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Research Article

Surgical Aspects Influencing Tympanoplasty Outcomes

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Abstract

Background: Tympanoplasty (TP) is a surgical procedure that aims to repair a persistently perforated eardrum via grafting. Different surgical techniques and graft materials were used for TP with variable success rates.

Purpose: This study aims to determine predictors of failure of TP and compare different graft materials used.

Materials and Methods: Retrospective review of all the medical records of patients that underwent tympanoplasties at King Abdulaziz University Hospital from 2011 to 2013. Predicting factors included smoking, associated comorbidities, past ear surgeries, symptoms, anatomy and cause of perforation, primary or revision, type of TP, technique, approach, usage of packing and graft materials (fascia, cartilage or allograft). Outcome of success was measured clinically by graft take-up and degree of air-bone gap (ABG) closure.

Results: A total of 80 cases were reviewed, and analysis showed no difference between graft types' success rate. The underlay surgical technique had a statistically significant better success rate (85.7%) compared the overlay technique (55.6%) (p=0.03). No other risks for failure were identified from our variables. ABG closure was best at hearing frequencies 250, 500 and 1k Hz. ABG closure at 2k and 4k Hz was not statistically significant.

Conclusions: Graft type has no significant effect on clinical outcome. Underlay technique is superior to overlay with a higher success rate. Functional hearing improvement after TP can be expected after surgery.

ABBREVIATIONS

TP: Tympanoplasty; TM: Tympanic Membrane; ABG: Air-Bone Gap; KAUH: King Abdulaziz University Hospital; HL: Hearing Loss; Db: Decibels

INTRODUCTION

Tympanoplasty (TP) is a surgical operation that aims to restructure a defected tympanic membrane (TM) and eradicate middle ear pathology in order to achieve a well-aerated middle ear and improve hearing function. Despite the fact that the majority of perforated eardrums heal on their own, some persist for months and increase the risk for developing infection or cholesteatoma [1,2]. Thus the indication for TP is persistent perforation of the eardrum, often caused by otitis media or trauma.

The success rate of TP among adults is variable in literature with a rate of 60 – 99% [3]. Numerous studies attempted to link certain variables to the outcome of this procedure including: size, location, and etiology of the perforation, pre-operative and post-operative audiometric results, dryness of the ear, condition of the contralateral ear, type of graft used, associated middle ear disease, surgical technique, age and smoking history of the patient, as well as the surgeon's experience [4-8]. Correlating many of these aforementioned factors in predicting the outcome of TP remain controversial.

Grafts made from different materials have been used to mend the defected TMs. The most commonly used graft is temporalis fascia [9]. Other types of autologous grafts have been successfully used including cartilage, subcutaneous tissue, and adipose grafts [10-14]. Autologous grafts are often preferred over the allografts similar to acellular dermal grafts (AlloDerm®) because of their cost-effectiveness [15,16]. The dispute over the type of graft that produces the most favorable results in TP remains unresolved.

This study aims to review the tympanoplasties carried out in King Abdulaziz University Hospital (KAUH) and to present

the clinical characteristics in relation to the outcomes of these procedures. An emphasis was placed on the type of graft used in correlation with their surgical outcomes in order to determine the most suitable graft material in a practical setting. An effort was made to weigh our findings against the existing literature.

MATERIALS AND METHODS

Study design and setting

Retrospective review of all tympanoplasties performed at KAUH, a tertiary care teaching hospital in Jeddah, Saudi Arabia over a 3 year period from 2011 to 2013.

Data Analysis

A review of the paper-based and computer-based medical records of the patients that underwent tympanoplasty at KAUH was conducted.

Patients' demographics were recorded including gender and age. The clinically relevant data were reviewed discreetly with respect to the patients' confidentiality. The evaluation points include: indications for surgery, size, site and cause of perforation, associated symptoms and pathological findings in both ears, surgical technique and approach, type of utilized graft, material used for packing, follow-up period, whether it was primary or revision TP, patient's smoking history, as well as surgical outcome and complications.

