

Effect of Dexamethasone Administration to the Fenestra During Stapedotomy on Postoperative Dizziness

Stapes Cerrahisi Sırasında Fenestra Üzerine Deksametazon Uygulamasının Postoperatif Baş Dönmesi Üzerine Etkisi

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ABSTRACT Objective: To evaluate the effect of dexamethasone administration to the fenestra during stapedotomy on early postoperative dizziness. **Material and Methods:** Of all 85 patients, who underwent stapedotomy for otosclerosis, were divided into 2 groups according to whether dexamethasone was administered immediately after fenestra was opened during surgery. In the dexamethasone group, 4 drops (0.8 mg/0.2 mL) of dexamethasone phosphate was administered to fenestra using a 21-gauge injector immediately after stapedotomy during the surgery. These 2 groups were compared in terms of the severity of postoperative dizziness and its effect on quality of life, hearing thresholds, length of stay in the hospital and drugs used for dizziness. **Results:** The postoperative air-bone gap was 14±6 decibel in both the dexamethasone and control groups. The severity of dizziness on the day of the surgery was 4.68/10 points (range, 2-9) and 5.24/10 points (range, 2-8) in the dexamethasone and control groups, respectively (p=0.048). On the day of discharge, the severity of dizziness was 3.1/10 points (range, 0-9) and 3.78/10 points (range, 1-6) in the dexamethasone and control groups, respectively (p=0.008). The postoperative use of metoclopramide HCl was 0.33±0.764 units and 0.87±1.07 units in the dexamethasone and control groups, respectively (p=0.003). **Conclusion:** The results suggest that dexamethasone administration to the fenestra during otosclerosis surgery may reduce the severity of dizziness and the frequency of antiemetic drug use in the early period after stapedotomy while it has no effect on the hearing thresholds and dizziness in the long term period.

Keywords: Stapedotomy; dizziness; dexamethasone; dizziness handicap inventory; otosclerosis

ÖZET Amaç: Stapedotomi sırasında fenestraya deksametazon uygulamasının erken postoperatif baş dönmesi üzerine etkisini değerlendirmek. **Gereç ve Yöntemler:** Otoskleroz nedeniyle stapedotomi uygulanan toplam 85 hasta, ameliyat sırasında fenestra açıldıktan hemen sonra deksametazon uygulanıp uygulanmamasına göre 2 gruba ayrıldı. Deksametazon grubunda, 4 damla (0,8 mg/0,2 mL) deksametazon fosfat operasyonda stapedotomi hemen sonrası fenestra üzerine 21-gauge enjektör ucundan damlatılmıştır. Bu 2 grup, ameliyat sonrası baş dönmesinin şiddeti ve yaşam kalitesine etkisi, işitme eşikleri, hastanede kalış süresi ve baş dönmesi için kullanılan ilaçlar açısından karşılaştırıldı. **Bulgular:** Ameliyat sonrası hava-kemik aralığı hem deksametazon hem de kontrol gruplarında 14±6 desibel idi. Ameliyat sonrası aynı gün, baş dönmesinin şiddeti deksametazon ve kontrol gruplarında sırasıyla 4,68/10 puan (dağılım 2-9) ve 5,24/10 puan (dağılım 2-8) idi (p=0,048). Taburculuk gününde, baş dönmesi şiddeti deksametazon ve kontrol gruplarında sırasıyla 3,1/10 puan (dağılım, 0-9) ve 3,78/10 puan (dağılım, 1-6) idi (p=0,008). Postoperatif metoklopramid HCl kullanımını deksametazon ve kontrol gruplarında sırasıyla 0,33±0,764 ünite ve 0,87±1,07 ünite idi (p=0,003). **Sonuç:** Sonuçlar otoskleroz cerrahisi sırasında fenestraya deksametazon uygulanmasının stapedotomi sonrası erken dönemde baş dönmesi şiddetini ve antiemetik ilaç kullanım sıklığını azaltabileceğini bunun yanında uzun dönemde işitme eşikleri ve baş dönmesi üzerinde herhangi bir etki oluşturmayacağını düşündürmektedir.

