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ORIGINAL RESEARCH

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Post-stapedotomy dizziness after applying topical steroid on footplate: A randomized controlled trial

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Abstract

Background: Otosclerosis is characterized by abnormal bone growth in the otie capsule. Nowadays, stapedotomy is commonly used for otosclerosis treatment. Currently, postoperative dizziness has been associated with stapedotomy. In 1981, intratympanic dexamethasone was utilized to manage inner ear disorders like tinnitus and acute sensorineural hearing loss. However, there is much uncertainty regarding the effect and safety of topical steroid therapy in the middle ear during stapedotomy. In the present study, we assessed the effect of topical steroid therapy during stapedotomy on postoperative dizziness.

Methods: Otosclerosis patients eligible for stapedotomy were randomly divided into two groups based on dexamethasone administration or placebo. Audiometric and tympanometry results were observed and recorded for the involved frequencies. The Dizziness Handicap Inventory was used to quantify patient perceptions of dizziness and balance issues. Audiometry and dizziness assessments were repeated at discharge and 4 months after the operation.

Results: The study comprised 72 otosclerosis patients undergoing stapedotomy. At discharge, the intervention group showed a significant reduction in the incidence of dizziness compared to the placebo group. However, in the 4-month follow-up after the operation, both groups experienced a decrease in dizziness incidence, with no significant difference between them. There was also no significant difference in audiometric levels between the two groups. Interestingly, the intervention group had a significantly lower need for systemic anti-dizziness drugs after surgery compared to the control group.

Conclusion: Topical dexamethasone during stapedotomy effectively minimizes dizziness at discharge and reduces the need for postoperative anti-dizziness medication.

Level of evidence: 2.

KEYWORDS
corticosteroid, dizziness, otosclerosis

1 | INTRODUCTION

Otosclerosis is a disease of the otic capsule characterized by abnormal new bone formation. Otosclerosis patients experience sensorineural, conductive, or mixed hearing loss.[1,2] Treatment options typically involve medication or surgery. Stapedectomy or stapedotomy are preferred surgical treatment choices.[3] On the other hand, less commonly, some health professionals opt for medical treatments using bisphosphonates or fluoride compounds, usually during the early stages of the disease, either separately or in conjunction with calcium and vitamin D. Glucocorticoids and calcitonin have also been considered in otosclerosis with sensorineural component.[4–6]

Shea introduced the surgical treatment of otosclerosis in 1956; however, the technique underwent many changes since then. Currently, stapes surgery is a relatively efficient and safe procedure.[7] Stapedotomy could be performed by laser or manual perforators.[8] Recently, it has been proposed that radiological incudo-stapedial angle could be of predictive value in assessment of reverse stapedotomy feasibility.[9] The small fenestra stapedotomy has more favorable audiological outcomes and fewer complications than stapedectomy.[7] However, one of the adverse effects of stapedotomy is dizziness, with an incidence ranging from 3.4% to 55%.[10] One of the possible causes of post-stapedotomy dizziness is membranous labyrinth irritation, primarily affecting the utricle's macula due to its proximity to the fenestra. Perilymph aspiration is another contributing factor to early dizziness. Fortunately, severe dizziness resolves entirely within about 6 days without any discomfort for some individuals. Although most studies on otosclerosis surgery have focused on hearing thresholds, postoperative dizziness can negatively impact the patient's quality of life and prolong hospital stays and medical therapy.[11,12] Besides, dizziness and its effect on the quality of life after stapedotomy has not been thoroughly studied in the literature.[13]

Since 1981, intratympanic dexamethasone administration has been employed as the freestanding treatment, combined with other therapies, or as a rescue treatment for inner ear disorders (e.g., tinnitus), and sudden sensorineural hearing loss.[14] Previous research found that a 4 mg/mL intratympanic dexamethasone injection had no adverse effects on outer hair cell activity, as determined by otoacoustic emissions; thus, it was considered safe.[15] Additionally, studies showed that intratympanic dexamethasone has a 47%–91% efficacy rate in reducing vertigo in patients with Meniere disease.[16] Dexamethasone's effectiveness has been associated with its anti-inflammatory mechanisms within the labyrinth, Na^+ ion control, and osmotic homeostasis.[17]

However, research on the efficacy of using corticosteroids during stapedotomy to reduce postoperative dizziness has been limited. Therefore, the objective of this study was to assess the impact of topical administration of dexamethasone on the middle ear during stapedotomy on post-stapedotomy dizziness.