In this study, size of perforation has been classified into perforations larger or smaller than 50% of the size of the entire eardrum. The site of the perforation was defined as being either central or marginal. Marginal perforations involved the annulus. Surgical techniques are either overlay (lateral) grafting or underlay (medial) grafting, whereas surgical approaches include transcanal, endaural, and postauricular. The types of grafts available were homografts including temporalis fascia and cartilage/perichondrium, or alloplast ones including AlloDerm® and Tutoplast®. The types of TP performed include; type I which is simple myringoplasty, type II TP involving grafting onto the incus or the malleus, and type III which involves placing a graft over the stapes suprastructure. Tympano-mastoidectomy encompasses, in addition to the TP, removal of damaged mastoid bone. Tympano-ossiculoplasty includes ossicular reconstruction with in the middle ear. The available packing materials were Gelfoam, Silastic sheets, ear wicks, and cotton-balls.

Patients' hearing loss (HL) was objectively quantified via audiological testing; namely: audiometry, which measures hearing acuity at different sound pitches and intensities by air and bone conductions. Hearing gain was assessed in all cases regardless of graft uptake status by comparing pre- and post-operative audiograms looking for closure of the ABG and gain in air conduction hearing. Patients' follow-up periods were divided into; less than 3 months, three months up to 6 months, and more than 6 months and no follow-up for ease of interpretation.

The outcomes of TP were assessed based on two elements; an anatomical outcome and a functional one. Success in closing the TM (graft acceptance rate) based on the clinical notes of the examination performed by a qualified otolaryngologist, and hearing gain in air conduction and closure or narrowing of the ABG in the post-operative audiogram when compared to the pre-operative audiogram respectively represent such outcomes. Only complete healing of the defect without residuals was accepted as success. Any closure of the ABG is considered clinically significant, an ABG closure to 10 decibels (db) or less is considered ideal.

The statistical Package used for this study is IBM SPSS version 22. This study used simple descriptive statistics to show the nominal variables in a form of counts and percentages, as well as means± standard deviations for the scalar variables. The relative frequencies were calculated after exclusion of missing data. To establish a relationship between categorical variables, the chi-square test with a 95% confidence interval was utilized. To determine the difference between pre and post related measures, this study used paired t-test after normality has been assumed. Results were deemed significant using a conventional p-value≤0.05.

RESULTS

The total number of patients who underwent tympanoplasties at KAUH during the study period was 80 patients, 47(58%) were females and 33(41%) were males. The mean age was 34.6±13.3 years, with a range of 10-69 years.

Pre-operative assessment

Patients presented to the otolaryngology clinics with various complaints. Thirty-three (41%) complained of ear pain, of which 29 (88%) were in the operative ear, 2 (6%) in the opposite ear, and 2 (6%) in both ears. Fifty-five (69%) complained of ear discharge, of which 47(85.5%) were in the operative ear, **3**(5.5%) in the opposite ear, and 4 (9%) in both ears. The type of the discharge was mostly muco-purulent in (41cases, or 87%), serous (4 cases, or 8.5%), and bloody (2 cases, or4.5 %).Seventy-three patients noticed HL accounting for 91% of the cases, of which 46(63%) noted the HL in the perforated ear only, and 27(37 %) in both ears. Tinnitus was found in 20 (25%), vertigo in 14 (17.5%) of the cases. Infection was reported in 59 (74%) cases as the most common cause of perforation, followed by myringotomy in 5(7%), trauma in 4(5.7%), and iatrogenic in 2(2.8%) of the cases.

Amongst the patients included in this study, 4 cases (5%), had history of bronchial asthma, (3 cases (3.8%), had diabetes mellitus, and (6 cases (7.5%), had hypothyroidism. Sixteen patients (20%) were previously diagnosed with allergic rhinitis. Past surgical history was significant for myringotomy with insertion of a ventilation tube in 13 cases (16.3%), and tonsillectomy in (6 (7.5%) of cases. Only (4 cases (5%) were smokers.

On examination, the site and size of perforation and associated pathologies were noted. Central perforations accounted for 58 (84%), and marginal for 11 (16%) cases. Anterior perforations were present in 17 (23.3%) of cases and absent in 56 (76.7%). The size of perforation was less than half in 28 (41.8%). It was more than half in 39 (58.2%), among which there were22patients (56.4%) subtotal perforations. The presence of cholesteatoma was documented in 10 cases (12.5%).

