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ARAŞTIRMA YAZISI / RESEARCH ARTICLE

STAPEDOTOMİ DENEYİMİ; SONUÇLAR VE KOMPLİKASYONLAR ÜZERİNE KLİNİK BİR ÇALIŞMA

STAPEDOTOMY EXPERIENCE; A CLINICAL STUDY ON OUTCOMES AND COMPLICATIONS

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ÖZET

AMAÇ: Otoskleroz cerrahisi, otolojik cerrahi ameliyatlarının en hızlı sonuç verenlerinden biridir. Operasyon süresinin kısa olması, operasyon sonrası hastayı tatmin eden bir işitme iyileşmesi ve hastanede kalış süresinin kısa olması önemli avantajlarıdır. Otoskleroz ameliyatının amacı, hastalığa bağlı kemikçik zincirindeki hareketsizliği gidermek ve tekrar ses iletimini sağlamaktır. Bu çalışma, üçüncü basamak bir klinikte otoskleroz nedeniyle stapes ameliyatı geçiren hastaların postoperatif işitme kazanım oranlarını ve komplikasyonlarını güncel literatür ışığında değerlendirmeyi amaçlamaktadır.

GEREÇ VE YÖNTEM: Otoskleroza bağlı iletim tipi işitme kaybı nedeniyle opere edilen 49 hasta retrospektif olarak değerlendirildi. Preoperatif ve postoperatif odyolojik değerlendirmeler ve ameliyat esnasında olan ve postoperatif komplikasyonlar incelendi. Hastaların 6'sı her iki kulağından ameliyat edildi. Çalışmaya 6'sı bilateral olmak üzere toplam 36 hasta dahil edildi (42 kulak).

BULGULAR: Çalışmamız sonucunda otoskleroz nedeniyle opere edilen 36 hastanın 42 kulağının 37'sinde (% 88), (hava-kemik aralığı sınırlarının 20 dB'nin altında olması başarı kriteri ile) literatürle uyumlu olmayan fonksiyonel başarı elde edildi. Literatürde başarısız olduğu düşünülen 30 dB'nin üzerinde hava kemik aralığı hiçbir hastamızda tespit edilmemiştir. Tüm vakalar ameliyat öncesi ve sonrası işitme eşikleri açısından değerlendirildi ve ortalama kemik iletim kazancı 4. 8 dB olarak izlendi.

SONUÇ: Stapes ameliyatı ,nadir durumlarda başarısızdır ve stapes ameliyatı sırasında da ciddi komplikasyonlarla karşılaşılabileceği unutulmamalıdır.

ANAHTAR KELİMELER: Otoskleroz, Stapedotomi, Hava-kemik aralığı, Komplikasyon

ABSTRACT

OBJECTIVE: Otosclerosis surgery is one of the otologic surgeries producing the fastest results. It offers crucial advantages such as short operation time, high level of satisfaction during the postoperative hearing recovery and short hospital stay. The purpose of otosclerosis surgery is to relieve the immobility in the ossicular chain due to the disease and to provide the voice transmission again. This study aims to evaluate the postoperative hearing gain rates and complications of patients who underwent stapes surgery for otosclerosis in a tertiary clinic in light of the current literature.

MATERIAL AND METHODS: 49 patients who were operated on for conductive hearing loss due to otosclerosis were evaluated retrospectively. Preoperative and postoperative audiological evaluations and intraoperative and postoperative complications were examined. Six of the patients were operated on both ears. A total of 36 patients, six of whom were bilateral, were included in the study (42 cases).

RESULTS: As a result of our study, in 37 (88%) of 42 ears of 36 patients operated for otosclerosis,(with the success criterion of air-bone gap limits below 20 dB) functional success incompatible with the literature was obtained. Air bone gap above 30 dB, which is considered to be a failure in the literature, was not detected in any of our patients. All cases were assessed in terms of hearing thresholds preoperatively and postoperatively, resulting in a mean bone conduction gain of 4. 8 dB.

CONCLUSIONS: For stapes surgery, in rare cases, surgery can be unsuccessful and it should be kept in mind that serious complications may also be encountered during stapes surgery.

