

An Evaluation of Prognostic Factors in Tympanoplasty with Titanium Prostheses*

Titanyum Protezlerle Yapılan Timpanoplastide Prognostik Faktörlerin Değerlendirilmesi

Abstract

Aim: This study aimed to assess the effects of preoperatively measured middle ear risk index (MERI) and intraoperative ossicular chain findings on postoperative hearing in patients who underwent ossiculoplasty performed by using universal titanium prostheses.

Materials and Methods: Patients who underwent ear surgery using universal titanium prostheses due to malfunctioning in the incus were included. Preoperative ear examination results, surgical findings, and MERI scores were assessed. Preoperative and postoperative air-conduction and bone-conduction hearing thresholds and air-bone gap were assessed at 0.5, 1, 2, and 4 kHz frequencies.

Results: We found that presence of the malleus and stapes suprastructure and prognostic MERI grading affected the reconstruction success rate. The air-bone gap results were found to be 100%, 87.5% and 12.5% in the mild, moderate, and severe MERI groups, respectively.

Discussion and Conclusion: In line with the literature, we observed that preoperative MERI scoring might help surgeons develop a patient-specific operation strategy by providing guidance during ossiculoplasty.

Keywords: ear surgery; hearing reconstruction; middle ear risk index; tympanoplasty

Öz

Amaç: Bu çalışmada evrensel titanyum protezler kullanılarak ossiküloplasti yapılan hastalarda ameliyat öncesi ölçülen orta kulak risk indeksi (OKRİ) ve intraoperatif kemikçik zinciri bulgularının postoperatif işitme üzerine etkilerini değerlendirmek amaçlanmıştır.

Gereç ve Yöntemler: Çalışmaya inkusu arızalı olup evrensel titanyum protez kullanılarak kulak cerrahisi yapılan hastalar dahil edildi. Preoperatif kulak muayenesi sonuçları, OKRİ skorları ve ameliyat bulguları değerlendirildi. Preoperatif ve postoperatif hava iletimi ve kemik iletimi işitme eşikleri ve hava-kemik aralığı 0,5, 1, 2 ve 4 kHz frekanslarında değerlendirildi.

Bulgular: Çekiç kemiği ve üzengi suprastrüktürü varlığının ve prognostik OKRİ derecelendirmesinin rekonstrüksiyon başarı oranını etkilediği görüldü. Hava-kemik aralığı sonuçları hafif, orta ve ağır OKRİ gruplarında sırasıyla %100, %87,5 ve %12,5 olarak tespit edildi.

Tartışma ve Sonuç: Literatürle uyumlu olarak, preoperatif OKRİ skorlarının cerrahlara ossiküloplasti sırasında rehberlik ederek hastaya özel operasyon stratejisi geliştirmede yardımcı olabileceği görülmüştür.

Anahtar Sözcükler: işitme rekonstrüksiyonu; kulak cerrahisi; orta kulak risk indeksi; timpanoplasti

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INTRODUCTION

Chronic otitis media surgery is aimed at ensuring a dry and safe ear while preserving or restoring hearing as far as possible. Wullstein (1) and Zöllner (2) have become leading figures of functional intervention by introducing the concept of tympanoplasty. Although there are certain established and relative indications for mastoidectomy, preoperative general health of the patient, extent of the disease and condition of the contralateral ear, and doctor and patient preferences are decisive factors in determining the type of mastoidectomy (3).

Primary factors affecting the pathophysiology of chronic otitis are the Eustachian tube function, middle ear mucosa, ossicular chain, condition of the eardrum, pathology leading to ossicular defect, and material used in ossicular reconstruction (4–9). Currently, there are various studies (4,5) focusing on the prognostic factors for success and failure in chronic otitis surgery, although there are no globally accepted success criteria. Kartush (6) used a middle ear risk index (MERI) system with numerical variables allowing for comparison within ossicular reconstruction studies. His MERI assessment criteria included presence and intensity of otorrhea, presence of perforation, presence of cholesteatoma, condition of the ossicles, history of previous surgery and type of the surgery. In 2001, the MERI system was updated and two points were added for middle ear granulation tissue and effusion and for smoking (7).

In this prospective study, we aimed to assess the effects of preoperatively measured middle ear risk index (MERI) prognostic grading and intraoperative ossicular chain findings on postoperative hearing in patients who underwent ossiculoplasty by using universal titanium prosthesis. All results were presented with reference to the literature.