Anahtar Kelimeler: Stapedotomi; baş dönmesi; deksametazon; baş dönmesi engellilik envanteri; otoskleroz

Otosclerosis is a disease of the otic capsule characterized by abnormal new bone formation. Patients with otosclerosis show conductive, sensorineural, or mixed hearing loss.¹ About 40 years ago, Shea de-

scribed the use of stapedectomy and ossicular chain reconstruction for the treatment of conductive hearing loss.² Recently, surgery using stapedotomy to open the small fenestra has been frequently performed.

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Peer review under responsibility of Journal of Ear Nose Throat and Head Neck Surgery.

Received: 3 Aug 2021

Received in revised form: 19 Oct 2021

Accepted: 20 Oct 2021

Available online: 02 Nov 2021

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However, stapedotomy has been associated with the incidence of dizziness, with a frequency ranging from 3.4% to 55%.³ One of the possible causes of dizziness observed immediately after surgery is the irritation of the membranous labyrinth. In particular, the macula of the utricle is affected because of its close proximity to the fenestra. Another cause of early dizziness is the aspiration of perilymph. Although dizziness may be severe in some patients, they completely recover in approximately 6 days without experiencing any discomfort.⁴ In the literature, the results of otosclerosis surgery have usually been evaluated in terms of the patients' hearing thresholds.⁵ Postoperative dizziness after otosclerosis surgery can seriously affect the quality of life of the patient, and prolong the duration of hospital stay as well as medical treatment. However, only a limited number of studies in the literature have investigated dizziness and its effects on the quality of life of patients undergoing stapedotomy.

The administration of intratympanic dexamethasone has been used as a standalone treatment, in combination with other treatments, or as a salvage therapy for inner ear pathologies such as tinnitus since 1981 and sudden sensorineural hearing loss since 1996.^{6,7} Previous studies demonstrated that 4 mg/mL of intratympanic dexamethasone administration did not adversely affect the outer hair cell function measured via otoacoustic emissions, and it was therefore considered safe.⁸ Studies have also demonstrated that intratympanic dexamethasone has an effectiveness of 47-91% in controlling dizziness in patients with Meniere disease.^{9,10} This effect of dexamethasone has been attributed to anti-inflammatory mechanisms within the labyrinth, Na⁺ ion regulation, and osmotic hemostasis.¹¹

The aim of this study was to evaluate the effect of dexamethasone administration to the fenestra during stapedotomy on early postoperative dizziness. In addition, the duration of hospitalization, quality of life, and the need for drugs used to control dizziness were compared between the patients who were and were not administered dexamethasone.

MATERIAL AND METHODS

STUDY DESIGN AND GROUPS

This study was approved by the appropriate Institutional Review Board and Ethics Committee (Baskent University Medical and Health Sciences Research Council and Ethics Committee, Date: 22.05.2020, Number: 94603339-604.01.02) and has been performed according to the ethical standards of the Helsinki Declaration. Informed written consent for surgery was obtained from all patients. This retrospective study included 85 patients who underwent stapedotomy under a diagnosis of otosclerosis at Başkent University Ankara and Adana Hospitals between March 2014 and March 2020. The patients' demographic characteristics, hearing records from the 6 months after and before the surgery (airway and bone conduction pure tone hearing thresholds), as well as data on preoperative dizziness, systemic diseases, severity of dizziness, the effect of postoperative dizziness on the quality of life, duration of hospital stay, and the use of dimenhydrinate, metoclopramide, and ondansetron were obtained from the electronic medical records.

Patients with systemic diseases, those who had experienced preoperative dizziness, had undergone stapedotomy in the other ear, had a history of ear surgery, had undergone revision stapedotomy or stapedotomy with pick, had piston lengths other than 4.5 mm, and were administered intravenous (IV) steroids during surgery were excluded from the study. In total, 71 of 156 patients were excluded from the study due to exclusion criteria. All patients had undergone 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). The phases of the surgery performed under general anesthesia were as follows: 1) removal of the tympanomeatal flap; 2) curettage of the posterior part of the external auditory canal to ensure sufficient view of the footplate and facial canal in required cases; 3) separation of the incudostapedial joint and stapes tendon, as well as fracture of the feet of the stapes; 4) microdrill fenestration (0.7 mm) of the footplate; 5) place-

ment and fixture of a 0.6-mm-diameter Teflon prosthesis (length, 4.5 mm); and 6) supporting the base with soft tissues.