KEYWORDS: Otosclerosis, Stapedotomy, Air-bone gap, Complication

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INTRODUCTION

Otosclerosis is a disease originating from the labyrinthine capsule and the staple base, which can cause hearing loss and occasional equilibrium disorders depending on the size of the pathology, histologic activity, and location of the affected region (1). The prevalence of otosclerosis in the white race is estimated to be 0. 3% on average, ranging from 0. 1% to 1%. The frequency of females is 2-3 times higher than that of males (2). This study aims to evaluate the postoperative hearing gain rates and complications of patients who underwent stapes surgery in a tertiary clinic due to otosclerosis in light of the current literature.

MATERIALS AND METHODS

In this study, 49 patients who were operated on for conductive hearing loss between June 2017 and June 2019 in a tertiary hospital otorhinolaryngology department were evaluated retrospectively. Six of the patients were operated on both ears. 13 patients who did not follow the follow-up period and had no results were excluded from the study. A total of 36 patients, six of whom were bilateral, were included in the study (42 cases). Age, gender, unilateral or bilateral status, operation date, follow-up period, operation findings, hearing results, and complications were recorded. In the preoperative and postoperative audiological examinations, air conduction thresholds were measured at frequencies of 250, 500, 1000, 2000, 4000, 8000 Hz and bone conduction thresholds were measured at frequencies of 500, 1000, 2000, 4000 Hz. Air and bone conduction pure tone averages and air-bone gap values of the patients were calculated using the values of 500, 1000, 2000, and 4000 Hz frequencies. The postoperative air-bone gap was calculated by removing postoperative bone conduction thresholds from postoperative air conduction thresholds of patients. Postoperative air-bone gap range was considered to be very good for those with 0-10 dB, those with 11-20 dB were considered to be good, those with 21-30 dB were considered acceptable, and those with more than 30 dB were considered unsuccessful. To evaluate hearing results at high frequencies, 8 kHz hearing values were used. Bone conduction gain or loss were calculated for all patients. Bed rest was recommended after the operation to all patients. Patients were informed about the conditions that might increase the internal ear pressure in the early postoperative period (coughing, constipation, etc.) On postoperative day 7, the patient's external ear canals were evacuated and sutures were taken. Their first audiograms were performed in the postoperative 1st month. Then, the patients were called for controls at the 3rd month, 6th month, and 1st year. Then, patients were called to check once a year. The most recent audiological examination was chosen as a postoperative audiological examination.

The follow-up period of the patients ranged from 3 months to 1 year. All patients were evaluated for postoperative success rates with results of postoperative air conduction gain, bone gain or loss, and pure tone averages. Complications during or after the operation were evaluated and recorded. The revision reasons for the patients who need revision surgery and the results of revision operations were evaluated.

Statistical Analysis

SPSS (Statistical Package for Social Sciences) Windows Program was used for statistical analysis. Descriptive statistics were used to evaluate the data obtained, and Kruskall Wallis and Shapiro Wilk tests were used. Wilcoxon test was used to compare recurrent measurements pre- and postoperatively in the dependent groups. The analyzes were performed in the SPSS / 18 program and $p < 0.05$ was considered significant.

Ethical Commitee

Approval was obtained from the Ethics Committee of Afyonkarahisar Health Sciences University for the study. (05.02.2021 Ethics committee code: 2011-KAEK-2)

RESULTS

Of the 36 patients included in the study, 22 were female and 14 were male. The mean age was 38. 6 (15-59) and the mean duration of complaints was 5. 4 years. A total of 28 patients had complaints in both ears, and the other eight patients had unilateral complaints. When the preoperative history of the patients was evaluated, 20

patients presented with only hearing loss and 12 patients had tinnitus and 3 patients had vertigo complaints. 6 of the 36 patients included in the study were operated on bilaterally. Stapedotomy was performed in all cases by the same surgeon and a standard 0.6 mm Teflon piston was used.

All patients were evaluated with preoperative and postoperative audiological examinations. The mean air conduction and bone conduction values of all patients before and after the surgery were shown according to frequencies in **Figures 1and 2** respectively.