MATERIALS AND METHODS

This study included 19 patients who had chronic otitis media surgery and underwent ossicular reconstruction using universal titanium prostheses at the ear, nose & throat clinic of a tertiary hospital. It was performed in accordance with the local and international ethi-

cal standards, having been approved by the Clinical Research Ethics Committee of the hospital. Written informed consent was obtained from all patients preoperatively.

The patients' ears were routinely examined by otomicroscopy preoperatively. Findings of the examinations and surgeries were recorded on a form. In addition, MERI scores were assessed preoperatively. Preoperative and postoperative air-conduction (AC) and bone-conduction (BC) hearing thresholds and air-bone gap were assessed at 0.5, 1, 2 and 4 kHz frequencies by using AC-40 model inter-acoustic audiometry. Accordingly, average values of preoperative and postoperative pure tone and average air-bone gap differences at 0.5, 1, 2 and 4 kHz frequencies were calculated. Partial ossicular reconstruction material was used when stapes suprastructure was present and total ossicular reconstruction material when it was absent. Universal titanium (Medtronic Xomed) with a grooved round dense hydroxyapatite (HA) head (Vincent head), titanium metal interconnections and Flex/HA shaft were used for partial ossicular reconstruction prosthesis (PORP). Universal titanium (Medtronic Xomed) with a round dense hydroxyapatite (HA) head or universal titanium (Medtronic Xomed) head (Ti head) prosthesis were used for total ossicular reconstruction prosthesis (TORP).

Average air-bone gaps (ABG), average air-bone gap gains (ABGG), and hearing gains (HG) at 0.5, 1, 2 and 4 kHz frequencies were calculated for each patient. The success criteria were set as ABG being <20 dB or HG being >10 dB.

Statistical analysis

NCSS (Number Cruncher Statistical System) 2007 & PASS 2008 Statistical Software (Utah, USA) program was used for the statistical analysis of the results. Repeated measures analysis of variance was used to compare pre-op and post-op measurements. Kruskal-Wallis test was used in intergroup comparison of the parameters with non-normal distribution and Mann-Whitney *U* test was used to detect the group causing the difference. Quantitative data were compared by using the chi-square test. $p < 0.05$ was considered statistically significant.

Table 1. Intraoperative middle ear findings

		n	%
Malleus	Normal	14	73.7
	Absent	5	26.3
Incus	Normal	1	5.3
	Long arm defect	9	47.4
	Absent	9	47.4
Stapes	Normal	7	36.8
	No suprastructure	12	63.2
	Fibrosis	1	5.3
	Granulation	9	47.4
Middle ear mucosa	Hypertrophic	2	10.5
	Cholesteatoma	2	10.5
	Normal	3	15.8
	Sclerotic plaques	1	5.3
	Squamous epithelium	1	5.3

RESULTS

Chronic otitis media surgery with ossiculoplasty was performed in a total of 22 patients. The mean patient age was 32.21 ± 8.75 (range 17–51) years. The mean patient follow-up time was 16.26 (range 6–25) months. Of the patients, 8 (42.1%) were male and 11 (57,9%) were female, 10 (52.6%) were smokers and 9 (47.4%) were non-smokers. During the follow-up period, rejection of the prosthesis material was observed in 2 patients and recurrence of cholesteatoma in 1. Accordingly, these 3 patients were excluded and the assessment was performed with the remaining 19 patients. In 1 (5.2%) of the cases, the incus was normal; in 9 (47.4%), it had defective long arm; and in 9 (47.4%) it was absent. In 7 (36.8%) patients the stapes was normal while the stapes suprastructure was absent in 12 (63,2%). When intraoperative parameters were evaluated, the most common pathology was granulation in the middle ear mucosa; the distribution of the other pathologies is shown in Table 1.

In the preoperative assessment, 8 (42.1%) of the patients were assigned to the severe MERI group, 8 (42.1%) to medium MERI, and 3 (15.8%) to mild MERI. There was statistically significant difference in terms of ABGG at post-op month 6 by MERI risk grouping (Table 2). In order to understand which group caused the ABGG difference, group results were com-

pared in pairs. The comparison showed that ABGG at post-op month 6 was significantly higher in the mild MERI group, compared to the moderate or severe MERI groups. ABGG at post-op month 6 did not differ significantly in the moderate and severe MERI groups.