The patients were divided into 2 groups according to whether they were administered dexamethasone. In the dexamethasone group, 4 drops (0.8 mg/0.2 mL) of dexamethasone (dexamethasone-21-phosphate disodium salt, Dexamed 8 mg/2 mL ampoule; Osel Drug Industry and Trade Inc., Turkey) was administered to fenestra using a 21-gauge injector immediately after stapedotomy during the surgery under microscopic vision (between the 4th and 5th steps). With this method, dripping of dexamethasone across the fenestra into the inner ear to bathe the inner ear structures. These patients were operated on by a single surgeon. The use of dexamethasone was the routine practice of the surgeon. The control group included patients who were not administered dexamethasone between the 4th and 5th steps. These patients were operated on by 2 other different surgeons. All surgeries were performed by 3 surgeons working in the same center with more than 10 years of otologic surgery experience. None of these surgeons attended the patient selection process and the data analysis. These 2 groups were compared on the basis of the responses to a postoperative dizziness questionnaire, duration of hospital stay, and drugs used for controlling dizziness. The quantities of dimenhydrinate (Dramamine 50 mg ampoule; Ali Raif Drug Industry Inc., Turkey) used during the hospital stay as well as those of metoclopramide HCl (10 mg Metpamid ampoule; Sifar Drugs Trade and Industry Inc., Turkey) or ondansetron (Zofran 4 mg/2 mL Injection; Glaxo Smith Kline Pharmaceuticals Industry and Trade Inc., Turkey) used for treating nausea and vomiting were also recorded.

The severity of dizziness was determined from routine medical records, and was recorded separately for the early postoperative period (the day of surgery) and the day of discharge. Accordingly, the severity of dizziness experienced by the patient was noted on a scale of 0-10 (with 0 indicating "I never had dizziness" and 10 indicating "It could not be worse; I had dizziness"). The effect of dizziness on the quality of life was determined during the follow-up at the 6th

postoperative month on the basis of the patients' responses to physical subscale questions (P1, P4, P8, P11, P13, P17 and P25) of the Dizziness Handicap Inventory (DHI), whose validity and reliability have been established in Turkish. Possible score ranges are 0-32 for physical subscale of the DHI; a higher score indicates worse handicap.¹²

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS Statistics for Windows/Macintosh, Version 17.0 (SPSS Inc., Chicago, USA). Categorical measurements were expressed as numbers and percentages, and continuous measurements were expressed as means and standard deviations (median and minimum-maximum, where necessary). The chi-square test or Fisher's exact test was used to compare the categorical variables. For comparing the continuous measurements between the groups, an independent t-test was used for parametric variables, and the Mann-Whitney U test was used for nonparametric variables. The level of statistical significance was set at 0.05 for all the tests.

RESULTS

A total of 85 patients, 22 (25.9%) men and 63 (74.1%) women were included in the study ($p=0.622$). The dexamethasone group comprised 40 patients, including 9 men and 31 women, and the control group comprised 45 patients, including 13 men and 32 women. The mean age of the patients was 43.4 years (43.3 ± 11.3 years in the dexamethasone group and 43.5 ± 8.84 years in the control group; $p=0.850$) (Table 1).

In the dexamethasone group, 16 (40%) left-ear and 24 (60%) right-ear surgeries were performed; in the control group, 19 (42.2%) left-ear and 26 (57.8%) right-ear surgeries were performed ($p=1.00$). In the operated ears, the preoperative pure tone mean airbone (AB) gap was 34 ± 9 decibel (dB) in the dexamethasone group and 33 ± 10 dB in the control group. The postoperative AB gap was 14 ± 6 dB in both the dexamethasone and control groups. The improvement in AB hearing threshold was 20 ± 10 dB in the dexamethasone group, whereas it was 19 ± 10 dB in the control group ($p=0.721$) (Table 1).