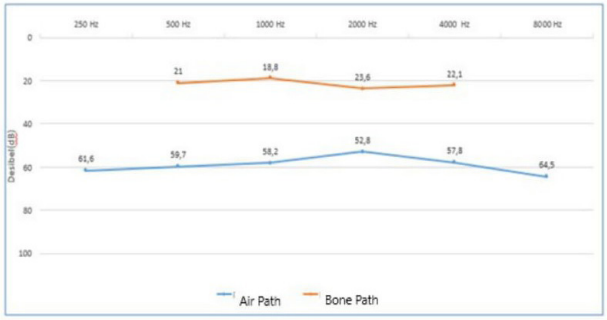

Figure 1: Preoperative mean air conduction and bone pathway of all cases

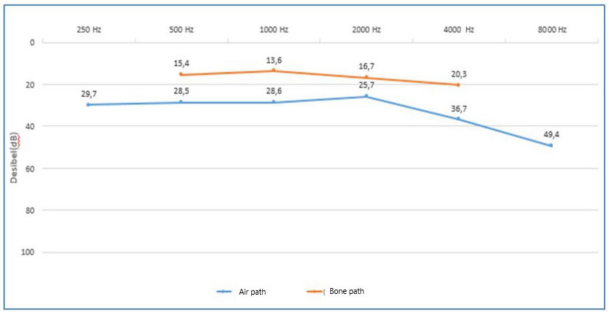

Figure 2: Postoperative mean air conduction and bone pathway of all cases

The mean preoperative air conduction hearing thresholds were 59. 1 dB (Min: 39 dB Max: 89 dB), while the mean preoperative bone conduction hearing threshold was 21. 4 dB (Min: 10 dB Max: 42 dB). The mean postoperative air conduction hearing thresholds were 33. 1 dB (Min: 15 dB Max: 60 dB), and the mean postoperative bone conduction hearing thresholds were 16. 5 dB (Min: 7 dB Max: 40 dB). When the pure tone audiometry of all patients was examined in general, the mean preoperative pure tone average was 56. 9 dB (Min: 43 dB Max: 85 dB) and the mean postoperative pure tone average was 27. 7 dB (Min: 8 dB Max: 58 dB). An average volume of 29 dB of pure tone was achieved in all patients.

When the whole of the cases was evaluated, the gain was obtained in both air conduction hearing thresholds and bone conduction hearing thresholds compared to preoperative hearing thresholds. The average air conduction hearing thresholds were statistically significant ($p<0.001$). The average bone conduction hearing thresholds were found to be significant except for the frequency of 4000 Hz ($p<0.001$). An average gain of 1. 8 dB was achieved in the bone conduction of hearing thresholds at 4000 Hz, but this was not statistically significant ($p=0.187$).

Postoperative air-bone gaps (ABG) were used to evaluate the success of the surgeries.

- Results with 0-10 dB: very good
- 11-20 Db: good
- 21-30 dB: acceptable
- Results higher than 30 dB were considered unsuccessful.

When the average of all cases was evaluated, the mean ABG was 35.7 dB (Min:23 dB Max:51 dB), and the mean postoperative ABG was 13.3 dB (Min:0 dB Max:26 dB). An average ABG gain of 22 dB was obtained. When patients were grouped according to ABG earnings, 1 (2.3%) patient had 0-10 dB, 19 (45.2 %) patients had 11-20 dB, 15 (35.7 %) patients had 21-30 dB and 7 (16.6 %) patients had over 30 dB ABG gain.

When all cases were evaluated in terms of preoperative and postoperative bone conduction hearing thresholds, an average gain of 4.8 dB (Min:-6 dB, Max:18 dB) was obtained. When the patients were grouped according to the increase or decrease in bone conduction hearing thresholds in the postoperative period, 0-5 dB gain in 22 patients, 5-10 dB gain in 11 patients, 11-15 dB gain in 4 patients, and 15 dB gain in 1 patient were found. In 4 patients, postoperative bone conduction hearing thresholds were decreased. The loss in bone conduction hearing thresholds was not more than 15 dB in any of the cases. When the patients were evaluated in terms of complications, four patients developed chorda tympani damage during surgery. Three patients underwent minimal perforation of the tympanic membrane during surgery. These patients were treated with a tragal cartilage perichondrium at the same session. In the postoperative period, no permanent tympanic

membrane perforation occurred. In one patient, incus dislocation occurred. The incus was reinserted during the operation. Two patients underwent exploration due to conductive hearing loss. The operation in these two patients was terminated at this point. No complications were observed in these two patients in the postoperative period. Since stapedotomy was not performed, these patients were not included in this study in terms of postoperative hearing levels.