At post-op month 6, there was statistically significant correlation between the ABG and MERI groups (Table 3). In mild MERI, ABG <30 dB was 100%, in moderate MERI 87,5% and in severe MERI 12,5%. As the MERI grade increased, the ABG values at post-op 6 month also increased.

At post-op month 6, the ABG and AC measurements of patients without malleus were statistically higher than the ABG measurements of patients with malleus (Table 4) while HG was statistically higher in patients with malleus, compared to those without malleus.

At post-op month 6 and month 12, the ABG measurements according to stapes presence did not significantly differ between the groups (Table 5), although the ABGG and HG measurements were statistically higher in patients with normal stapes than in patients with no stapes suprastructure.

DISCUSSION AND CONCLUSION

In our study, we found that presence of malleus, presence of stapes suprastructure, and prognostic grading of MERI affected the reconstruction success rate. In the literature, the ossicular autograft used most commonly in ossiculoplasty is the incus due to its easy availability and lowest rejection risk. In cases where recurrence risk is high or the incus is extremely defective, alloplastic material is used. This study was conducted in patients in whom we used universal titanium prostheses since the incus was malfunctioning.

The literature lacks consensus on the success criteria for ossiculoplasty. Jackson et al. suggested 30 dB closure as a success criterion in TORP and 20 dB closure of air-bone gap in PORP. In both studies, ABG was calculated based on 0.5, 1, and 2 kHz frequencies (10,11). On the other hand, the Japan Clinical Otology Committee suggested <20 dB post-op air-bone gap or post-op 40 dB air-conduction threshold or >15 dB hearing gain as a criterion of success (12) based on 0.5, 1,

Table 2. Assessments of ABGG by MERI risk grouping

Post-op ABGG	MERI risk group			P
	Mild (n=3)	Moderate (n=8)	Severe (n=8)	
	Mean±SD (Median)	Mean±SD (Median)	Mean±SD (Median)	
Post-op month 6	31.0±14.0 (25)	13.12±9.77 (16)	1.87±12.49 (-2.5)	0.018*
Post-op month 12	32.0±2.21 (32)	12.0±9.18 (12)	-3.80±6.30 (-3)	-

* p<0.05, Kruskal-Wallis test.

and 2 kHz frequencies (12). In this study, we used <20 dB air-bone gap and >10 dB hearing gain as success criteria in accordance with the American Hearing and Balance Committee (13).

In our study, air-conduction measurements revealed statistically significant decreases at post-op month 6 and month 12, compared to the pre-op measurements. The success rate was 63.2% at post-op month 6 and 64.3% at post-op month 12. Intraoperative results were compared by hearing reconstruction success and risk groups by the MERI 2001 prognostic grading system (7). The assessed criteria were presence of the malleus handle, presence of stapes suprastructure, and MERI risk group.

As mentioned previously, malleus handle presence was reported in the literature as one of the factors affecting the outcome. Austin had developed a prognostic grading system based on the presence of the malleus arm and stapes suprastructure. In his study, absence of malleus arm and stapes suprastructure was reported to be a worst-outcome indicator (14).

Similarly, Black (4), Dornhoffer and Gardner (5), Albu et al. (9), Brackmann et al. (15), Goldenberg (16), De Vos et al. (17), Yung and Vowler (18), and Bared and Angeli (19) reported that presence of malleus arm had a significant effect on the post-op ABG. Bared and Angeli (19) found an ABG of 18.9 dB when the malleus arm was present and 24.4 dB when it was absent. Yung and Vowler (18) evaluated a large case series of ossiculoplasty at post-op month 6 and year 5 and reported the absence of malleus arm and presence of otorrhea as the worst prognostic factors at post-op month 6. They found that at month 6 presence of malleus arm brought 6.36 times more success, while the worst prognostic factor in the 5-year follow-up was absence of malleus arm only, presence of malleus arm bringing 2.65 times more success. Non-presence of the stapes, revision surgery and presence of otorrhea

were reported as less negative prognostic factors (18). In accordance with the mentioned literature results, our study also found the presence of malleus arm to be effective on ABG, ABGG, and HG.