2 | MATERIALS AND METHODS

2.1 | Design overview

This trial was a prospective, two-arm, double-blinded, placebo-controlled clinical trial conducted at Taleghani Hospital. The study was approved by the local ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.MSP.REC.1401.358), and the trial was registered with IRCT under trial number (IRCT20221114056502N1). All participants gave written informed consent.

2.2 | Setting and participant eligibility

The current study was performed at the Department of Otolaryngology and Head and Neck Surgery, Taleghani Hospital, Tehran, Iran. The inclusion criteria were as follows: Adults who had otosclerosis based on the negativity of Reine's test with a 512 Hz tuning fork, an air-bone gap of at least 20 dB in 0.5, 1, 2, and 3 kHz, and were a surgical candidate. All participants were at least 18 years old. Exclusion criteria composed of sensitivity to corticosteroids, asthma, hypertension, a history of middle ear surgery, and anti-vertigo medication consumption within the prior month.

2.3 | Sample size calculation

According to the study by İnan et al.[13] we calculated the sample size with alpha set at 0.05 and power at 0.8. The estimated sample size to detect a clinically meaningful effect was set at 35 patients in each group. Considering 10% drop out, we set the sample size to 37 patients allocated to each group.

2.4 | Randomization and interventions

Participants were randomized 1:1 into two groups: topical dexamethasone (intervention group) and 0.9% NaCl (control group) using the block randomization method with blocks of four.

Both the participants and researchers were blinded in terms of the allocated treatments throughout all aspects of data collection. The medication (dexamethasone or 0.9% NaCl) was aspirated into a syringe and labeled as A or B by one person out of the research team. Then, the labeled syringe, according to the group, was provided to the surgeon to administer. The allocation of groups was concealed to all research team members and the patient. All surgeries were performed by the senior author of this article in standard academic settings.

The Dizziness Handicap Inventory (DHI) questionnaire was employed to measure postoperative dizziness. Additionally, the amount of anti-vertigo medication was recorded. Patients did not receive any systemic corticosteroids during postoperative hospitalization. A 25 mg intra-muscular promethazine was prescribed if the patient experienced severe dizziness, preventing the patient from walking.

2.5 | Procedure

On treatment day 1, after providing written informed consent, participants underwent an initial baseline audiometric assessment. Then, all

participants underwent small fenestra stapedotomy using a microdrill (7 mm diameter diamond burr, Gyrus Medical Ltd., Castleton Court Fortran Road, St Mellons, Cardiff CF3 0LT, United Kingdom) under general anesthesia. We used a reverse stapedotomy technique in our patients. The steps of the surgery were as follows: (1) tympanomeatal flap removal; (2) for an adequate view of the footplate and facial canal in required cases, the posterior part of the external auditory canal was curetted; (3) footplate fenestration using micro drill (0.7 mm); (4) implantation and fixture of a Teflon prosthesis (0.6-mm diameter and 4.25 mm length); (5) incudostapedial joint and stapes tendon separation, and down fracture of the stapes supra structure and remove; (6) establishing support for the base by soft tissues.

In the intervention group, 0.5 cm^3 of dexamethasone (Caspian tamin) was administered to the middle ear around the stapes footplate immediately before prosthesis placement under microscopic vision (between the third and fourth steps). In the control group, instead of dexamethasone, 0.5 cm^3 of normal saline was dripped at the same location, and then a stapedotomy was performed.

Baseline questionnaires were composed of demographic and clinical data and baseline dizziness assessment by DHI, which was completed by all participants. Potential adverse effects of the assigned steroid and disease-related symptoms were assessed in follow-up.

2.6 | Outcomes and follow-up

Demographic data of patients, including age, gender, comorbidities, and drug sensitivity, were obtained. The audiometric results of the patients were recorded. We used the DHI in this study to quantify patient perceptions regarding any dizziness or balance problems. The DHI is a 25-item self-report questionnaire that quantifies the impact of dizziness on daily life by measuring self-perceived handicaps. The total score is the sum of all item scores. The maximum total score is 100 (28 points for physical, 36 points for emotional, and 36 points for functional), and the minimum is 0. Moreover, the physical subscale of DHI has a possible score range of 0–32, with higher scores indicating a more significant handicap (16).

We assessed postoperative dizziness with the DHI questionnaire at two time points: the early postoperative assessment (first postoperative day) and fourth postoperative month. Also, patients were followed on the seventh day for any surgical complications. Additionally, participants' hearing status was assessed at baseline and at the 4th postoperative month via audiometric evaluation.

