinically relevant.[14,15] Other factors, including smoking, radiation, and HIV status, showed no statistical significance, consistent with previous literature. Due to incomplete medical records for 45.4% of subjects, smoking data could not be fully analyzed, as detailed smoking histories were rarely documented in outpatient visits. In the second group of procedural factors, there was no statistical difference between the persistent perforation and spontaneous closure groups, nor between the procedural and non-procedural groups. This may be attributed to the relatively low incidence of perforation in this cohort.

Most of the studies in the systemic literature reviews used dexamethasone for injections, whereas in our practice, methylprednisolone has been the preferred steroid since 2007 due to its higher concentration and longer duration of action.[25,26] Although we hypothesized that steroid type might influence the perforation rate, this study found no statistical association between steroid type and perforation. However, Table 5 shows that two subjects who received dexamethasone injections had larger perforations that did not heal spontaneously. Topf's study suggested that multiple injections might increase the risk of persistent perforation.[14] In this study, most subjects received four injections, and while eight subjects in the spontaneous closure group received fewer than four, all subjects in the persistent perforation group received the full four injections. This may lend some support to the hypothesis that multiple injections could increase perforation risk, though the small number of persistent perforations limits the strength of this conclusion.

Diabetes mellitus was expected to be associated with delayed perforation healing. Although this study showed no significant association between diabetes and perforation healing, subjects with poorly controlled diabetes appeared to have a higher risk of persistent perforation, which is consistent with previous studies.[14,22,27] Two subjects in the persistent perforation group had diabetes. One had well-controlled diabetes with an HbA1c level of 6.0 and experienced perforation healing within 16 weeks. The other subject, with poorly controlled diabetes and an HbA1c level of 8.1, did not experience spontaneous healing.

In addition to evaluating perforation rates, this study also assessed hearing recovery outcomes. According to the 2019 Clinical Practice Guideline, the prognosis for hearing recovery depends on factors such as age, the presence of vertigo at onset, degree of hearing loss, audiometric configuration, and the duration between onset and treatment.[18] In this study, factors including age, hearing level, and onset-to-treatment duration were evaluated, along with additional factors like gender, underlying disease, diabetes mellitus, type of steroid used, purpose of injection, and number of injections. Subjects aged 60 years or older, and those with an initial PTA of greater than 80 dB, had a higher risk of no hearing recovery after the injection.[17,28-31] These findings align with other studies that identified age and degree of hearing loss at onset as poor prognostic factors. However, factors such as onset of hearing loss and underlying disease, often considered relevant to hearing recovery, were not statistically significant in this study.[17,28] This may be due to the study's sample size, which was calculated to evaluate tympanic membrane perforation repair rates, potentially limiting its power to detect smaller differences in hearing recovery.

The total overall hearing recovery rate in subjects with SSNHL was 29.1%, a rate comparable to the spontaneous recovery rates reported in the literature.[29,32] A subgroup analysis showed a 44% recovery rate in subjects with serviceable hearing at onset, compared to a 24% recovery rate in those with non-serviceable hearing, further supporting the degree of hearing loss at onset as a critical prognostic factor for recovery.

Limitation

A previous study by *Simani et al* reported time to perforation healing in days after injection and compared healing duration between risk and non-risk groups.[16] In this study, healing time was recorded in weeks, as patients were scheduled for weekly follow-ups in our practice. Data on healing duration for the spontaneous perforation

closure group were unavailable, as most patients were seen for tympanic membrane examination 1-2 weeks post-injection, depending on the physician's discretion. At the first post-treatment visit, medical records noted either a normal tympanic membrane or a hematoma at the injection site without perforation, making It difficult to determine the exact timing of perforation closure in the spontaneous perforation closure group.

Previous ear conditions, including prior trauma, history of infection, and the status of the eustachian tube, may influence perforation healing time. However, due to the retrospective nature of this study, data on these factors are limited and therefore excluded from the analysis.

Expected Benefit and application

The findings from this study enable physicians to better counsel patients on the expected outcomes of intratympanic injection procedures. Comprehensive medical advice, including potential complications and anticipated recovery rates, can be provided and included in the consent form prior to the procedure. For future studies, a 12-week evaluation period after the final injection is recommended for assessing tympanic membrane status.

CONCLUSION

The rate of persistent tympanic membrane perforation following intratympanic steroid injection is low, indicating a favorable risk-benefit ratio. Based on the data gathered from this study, 12 weeks appears to be the optimal timeframe for assessing tympanic membrane status, serving as a cutoff to differentiate subjects with and without perforations. Regarding hearing recovery, younger patients and those with less severe hearing loss at onset were more likely to experience recovery following intratympanic injection.

Data Availability Statement

The data that support the findings of this study are available upon request from the corresponding author, [K.S.]. The data are not publicly available due to containing information that could compromise the privacy of research participants.

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DECLARATION

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Conflict of Interest

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Registration number of clinical trial

None

Author Contributions

S.P.; Conceptualization, Methodology, Investigation, Data Curation, Writing - Original Draft, Review & Editing, Supervision V.C.; Methodology, Data Curation, Formal analysis, Writing - Original Draft P.P.; Supervision,Writing - Review & Editing, Validation S.A.; Methodology, Writing - Review & Editing, Validation K.T.; Conceptualization, Resources, Formal analysis, Writing - Original Draft, Validation S.L.; literature review, Methodology, Formal analysis, Writing - Original Draft, Validation K.S.; Conceptualization, Data Curation, Writing - Review & Editing.

Use of Artificial Intelligence

None

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