Intra-operative aspects

Sixty-one cases (76%) were primary tympanoplasties, while 19 (24%) were revisions. In 53% cases, the operated ear was the

right, and in 46% it was the left. The types of the TP performed were as following: type I in 51(64%), type II in 14 (17%), type III in 1 (1.5%), tympano-mastoidectomy in 10 (12.5%), tympano-ossiculoplasty in 4 (5%) of the cases. Underlay technique was used in 65 (85.6%), overlay in 9 (11.8%), sandwich in 1 (1.3%), and butterfly in 1 (1.3%). The surgical approach was transcanal in 10 (13.5%), post-auricular in 57 (76%), and endaural in 8 (10.5%). Temporalis fascia was the graft harvested and used in 48 (61%) of the cases. Cartilage/perichondrium was used in 21 (26.5%), and allograft in10 (12.5%) of the total. With regards to packing materials used, Gelfoam was used in 48 (60%), Silastic sheets in 51 (64%), ear wicks in 61 (76%), and cotton-balls in 3 (4%) of cases. The surgical techniques and approaches, type of tympanoplasties, and graft materials used with their associated success rates and p-values are shown in Table 1.

Post-operative evaluation

There was a complete closure of the perforation in 56 (80%), healing with residual perforations were in 7 (10%), failure of graft uptake were in 7 (10%) of the cases. Nine patients (11.3%) were unfortunately lost to follow-up. Thirty seven patients (46.3%) had been followed-up for a period of less than 3 months, 20 (25%) for 3 to 6 months, 14 patients (17.5%) for more than 6 months. There were no complications in 65 (89%). However, there was graft retraction in 2(2.7%), infection in 5(6.8%), and one case of facial nerve palsy (1.4%).

With respect to audiogram reports, the difference between the pre-operative and post-operative means for closure of ABG as well as air and bone conduction hearing threshold at different frequencies is presented in Table 2.

DISCUSSION

Tympanoplasties are frequently performed surgeries that aim to repair defected tympanic membranes. Hence, it is not surprising to find a high success rate in such surgeries particularly in simple myringoplasties. Many publications have noted a success rate that is 80%or higher [4, 8,10]. Our study had an analogous success rate of 80%.

Further analysis was performed in order to identify possible prognostic factors. In our study, it seems that males had a higher success rate of 93.3% compared to female patients who had a rate of 70%, and this was found to be statistically significant (p= 0.016). Therefore, male gender was a good prognostic factor in this study. The mean age for patients that had a successful TP was 33.5 years, while the mean age for those that failed was 38.6 years. Consequently, age was not linked as a prognostic factor in our present study. Similar to other studies, smoking was not a significant factor in TP [4]. Associated comorbidities including diabetes, hypothyroidism and asthma did not alter the outcomes significantly. Neither did the patient's prior history of ear surgeries performed on the operated ear including myringotomy with grommet insertion and tympanoplasty.

As for the site of the perforation, some authors suggested that anteriorly located perforations might be more challenging compared to other sites [17,18]. A possible explanation for such an observation was that the anterior part of the TM might be less vascularized [19]. Other studies reported that the site of a perforation does not have a significant impact on the outcome [8].According to our data, an anteriorly located perforation does not have a statistically significant influence on success rate (p=0.163). The size of the perforation has been suggested as a prognostic factor in literature with larger perforation leading to worse outcomes, however some studies state the contrary [4]. Though we noted a higher success rate of 87% in perforations smaller than 50% and a lower rate of 72.7% in perforations larger than 50%, it was not statistically significant to make such an association in this study (p=0.176). The most common cause of perforation was infection. No particular cause of perforation was associated with a higher failure rate (p=0.855). The presence of cholesteatoma was associated with a 20% failure rate, however this rate was not deemed statistically significant (p=1.0).

Table 1: The surgical aspects of tympanoplasty.

	Success	Failure	P-value
Technique			
Underlay	48 (85.7%)	8 (14.3%)	0.030
Overlay	5 (55.6%)	4 (44.4%)	
Type of Tympanoplasty			
One	34 (82.9%)	7 (17.1%)	0.603
Two	10 (71.4%)	4 (28.6%)	
Three	1 (100.0%)	0 (0.0%)	
Tympanomastoidectomy	7 (70.0%)	3 (30.0%)	
Tympano-ossiculoplasty	4 (100.0%)	0 (0.0%)	
Graft materials			
Synthetic	8 (80.0%)	2 (20.0%)	0.967
Fascia	32 (80.0%)	8 (20.0%)	
Cartilage/Perichondrium	15 (78.9%)	4 (21.1%)	
Unknown	1 (100.0%)	0 (0.0%)	
Approach			
Transcanal	7 (70.0%)	3 (30.0%)	0.299
Post-Auricular	39 (81.3%)	9 (18.8%)	
Endaural	7 (100.0%)	0 (0.0%)	
Unknown	3 (60.0%)	2 (40.0%)	

Table 2: The pre-operative and post-operative audiogram results.