Patients who did not complete the follow-ups were excluded from the study.

2.7 | Statistical analysis

The continuous variables are summarized as mean ± SD, and categorical variables are presented as frequency (percentage). The Fisher's exact test and chi-square test were employed for comparison of the categorical variables as required. The *t*-test was employed to compare the means of the two groups. A two-sided *p* value of ≤.05 was set as a statistically significant threshold. All data were analyzed using IBM SPSS Statistics for Windows (version 25, IBM Corporation, Armonk, NY; version 20.0).

3 | RESULTS

3.1 | Study participants

Patients were recruited from July 2021 to December 2022. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is presented in Figure 1. Overall, we screened 110 patients, of which 72 were included in the primary outcome measure final analysis (35 participants in the dexamethasone arm and 37 participants in the placebo arm). Two patients allocated to the control group and three patients allocated to the intervention group did not complete the follow-up; thus, were excluded from the final analysis.

In this trial, 72 patients (26 males) were enrolled. All patients were coequally randomized into two groups. The mean age and gender distribution of participants were similar in both the intervention and placebo groups (Table 1). None of the participants experienced significant inner ear damage in our trial. Notably, no emergency department visits or hospital admissions for stapedotomy-related dizziness were reported by patients within the 4-month follow-up period. Also, none of the participants experienced any worsening in clinical status during the study period. During hospitalization, none of the participants reported a major problem concerning severe vertigo, imbalance, or other corticosteroid-related adverse reactions. The intervention group had a significantly shorter hospital stay compared to the placebo group (1.09 ± 0.28 and 1.44 ± 0.50, respectively, *p*-value <.001).

3.2 | DHI assessment

As summarized in Table 2, at baseline assessment, the DHI score was 2.57 ± 4.05 and 1.64 ± 2.75 in the intervention and placebo groups, respectively (*p*-value = .58). While at the time of discharge, the DHI score was significantly lower in the intervention groups compared to the control group (4.51 ± 4.79 and 6.82 ± 5.10, respectively, *p*-value = .046), the DHI score was comparable between intervention and placebo groups at fourth postoperative month follow-up (*p*-value = .466). Additionally, the need for postoperative systemic anti-dizziness medicine during hospitalization was significantly lower in the intervention group compared to the placebo group (2 (5.7%), 10 (27%), respectively, *p*-value = .039).

3.3 | Audiometric assessment

According to audiometric evaluation, before surgery, the hearing level was 53.46 ± 8.02 and 53.74 ± 7.48 in the intervention and control