As mentioned previously, presence of stapes suprastructure is another prognostic factor that affects the success of hearing reconstruction. Albu et al. (9) reported that presence of the stapes significantly affected the ABG. They found an ABG of 15.7 dB when stapes suprastructure was present and 23.2 dB when it was absent. Yung and Vowler (18) reported absence of stapes suprastructure as a less negative prognostic factor. However, in their study where they used HAPLEX prostheses, Dornhoffer and Gardner (5) did not report stapes suprastructure presence as a factor affecting the hearing outcomes. In our study, stapes suprastructure presence was not statistically effective on ABG and HG while it was statistically significantly effective on ABGG.

Pathological condition of the middle ear was reported to be another success predictor by Black (4), Albu et al. (9), and Brackmann et al. (15). Albu et al. (9) classified chronic otitis media as simple otitis media, otitis media with granulation, and otitis media with cholesteatoma. Even though Dornhoffer and Gardner (5) could not find any correlation between pathological condition and surgical intervention, they reported the condition of the mucosa and presence of otorrhea as predictive factors for success.

As mentioned earlier, MERI grading is another system in evaluating the success of hearing reconstruction. In Pinar et al.'s study (20), where significantly more success was achieved when MERI scores were low, MERI scores were higher with open mastoidectomy than with closed mastoidectomy. The factors accounting for the significant correlation were stated as follows: (i) presence of cholesteatoma, ossicular chain disruption, and presence of pathology in the middle ear mucosa along with moderate to severe MERI; (ii)

Table 3. Assessment of ABG at post-op month 6 according to MERI risk grouping

		MERI risk group			<i>p</i>
		Mild (n=3)	Moderate (n=8)	Severe (n=8)	
		n (%)	n (%)	n (%)	
ABG	11–20 dB	1 (33.3)	3 (37.5)	0 (0)	0.016*
	21–30 dB	2 (66.7)	4 (50)	1 (12.5)	
	≥31 dB	0 (0)	1 (12.5)	7 (87.5)	
HG (n=19)	Successful	3 (100)	6 (75)	3 (37.5)	0.106
	Failure	0 (0)	2 (25)	5 (62.5)	
BC at 1, 2, 4 kHz	Successful	3 (100)	8 (100)	8 (100)	—
	Failure	0 (0)	0 (0)	0 (0)	

* $p < 0.05$, chi-square test.

Table 4. Hearing test results according to malleus presence

		Malleus		<i>p</i>
		Normal	Absent	
		Mean±SD (Median)	Mean±SD (Median)	
ABG	Post-op month 6	25.92±9.85 (26)	42.20±9.95 (37)	0.007**
	Post-op month 12	29.67±11.94 (30)	42.50±4.95 (42.5)	—
ABGG	Post-op month 6	15.28±13.61 (16)	-0.20±13.84 (-7)	0.070
	Post-op month 12	11.58±15.29 (12)	-5.0±2.82 (-5)	—
AC	Post-op month 6	41.50±13.96 (38)	60.80±6.26 (61)	0.014*
	Post-op month 12	44.08±13.12 (41.5)	58.0±4.24 (58)	—
HG	Post-op month 6	17.64±15.75 (20.5)	3.80±10.47 (1)	0.044*
	Post-op month 12	15.75±15.35 (16.5)	3.50±10.61 (3.5)	—

Mann-Whitney *U* test, * $p < 0.05$, ** $p < 0.01$.

Table 5. ABG assessment according to stapes presence

		Stapes		<i>p</i>
		Normal	No suprastructure	
		Mean±SD (Median)	Mean±SD (Median)	
ABG	Post-op month 6	26.0±5.19 (27)	32.67±14.38 (35)	0.261
	Post-op month 12	29.71±12.24 (30)	33.29±12.45 (39)	0.383
ABGG	Post-op month 6	20.71±13.62 (17)	5.67±13.28 (7.5)	0.048*
	Post-op month 12	17.0±17.30 (17)	1.43±8.26 (-2)	0.038*
AC	Post-op month 6	40.57±7.37 (40)	50.08±17.42 (54.5)	0.299
	Post-op month 12	43.71±10.48 (40)	48.43±15.86 (55)	0.620
HG	Post-op month 6	24.43±13.69 (25)	7.92±13.61 (11)	0.036*
	Post-op month 12	21.28±16.47 (26)	6.71±9.93 (11)	0.073

* $p < 0.05$, Mann-Whitney *U* test.

smoking, which, leading to local, regional and systemic adverse effects on the middle ear mucosa, caused higher MERI; and (iii) extended surgery. Pinar et al. (20) reported that in patients with higher MERI open mastoidectomy might be required to eradicate the disease.