TABLE 1: Demographic and auditory results of the patients.			
	Dexamethasone group	Control group	p value
n (female/male)	40 (31/9)	45 (32/13)	0.622
Age (years)	43.3±11.3	43.5±8.84	0.850
AB gap dB (preoperative)	34.8±9.33	33.8±10.8	0.768
AB gap dB (postoperative)	14.6±6.35	14±6.38	0.640
AB gap dB recovery	20.1±10.2	19.3±10.8	0.721

AB: Air-bone; dB: decibel.

The duration of postoperative dizziness was 5.03±2.11 days in the dexamethasone group and 4.98±2.22 days in the control group (p=0.855). The severity of dizziness on the day after the surgery was 4.68/10 points (range, 2-9) in the dexamethasone group and 5.24/10 points (range, 2-8) in the control group (p=0.048). On the day of discharge, the severity of dizziness was 3.1/10 points (range, 0-9) in the dexamethasone group and 3.78/10 points (range, 1-6) in the control group (p=0.008). The total score of the physical scale of the DHI was 10.25±6.24 in the dexamethasone group (range, 2-28) and 10.49±4.95 (range, 0-20) in the control group (p=0.607) (Figure 1). The duration of hospitalization was 1.1±0.64 days (range, 1-5) in the dexamethasone group and 1.1±0.43 days (range, 1-3 days) in the control group (p=0.754). The mean±standard deviation number of dimenhydrinate ampoules used in the hospital after the surgery was 0.85±1.31 units (range, 0-5) in the dexamethasone group and 0.36±0.60 units (range, 0-2) in the control group (p=0.167). The mean±standard deviation number of metoclopramide HCl

ampoules used after the surgery was 0.33±0.764 units (range, 0-4) in the dexamethasone group and 0.87±1.07 units (range, 0-4) in the control group (p=0.003). The mean±standard deviation number of ondansetron ampoules used was 0.08±0.267 units (range, 0-1) in the dexamethasone group and 0.04±0.298 units (range, 0-2) in the control group (p=0.270) (Figure 2).

DISCUSSION

Preoperative vestibular dysfunction is observed in 17-23% of patients with otosclerosis.^{13,14} In our study, patients with preoperative dizziness were excluded from the study in order to reveal the effects of dexamethasone on early postoperative dizziness. The severity of dizziness on postoperative day 0 was 4.68/10 points in the dexamethasone group and 5.24/10 in the control group. The severity of dizziness on the day of discharge was 3.1/10 in the dexamethasone group and 3.78/10 in the control group. These results indicate that patients who received dexamethasone after stapedotomy experienced less dizziness on the day after the surgery and on the day of discharge. Although approximately 70% of patients report paroxysmal imbalance after stapedotomy, a more severe dizziness is occasionally encountered. This has been defined as a possible complication of stapes surgery.¹⁵

The duration of dizziness after the surgery was similar in the two groups and lasted an average of 5 days. These results support the previous findings that dizziness did not last longer than a week after stape-

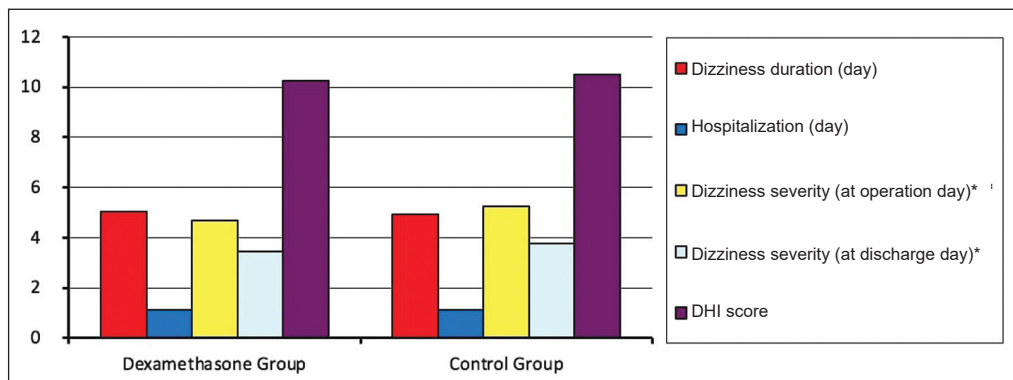


FIGURE 1: (*p<0.05). DHI: Dizziness Handicap Inventory. Effects of dexamethasone administration during stapedotomy on dizziness.