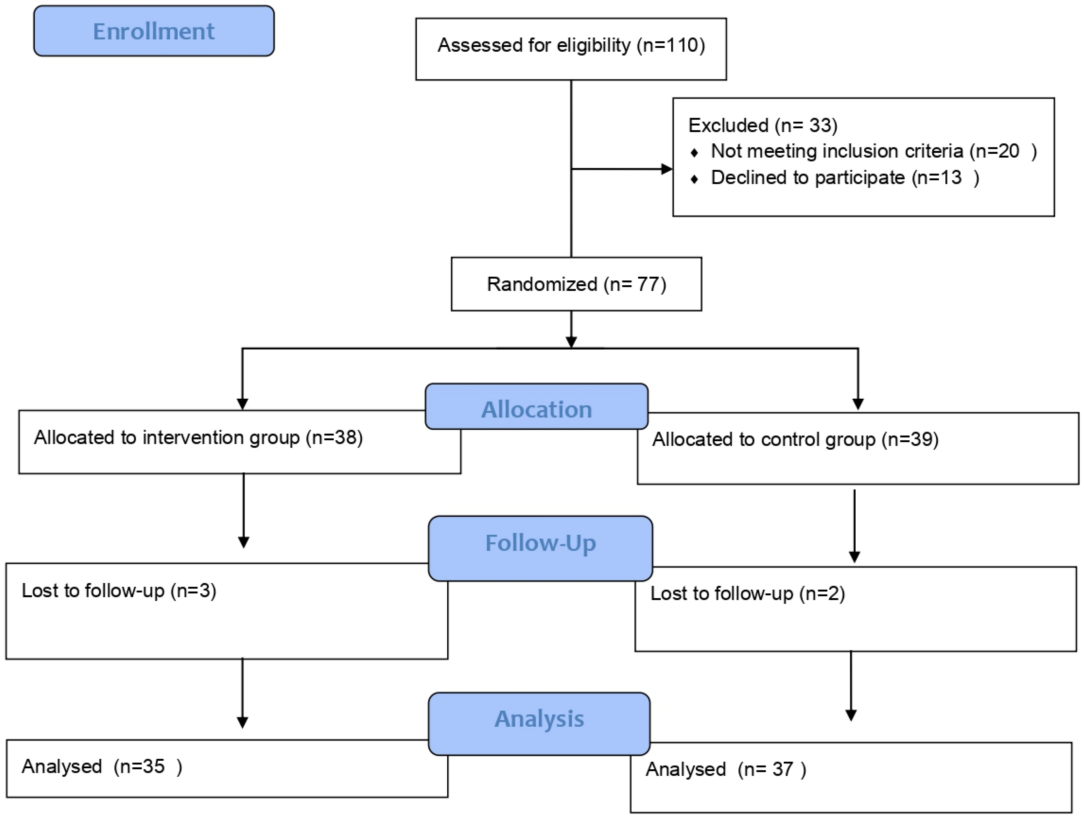

FIGURE 1 CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

TABLE 1 Demographic variables of the study population.

Variables	Groups		*p*-Value
	Intervention ($n = 35$)	Control ($n = 37$)	
Age	43.46 ± 9.84	42.77 ± 10.80	.776
Gender			.634
Female	23 (65.7%)	23 (62.2%)	
Male	12 (34.3%)	14 (37.8%)	

groups, respectively (*p*-value .757). Four months after surgery, the hearing level was still similar in the intervention and placebo groups (*p*-value = .978). The audio gaps were similar across intervention and placebo groups at baseline and fourth postoperative month follow-up.

4 | DISCUSSION

In this randomized, double-blinded, placebo-controlled trial of topical dexamethasone, patients receiving topical dexamethasone on footplate during stapedotomy experienced significantly improved dizziness assessed by DHI at the time of discharge compared to the placebo group. The need for systemic anti-dizziness medication and hospital stay was significantly lower in the dexamethasone group compared to placebo.

The protective effect of corticosteroids on the inner ear in an adult's sudden sensorineural hearing loss has been proven.[18] Besides, various studies demonstrated that corticosteroids could be protective in otologic procedures and cases of cochlear implantation, reducing electrode impedances and vestibular trauma.[19,20] Literature suggests that middle ear administration of corticosteroids allows them to propagate into the inner ear.[21]

Based on the fact that corticosteroids might positively impact sensorineural hearing thresholds by protective mechanisms of the inner ear (cochlea), various studies were done. In stapedotomy, the postoperative air-bone gap indicates the function of the implanted piston and the middle ear.[22] Moreover, corticosteroid is suggested to have an inhibitory effect on postoperative granulation tissue growth while alleviating vascular hyperplasia and fibrosis.[23]

Currently, limited evidence is available on the efficacy of topical corticosteroid administration during stapedotomy. Almost all studies investigated systemic corticosteroids. A retrospective study was performed assessing the preoperative administration of corticosteroids on the outcome of CO_2 laser stapedotomy, particularly concerning the audiological outcomes and morbidity. The primary outcome showed that systemic methylprednisolone has a positive effect on audiological outcomes, improving both sensorineural thresholds and closure of the air-bone gap. Additionally, vestibular complications, hospital days, and inner ear damage were similar between the two groups.[24] On the contrary, in our study, patients receiving topical

TABLE 2 The audiometric, tympanometric, DHI, medication need, and hospital stay of the patients.

Variables	Groups		*p*-Value
	Intervention ($n = 35$)	Control ($n = 37$)	
Audio level [dB]			
Before surgery	53.46 ± 8.02	53.74 ± 7.48	.757
4 months after surgery	24.03 ± 5.93	24.15 ± 6.05	.978
Audio gap			
Before surgery	31.57 ± 4.11	31.54 ± 3.55	.969
4 months after surgery	7.03 ± 2.23	6.69 ± 2.34	.405
DHI			
Before surgery	2.57 ± 4.05	1.64 ± 2.75	.580
On the discharge day	4.51 ± 4.79	6.82 ± 5.10	.046
4 months after surgery	1.89 ± 2.65	2.10 ± 2.34	.466
Need for postoperative anti-dizziness medication			.039
Yes	2 (5.7%)	10 (27.0%)	
No	33 (94.3%)	27 (73.0%)	
Length of hospital stay	1.09 ± 0.28	1.44 ± 0.50	<.001

Abbreviation: DHI, Dizziness Handicap Inventory.

dexamethasone during the stapedotomy had a significantly shorter hospital stay compared to placebo group. A shorter hospital stay reduces the total cost and might also alleviate hospitalization complications.