In the early postoperative period, 15 patients had vertigo complaints. All patients with vertigo complaints were treated with absolute bed rest and intravenous dimenhydrinate for the first three days. The symptoms of 12 patients completely disappeared within ten days at the latest. Vertigo complaints were severe in three patients and these patients were recommended for re-exploration. Two patients underwent re-exploration. The stapedotomy site was closed by spreading the temporal muscle fascia by removing the pistons of the patients who were not suspicious of the intraoperative perilymph fistula. One of the patient's complaints of dizziness regressed after re-exploration, but the patient had moderate sensorineural hearing loss in the postoperative period. Other patient's dizziness complaints did not regress. The patient was referred to the neurology clinic and the patient was diagnosed with multiple sclerosis. The patient did not continue his follow-up because he wanted to continue his treatment and follow-up at another center. Since this patient did not have audiometric tests after revision surgery, it was not included in this study in terms of postoperative hearing thresholds.

One patient developed grade 2 facial paresis on the 7th postoperative day. In this patient's intraoperative facial nerve examination, there was dehiscence in the tympanic segment of the facial canal. Since no abnormality was detected in the facial nerve, a stapedotomy was performed and the Teflon piston was inserted. No facial asymmetry was seen in the early postoperative period and findings were observed on the postoperative 7th day. Oral steroid treatment was started and the patient's symptoms resolved completely within three weeks. In one of the cases, the patient had dizziness and mild sensorineural loss of hearing in the 1st postoperative week. In the otoscopic examination, a red mark was observed in the posterior tympanic membrane and the patient was recommended for re-exploration for repetitive granuloma. The patient, who accepted the surgery, underwent re-exploration and was diagnosed with repetitive granuloma intraoperatively.

Granulation tissues were cleaned and the piston was removed and another piston was placed again. After revision surgery, the patient's complaints improved. Intraoperative and postoperative complications are summarized in **Table 1**.

Table 1: Number of cases according to intraoperative and postoperative complications

Incus dislocation	1	2.38%
Tympanic Membrane Perforation	3	7.14%
Corda tympanı damage	4	9.52%
Fasial paresis	1	2.38%
Mild vertigo	12	28.57%
Severe vertigo	3	7.14%
Sensorineural Hearing loss	1	2.38%
Repetitive granuloma	1	2.38%

DISCUSSION

Otosclerosis was first demonstrated in 1741 by Antonio Maria Valsalva, an anatomist, and surgeon, as a result of dissection of the temporal bone of a deaf patient. Otosclerosis is characterized by chronic, idiopathic, progressive hearing loss, and bone metabolism disorder of the otic capsule seen only in the human temporal bone.

Although it usually causes conductive hearing loss, mixed or sensorineural hearing loss can also be seen and a clinical approach is planned according to the type of hearing loss (3). The cause and pathogenesis are not fully known. Clinically, it is manifested mainly by hearing loss. Hearing impairment is characterized by slow progression, and first, a conduction-type loss that generally affects low frequencies is observed (4). 25% of patients with otosclerosis describe vestibular complaints. This picture is defined as otosclerotic inner ear syndrome. Although rare, some patients may suffer from dizziness without hearing loss and tinnitus (5). In our study, 20 patients presented with complaints of hearing loss and 12 patients with tinnitus, and three patients with vertigo complaints. Three of these complaints were present all together in one patient. For treatment, follow-up, amplification, medical treatment (sodium fluoride,

vitamin D, calcium carbonate), and surgical treatment methods are used. When hearing loss above 40 dB is especially bilateral, it also affects the patient's social life and requires medical intervention. Surgical results are quite successful in mild to moderate hearing loss. However, some authors argue that hearing loss over 70 dB is in advanced stages and surgery is not very effective and it is appropriate to maintain these patients with a hearing aid. In otosclerosis, the main cause of sensorineural hearing loss is the effect of the cortical organ and neural structures, but the inactivity in the perilymph-endolymph fluid system which is caused by the loss of motion in the stapes base also contributes to this (6).