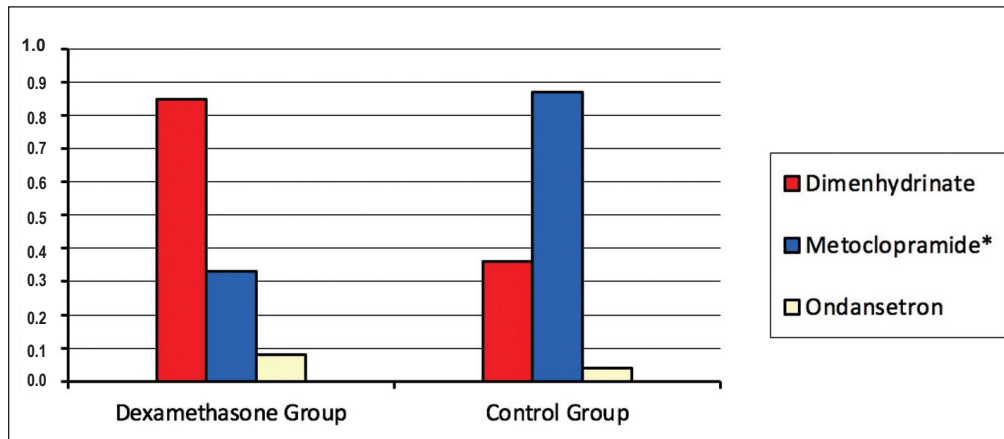


FIGURE 2: (* $p < 0.05$; vertical axis: mean number of drugs administered per person).
Effects of dexamethasone administration during stapedotomy on postoperative antiemetic drug requirement.

dotomy. Özmen et al. reported that almost all patients experienced dizziness, which improved within 1 week, and Birch et al. reported dizziness lasting longer than a week in only 4% of the patients.^{5,16}

The DHI is a reliable, comprehensively validated and clinically useful tool to measure self-perceived handicap associated with the symptom of dizziness from a variety of causes. DHI physical subscore and total score was higher than healthy persons.^{17,18} The handicap perceived by patients was primarily caused by physical factors.¹⁹ De Vilhena et al. determined the mean postoperative total DHI scores to be 10 (range, 2-18).²⁰ Our results were similar to these findings and indicated the development of mild dizziness after stapedotomy in accordance with the DHI scores. The scores obtained from the physical subscale of the DHI were lower in the dexamethasone group than in the control group; however, the difference was not statistically significant. Özmen et al. reported vestibular complaints of varying degrees in 82% of the patients after the surgery.⁵ Kujala et al. also reported nystagmus affecting the opposite ear or diverting nystagmus detected using electronystagmography in up to 69% of the patients undergoing stapes surgery.²¹

In the present study, among the drugs, dimenhydrinate, metoclopramide HCl, and ondansetron, which were administered to the patients when necessary during hospitalization, the use of metoclopramide HCl was lower in the dexamethasone group.

This could be related to the fact that the severity of dizziness during hospitalization was lower in the dexamethasone group.