Recently, in 2021, İnan et al.[13] conducted a study on 85 patients evaluating the early postoperative dizziness after dexamethasone injection to the fenestra. During the surgery, they administered four drops of dexamethasone phosphate (0.8 mg/0.2 mL) to fenestra. Finally, this study concluded that dexamethasone administration to the fenestra may reduce dizziness severity and the antiemetic drug (metoclopramide HCl) use frequency within the early post-stapedotomy period. This short-term outcome was in line with our study; however, we must keep in mind that dexamethasone injection into the fenestra seems to be an invasive procedure, and the topical administration of the dexamethasone might have a similar effect. Pneumolabyrinth has been reported following intratympanic steroid injection; however, none of our participants experience such complication.[25] Meanwhile, the comparative effectiveness and safety of dexamethasone topical and injection into the fenestra administration have not been studied.

The observed protective effect of topical dexamethasone administration on postoperative dizziness might be attributable to inhibition of vestibular inflammation. Furthermore, applying the topical form of corticosteroid would mitigate the undesirable adverse systemic effects, elevated blood pressure, and sugar levels, and psychological effects, while achieving higher intra-tympanic concentration. In our study, topical treatment is single-dose topical dexamethasone; thus, adverse effects beyond the acute phase were not expected. Because topical dexamethasone was used during stapedotomy just before prosthesis implantation, this treatment decreases the interval between the vestibular system trauma and the beginning of treatment. The efficacy of topical corticosteroids in conjunction with systemic treatment versus the topical corticosteroid alone and the effectiveness of other forms of topical corticosteroids should be subject to further investigation.

Based on these observations, topical dexamethasone administration could be considered a fairly safe procedure for minimizing post-surgical dizziness in stapes surgery.

4.1 | Strengths and limitations

One of the strengths of this study is the careful consideration of patients as both intervention and placebo, enhancing result accuracy. One of the limitations of this study was the slight imbalance in baseline DHI between groups when evaluated by standardized mean difference (SMD), despite randomization and insignificant *p*-value (SMD = 0.27). Notably, the imbalance was toward higher DHI in the intervention group, and despite this imbalance, patients allocated to the intervention group experienced a significantly lower DHI during follow-ups. The small sample size was the primary limitation of generalizability in this study. Additionally, the use of corticosteroid drops is a specific approach; hence, future research should explore different corticosteroid types and larger sample sizes to enrich understanding.

5 | CONCLUSION

In this trial, the utilization of dexamethasone during stapedotomy (before implanting the prosthesis) significantly reduced the dizziness, the need for anti-dizziness medications during hospitalization, and hospital stay. However, this dizziness-reducing benefit diminished in 4-month follow-up. Based on the study findings, the use of dexamethasone during stapedotomy is recommended as it substantially

alleviates dizziness upon discharge, reduces the reliance on anti-dizziness medications in the aftermath of the procedure, and shortens hospitalization duration.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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REFERENCES