The most commonly used parameter to demonstrate the functional success of otosclerosis surgery is the postoperative air-bone gap. Some studies accept the success of the postoperative ABG value to decrease to 10 dB and below, and some studies accept success as 20 dB and below (7-9). In this study, functional success was considered to be 20 dB or less of ABG and functional success was achieved in 88% of our cases.

It is known that the incidence of 4 kHz frequency in which the negative effects of surgery will be seen in the audiological evaluation will show a low success. It is known that 4 kHz frequency is not shown in some studies in the literature (10). In this study, 4 kHz frequency was routinely included in the evaluation and hearing values were determined. In our study, the mean preoperative ABG was found to be 35.7 dB (min:23 dB max:51 dB), while the postoperative mean ABG was 13.3 dB (Min:0 dB Max:26 dB).

When all cases were evaluated, approximately 22 dB average ABG gain was obtained. Postoperative improvement of a bone pathway in stapes surgery was first described by Carhart. In otosclerosis patients with no cochlear involvement, the bone path thresholds expected to be at normal levels may decrease 20-30 dB, especially at 2 kHz frequency. It is thought that 2 kHz, which is the closest octave frequency to the middle ear resonance frequency, and the decrease in the adjacent octave frequencies appear as a result of the disappearance of the energy increase through ossicles by stapes fixation (11). The elimination of this fixation resulted in postoperative bone pathway improvement (Carhart effect) by different authors was estimated in the range of 5-10 dB at 0. 5 kHz, 10-20 dB at 1 kHz, 15-30 dB at 2 kHz, 5 -20 dB at 4 kHz (11). In our study, when all patients were evaluated in terms of preoperative and postoperative bone pathway hearing thresholds, an average of 4. 8 dB (min:-6 dB, max:18 dB) bone pathway gain was obtained.

Stapes surgery is a sensitive procedure with high morbidity rates. It is quite common for the oval window to be located deeply and is generally not a problem during operation. However, the narrow-angle of the base-stapes axis may cause difficulties in conventional techniques.

The thickness of the stapes base or obliterative otosclerosis is undesirable. In these cases, the use of peaks, perforators, or rounds may increase the risk of complications whereas laser application will be a safe procedure. The protrusion of the facial canal is a factor that narrows the field of view of the stapes base. The presence of the stapedial artery is an anomaly that may cause serious problems during surgery. It is usually found in the bone duct of the promontorium and is detected incidentally. Prosthesis placement is difficult in these cases.

Motta et al. emphasized that narrowing of the external auditory canal, incus lenticular process erosion, difficulty in approaching the oval window, facial nerve prolapse, bleeding, and excessive perilymphatic leakage are the main difficulties during the operation (12). In our study, when the patients were evaluated for complications, four patients developed chorda tympani damage during surgery. Three patients had a minimal perforation of the tympanic membrane during surgery. These patients were repaired with tracheal cartilage perichondrium in the same session. No postoperative tympanic membrane perforation developed in any patient. Incudomalleolar joint dislocation developed in one patient during surgery. During the operation, the incus was resumed. Stapedial arterial bleeding was observed in two patients and bleeding was controlled carefully by slowing with spongostane. It was observed that the facial nerve was on the oval window in two patients who underwent exploration for

conductive hearing loss. The operation was terminated in these two patients. There were no complications in these two patients in the postoperative period. Because stapedotomy was not performed, these patients were not included in this study in terms of post-op hearing levels.

In conclusion, we think that the stapedotomy procedure is a successful and safe method for the reconstruction of the hearing in otosclerosis patients. We have concluded that in rare cases surgery can be unsuccessful and it should be kept in mind that serious complications may be encountered.

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