Studies have demonstrated that the intracochlear administration of dexamethasone during cochlear implantation preserves residual hearing. The popularity of dexamethasone has increased with the development of the atraumatic round window approach and the use of atraumatic soft electrodes in cochlear implantation surgery. Although different studies report different administration methods for and doses of dexamethasone, most studies have demonstrated its effectiveness in protecting residual hearing and reducing side effects, such as fibrosis and ossification.²²⁻²⁴ James et al. demonstrated histologically that the administration of a single dose of dexamethasone to the round window in cochlear implantation could reduce the foreign body reaction.²⁵ Similar to cochleostomy, stapedotomy causes traumatic intralabyrinthine hemorrhage and triggers an increase in local inflammation. However, nowadays, stapedotomy that causes less trauma, such as that using a microdrill or laser, is generally a more commonly adopted approach. The administration of dexamethasone to the fenestra during surgery is considered an applicable method to control inflammation and reduce fibrosis around the piston. In the American Academy of Otolaryngology-Head and Neck Surgery guidelines, the intratympanic dexamethasone dose is specified as 16-24 mg in total or 10 mg/mL at a sin-

gle time with administrations of 0.4-0.8 mL.²⁶ In our study, 4 mg/mL dexamethasone was administered via injection onto the fenestra. To our knowledge, no study in the literature has demonstrated the effect of dexamethasone administration using this method.

In the present study, the improvement in air-bone hearing thresholds was 20.1 dB in the dexamethasone group and 19.3 dB in the control group. The air-bone gap was also within similar limits reported in the literature. The air-bone gap after stapedotomy was 16.4 dB in 75 cases reported by House et al., whereas it was 10 dB or less in 58% of the cases reported by Fish et al.^{27,28} Patients aged over 40 years are at an increased risk of achieving limited hearing gains. In this study, the mean age of the patients was 43.4 years. Nevertheless, no major complications, such as sensorineural hearing loss, were encountered in both the study groups. Moreover, no positive or negative effects on hearing were observed in terms of the administration of dexamethasone to the fenestra during the early period after stapedotomy. Similarly, Çelik et al. found no statistically significant difference between patients who did receive intra-operative single-dose IV corticosteroid injections and patients who did not receive IV corticosteroid injections group in terms of preoperative and postoperative air-bone conduction levels.²⁹ Székely et al. found the positive effect of corticosteroid treatment on postoperative hearing levels.³⁰

Despite the above encouraging results, our study has some limitations. One of the limitations of the study was that it was unclear whether the administration of dexamethasone to the fenestra would have an ototoxic effect. As reported previously, a single dose of 4 mg/mL dexamethasone, which is available in Turkey, could be administered safely.⁸ Moreover, in cochlear implantation, the administration of dexamethasone to the round window before the insertion of the implant has been shown to be effective in preserving residual hearing.³¹ Another limitation was that the patients were not randomized to the two different treatment groups; however, dexamethasone was administered on the basis of the current surgery protocols adopted by the surgeons involved in this study, and these were independent of the current study. The surgeons performing the surgery were also

excluded from screening the patients' files to reduce the selection bias. In our study, dizziness was evaluated on the basis of the patients' complaints, drug requirements, need for hospitalization, and quality of life. Another limitation was the evaluation of dizziness according to the DHI based on the individual complaints of the patient and drug use based on the complaints of postoperative dizziness instead of the recorded nystagmus data.

CONCLUSION

Despite these limitations, this study is potentially the first one to investigate the effects of dexamethasone administration to the fenestra during stapedotomy on postoperative dizziness. The results suggest that the administration of dexamethasone to the fenestra after opening it during otosclerosis surgery may reduce the severity of dizziness and the frequency of antiemetic drug use in the early postoperative period while it has no effect on hearing thresholds and dizziness in the long term. Further, prospective studies are needed to investigate the effect of administration of dexamethasone to the fenestra during stapedotomy on postoperative dizziness.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Serhat İnan, İsmail Yılmaz, Evren Hizal; **Design:** Serhat İnan, İsmail Yılmaz, Ömer Vural, Haluk Yavuz; **Control/Supervision:** İsmail Yılmaz, Haluk Yavuz; **Data Collection and/or Processing:** Serhat İnan, Ömer Vural; **Analysis and/or Interpretation:** Evren Hizal, Fulya Özer, Serhat İnan; **Literature Review:** Serhat İnan, Ömer Vural, Fulya Özer; **Writing the Article:** Serhat İnan, Evren Hizal, Ömer Vural; **Critical Review:** İsmail Yılmaz, Haluk Yavuz, Fulya Özer; **References and Fundings:** Serhat İnan; **Materials:** Serhat İnan.

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