Variable	Pre- operative	Post- operative	mean Difference	P-value
Bone 250	15.61±9.7	17.12±9.7	-1.515	.452
Bone 500	19.24±9.9	18.33±12.3	.909	.706
Bone 1K	17.88±12.2	18.33±12.8	-.455	.854
Bone 2K	23.64±14.6	24.39±16.6	-.758	.763
Bone 4K	22.12±17.6	25.91±18.7	-3.788	.132
Air 250	55.15 ± 16.7	43.33±20.6	11.818	.002[a]
Air 500	51.67±17.8	41.06±20.4	10.606	.002[a]
Air 1K	41.06±17.6	35.76±20.5	5.303	.079
Air 2K	39.24±19.0	36.52±21.0	2.727	.433
Air 4K	39.24±19.0	46.36±22.4	-7.121	.037[a]
Air Mean	41.69±19.5	41.31±17.9	.389	.917
ABG 250	39.55±14.1	26.06±16.2	13.485	<0.001[b]
ABG 500	33.03±15.0	22.42±14.4	10.606	<0.001[b]
ABG 1K	23.94±15.7	16.97±13.1	6.970	.007[a]
ABG 2K	14.55±11.0	11.97±9.9	2.576	.229
ABG 4K	24.85±14.7	20.45±15.1	4.394	.157
ABG Mean	24.92±13.2	20.14±11.3	4.778	.055

[a]significant using chi-square test @0.05 level
[b]significant using chi-square test @0.001 level

Majority of tympanoplasties done in our hospital were primary (61 cases, or 76%). More than 85% of the surgeries were carried out using an underlay technique. (Table 1) showed that the underlay technique were significantly associated with a more favorable outcome (p=0.03), a finding consistent with some existing literature [8], and conflicting with others [18]. Graft material did not alter the outcomes of TP in our study (p= 0.967). Conflicted evidence is available with some studies stating that there is no difference between different graft types [9,20], while others suggest that use of cartilage or fascia is preferred [10,11,18].The type of TP did not change the outcome significantly(p=0.603).The post-auricular approach was preferred in more than 75% of our cases, which may provide an easier access and clearer view of the perforation. The transcanal approach had a 30% failure rate in our study. A study by Albera et al suggested that a post-auricular approach would yield a better outcome with decreased likelihood of reperforation [21]. However, no specific approach in our study revealed a significant influence on the end results (p=0.299). With regards to the type of packing utilized, ear wicks, Silastic sheets and Gelfoam were very frequently used (>60%). No particular packing material was linked with a higher success rate.

Post-operatively 11.3% of patients did not come to the clinic for follow-up, 46.3% of them only followed-up for less than 3 months after the surgery, most likely they are the group of patients who improved and did not feel the need to revisit their treating physicians. Most (89%) of our patients were free from complications after the surgery. There was graft retraction in two cases and infection in five. One patient suffered from facial nerve palsy.

Pure tone audiometry was used to functionally evaluate the patients' improvements after surgery as elucidated in the methodology. There was a very significant mean hearing gain at 250 Hz of 13.5 dB (p<0.001), at 500 Hz of 10.61 dB (p<0.001), and at 1k Hz of 6.97 dB (p=0.007). Mean hearing gain at 2k and 4k Hz was 2.6 and 4.4 dB, though clinically significant, it was not statistically significant. Air conduction hearing improved by 11.82 dB at 250 Hz and by 10.61 at 500 Hz (p=0.002). It also improved by 5.3 dB at 1k Hz with p value approaching significance of 0.79, and by 2.7 dB at 2k Hz (p=0.433). Paradoxically, there was hearing loss at 4k Hz of -7.1 dB (p=0.037). This could be explained by inter-exam difference in reliability. Another explanation is that patients who have had perforations for a prolonged period and have been using ototoxic drugs may have developed sensorineural hearing loss. From the aforementioned data, we can deduce that lower tone frequencies were associated with better enhancement in hearing compared to the higher frequencies. The mean hearing gain observed in literature was variable ranging from 10 dB to 13 dB [22-24].

CONCLUSION

Tympanoplasty is a commonly performed operation in the Otorhinolaryngology department. The choice of graft type used remains a matter of preference of the surgeon. The authors recommend using the underlay technique, which was shown to yield better outcomes. Patients are likely to show hearing improvement in the lower hearing frequencies after the surgery compared to the higher ones.

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