Pinar et al. (20) showed that higher MERI increased the chances for open mastoidectomy and thus decreased the chances for success after ossiculoplasty. They reported higher MERI scores urged doctors to inform patients about the operation elaborately, which helped patients have more realistic expectations con-

cerning the results. Additionally, they reported MERI scores helped surgeons develop a case-specific operation strategy in each case (20).

Emir et al. (21) also performed a study on MERI scores and hearing results that they evaluated by ABG and HG. They found no correlation between the MERI scores and hearing results except in the incus interposition group. In the patients with autograft incus interposition the rate of a hearing gain >10 dB was 75.8% in moderate MERI and 40.5% in severe MERI. Emir et al. (21) preferred to use PORP instead of incus assessment in patients with otorrhea, tympanic membrane perforation and in staged procedures. They reported that pre-op middle ear factors affected the prosthesis success rate. They also stated that pre-op MERI scores might help predict the post-op ossiculoplasty success rate. In line with Pinar and Emir et al.'s studies (20,21), at post-op month 6 we found a statistically significant correlation between ABGs and MERI risk groups' values. The rate of an ABG result of <30 dB was 100%, 87.5% and 12.5% in the mild, moderate, and severe MERI groups, respectively. As the MERI scores increased, post-op month 6 ABG values also increased. Besides, average ABBG at post-op month 6 was significantly higher in mild MERI than in moderate and severe MERI.

Furthermore, we observed no complication of sensorineural hearing loss. We performed measurements of pre-op BC at 1, 2, and 4. kHz and repeated these measurements at post-op month 6 and month 12. We compared all results to check for any loss of sensorineural hearing. At post-op month 12 our measurements of BC at 1, 2, and 4. kHz were min. -20 dB and max. 0 dB. We also found a significant decrease in the measurements at month 12, compared the pre-op values. These results are also consistent with the literature.

Complications affect the success in ossicular reconstruction. In order of frequency, Silverstein (22) reported the causes for complication and failure to be disease recurrence, rejection of the prosthesis, fixation of the prosthesis, dislocation and lateralization of the prosthesis, erosion of the stapes base, and rejection of cartilage. Sheehy (23) reported a Plastipore prosthesis rejection rate of 50% and explained it by severe mucosal disease and tubal dysfunction. Similarly, Sheehy and Crabtree (24) reported recurrent cholesteatoma, infection and adhesion to be the primary reasons for redu-

ced post-op hearing, while Bojrab et al. (25) reported atelectasis, fibrosis, perforation and persistent otitis media as predisposing factors for prosthesis rejection.

Yung and Vowler (18) classified the long-term failures in ossiculoplasty in three categories: those caused by middle ear pathologies, prostheses, and surgeons. They reported persistent and recurrent middle ear pathologies to be the most common cause of failure. In addition, Vrabcic et al. (26) reported that risk of prosthesis rejection was significantly correlated with the post-op status of the middle ear (myringitis, recurrent otitis media, and atelectasis). According to Truy et al. (27), post-op Eustachian tube dysfunction is the primary reason for prosthesis rejection.

Dornhoffer and Gardner (5) reported the factors complicating a clear judgment about ossiculoplasty outcomes: the lack of large case series, diversity of the applied methods, use of prostheses with varying characteristics, pathologies varying from patient to patient (5). Zeitler and Lalwani (28) stated that a comparison of different prostheses also would be a challenging task due to the various parameters like the prosthesis site, surgical method, condition of the tympanic membrane, and underlying pathology.

In our study, prosthesis rejection was observed in 2 (9%) patients due to recurrent otitis media; the patients were monitored under medical treatment and excluded from the study. In one patient (4.5%) we had to remove the prosthesis due to cholesteatoma recurrence and excluded this patient as well. Revision surgery was done in 5 (22.5%) patients, due to prosthesis dislocation in 4 of them. Retraction was observed in a total of 3 (13.5%) patients. Eight patients in the severe MERI group developed complications while retraction occurred in 2 in the moderate MERI group.

Low patient number and short follow-up time are the major limitations that apply to our study. More accurate and reliable results can be obtained in further studies with more patients and longer follow-up.

In this study, we found that presence of the malleus handle and stapes suprastructure and prognostic MERI grading affected the success in hearing reconstruction. In line with the literature, we showed that pre-op MERI scores might help surgeons develop a patient-specific operation strategy by providing guidance during ossiculoplasty.

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