1. Foster MF, Backous DD. Clinical evaluation of the patient with otosclerosis. *Otolaryngol Clin N Am*. 2018;51(2):319-326.
2. Quesnel AM, Ishai R, McKenna MJ. Otosclerosis: temporal bone pathology. *Otolaryngol Clin N Am*. 2018;51(2):291-303.
3. Gillard DM, Harris JP. Cost-effectiveness of stapedectomy vs hearing aids in the treatment of otosclerosis. *JAMA Otolaryngol Head Neck Surg*. 2020;146(1):42-48.
4. Nazarian R, McElveen JT, Eshraghi AA. History of otosclerosis and stapes surgery. *Otolaryngol Clin N Am*. 2018;51(2):275-290.
5. Mansour S, Magnan J, Nicolas K, Haidar H. Otosclerosis. *Middle Ear Diseases: Advances in Diagnosis and Management*. Springer; 2018:1-83.
6. de Oliveira PN, de Oliveira VA. Medical management of otosclerosis. *Otolaryngol Clin N Am*. 2018;51(2):441-452.
7. Shea JJ. Thirty years of stapes surgery. *J Laryngol Otol*. 1988;102(1):14-19.
8. Covelli E, Elfarargy HH, Filippi C, Margani V, Volpini L, Barbara M. Thulium laser in stapedotomy surgery. *Acta Otolaryngol*. 2022;142(3–4):234-240.
9. Barbara M, Elzayat S, El-Shirbeny HA, et al. Assessment of the ability of the radiological incudo-stapedial angle to predict the stapedotomy technique type: a prospective case-series study. *Eur Arch Otorrinolaringol*. 2023;280(11):4879-4884. doi:10.1007/s00405-023-08008-7
10. Alberti A, Figuerola E, Romero-Farina G, Quer M, Larrosa F. Long-term hearing outcomes following stapedotomy in patients with otosclerosis and preoperative small air-bone gap. *Audiol Neurootol*. 2018;22(6):350-355.
11. Isaacson B. Anatomy and surgical approach of the ear and temporal bone. *Head Neck Pathol*. 2018;12(3):321-327.
12. Hamdy MM, El khousht M, Elserafy GM, Saad AM, El Deeb MS. Balance after stapedectomy. *Int J Health Sci*. 2022;6(S1):2150-2160.
13. İnan S, Yilmaz İ, Vural Ö, Yavuz H, Özer F, Hizal E. Effect of dexamethasone administration to the fenestra during stapedotomy on postoperative dizziness. *KBB ve BBC Dergisi*. 2021;29(4):264-270.
14. Sakata E, Itoh A, Ohtsu K, Nakasawa H, Iwashita N. Pathology and treatment of cochlear tinnitus by blocking with 4% lidocaine and decadron infusion. *Pract Otol (Japan)*. 1982;75:2525-2535.
15. Ata N, Öztürk K, Gezgin B. Comparison of the effects of the temperature of intratympanic dexamethasone injections on vertigo. *Am J Otolaryngol*. 2019;40(5):653-655.
16. Weckel A, Marx M, Esteve-Fraysse M-J. Control of vertigo in Ménière's disease by intratympanic dexamethasone. *Eur Ann Otorhinolaryngol Head Neck Dis*. 2018;135(1):7-10.
17. Skarzynska MB, Skarzynski PH. Corticosteroids in otorhinolaryngology. *Corticosteroids—A Paradigmatic Drug Class*. IntechOpen; 2021.
18. Wilson WR, Byl FM, Laird N. The efficacy of steroids in the treatment of idiopathic sudden hearing loss: a double-blind clinical study. *Arch Otolaryngol*. 1980;106(12):772-776.
19. Kiefer J, Ye Q, Tillein J, Adunka O, Arnold W, Gstöttner W. Protecting the cochlea during stapes surgery: is there a role for corticosteroids? *Otosclerosis and Stapes Surgery*. Karger Publishers; 2007:300-307.
20. Ye Q, Tillein J, Hartmann R, Gstoettner W, Kiefer J. Application of a corticosteroid (Triamcinolon) protects inner ear function after surgical intervention. *Ear Hear*. 2007;28(3):361-369.
21. Covelli E, Filippi C, Filipo R, et al. Evaluation of prednisolone and prednisolone sodium succinate concentrations in human plasma and inner ear perilymph during cochlear implantation 24 h after intratympanic injection. *Acta Otolaryngol*. 2022;142(9–12):658-663. doi:10.1080/00016489.2022.2146747
22. Kanona H, Bhutta M, Lavy J. Our approach to revision stapes surgery and the outcomes from 49 procedures at a UK tertiary centre. *Clin Otolaryngol*. 2017;42(4):931-935.
23. Hølund B, Junker P, Christoffersen P, Lyon H, Lorenzen I. The effect of D-penicillamine and methylprednisolone on the morphology of experimental granulation tissue in rats. *Acta Pathol Microbiol Immunol Scand A: Pathology*. 1982;90(1–6):51-55.
24. Székely L, Gáborján A, Dános K, et al. Mid-term evaluation of perioperative i.v. corticosteroid treatment efficacy on overall and audiological outcome following CO_2 laser stapedotomy: a retrospective study of 84 cases. *Eur Arch Otorrinolaringol*. 2020;277:1031-1038.
25. Covelli E, Attanasio G, Cagnoni L, Viccaro M, Filipo R. Pneumolabyrinth after intratympanic steroid injection in patient with prosthesis of the stapes: a case report. *Am J Otolaryngol*. 2013;34(6):759-761.

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