



Effect Of the Size of Tympanic Membrane Perforation on The Success of Type-1 Tympanoplasty, Baghdad, 2018.

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Abstract

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Background: Type I Tympanoplasty is a commonly performed operation in the ENT department that aims to repair a defect in the tympanic membranes, to improve hearing to a serviceable level, and to minimize the occurrence of complications.

Aim of the study: To evaluate the impact of tympanic membrane perforation size on graft take and on hearing improvement in type I tympanoplasty.

Methods: This prospective study was carried out at Al-Shaheed Ghazi Al-Hariri teaching hospital for specialized surgeries in the period between 1st July 2016 to 1st January 2018, in which 50 patients with tympanic membrane perforation underwent type I Tympanoplasty using an underlay temporalis fascia graft. Preoperative and postoperative examination of the patients was carried out by clinical and audiological assessment.

Result: The graft success rate was 84%. Significant predictors of failure included smoking and perforation size >50%. For successful takes, hearing improvement showed a direct correlation with perforation size; the mean air-bone gap (ABG) reduction was 5.25 dB, 14.05 dB, 21.24 dB, and 20.63 dB for small, medium, large, and subtotal perforations, respectively.

Conclusions: The size of tympanic membrane perforation is an important factor affecting graft taking. Hearing loss was associated proportionally with the size of tympanic membrane perforation. Postoperative hearing gain for graft success cases was directly related to the preoperative size of the tympanic membrane perforations.

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1. Introduction

The functional performance of the middle ear is critically dependent on the integrity of the Tympanic Membrane (TM) and the ossicular chain. Structurally, the TM develops embryologically when the endoderm of the middle ear precursor sac encounters the ectoderm of the first pharyngeal groove, with Mesenchyme growing between them to form the middle, fibrous layer. Similarly, the ossicles originate from the cartilages of the first and second branchial arches. 1 In its adult form, the TM constitutes the lateral wall of the tympanic cavity, divided into the sparsely reinforced pars flaccida and the structurally complex pars tensa. 1 The TM's primary function is to efficiently transmit sound pressure via ossicular coupling to the oval window. This mechanism is essential for overcoming the significant impedance mismatch (approximately 30 dB loss) between the low-impedance air in the external auditory canal (EAC) and the high-impedance fluid within the cochlea. 2 This acoustic gain is achieved through the Acoustic Transformer Theory, primarily driven by the Hydraulic Lever Effect (resulting from the ≈21:1 ratio of TM surface area to the oval window surface area). 3 TM perforation critically compromises the TM's function by reducing the necessary surface area for sound collection and eliminating the pressure gradient across the membrane. This disruption leads to impaired ossicular movement and subsequent conductive hearing loss. 4, 5 Clinically, perforation size is graded using the Griffin grading system, which ranges from Grade I (≤25% of TM surface area) up to Grade IV (75%–100%). 6 Type I Tympanoplasty is specifically classified as TM repair performed in the presence of an intact native ossicular chain. This procedure relies entirely on the successful reconstruction of the TM surface. Temporalis fascia remains the most frequently used graft material, although perichondrium has also proven effective. 7 The graft may be placed using either the Lateral Graft Technique (Overlay) or the Medial Graft Technique, with the surgical approach (transcanal, endaural, or postauricular) selected based on the surgeon's preference and the perforation's visibility. 7 A vast body of research indicates that the outcomes of Tympanoplasty are influenced by multiple variables, including the size and location of the

perforation, the presence of middle ear disease, the type of graft used, and the surgeon's experience. 8, 9 To objectively assess surgical success, established audiometric criteria are used, principally the mean hearing gain and the reduction of the Air-Bone Gap (ABG). The Committee on Conservation of the American Academy of Ophthalmology and Otolaryngology recommended standardized reporting, including stating the mean hearing gain in the 500-2000 Hz range and, crucially, reporting the reduction of the ABG to ≤ 10 dB (considered optimal closure), ≤ 20 dB, and ≤ 30 dB. 10 The persistent need to define the precise impact of TM perforation size on the success of Type I Tympanoplasty, particularly within specific local clinical environments, warrants further investigation. This study in Baghdad aimed to provide regional data to clarify this relationship, thereby informing preoperative decision-making and patient counseling.

2. Patients and methods

This prospective study was carried out at Al-Shaheed Ghazi Al-Hariri teaching hospital for specialized surgeries – Medical City Teaching Complex in the period between 1st July 2016 to 1st January 2018, in which 50 patients with TM perforation underwent type I Tympanoplasty.

Preoperative evaluation: Full ENT history focuses on ear symptoms (discharge, hearing loss, otalgia, tinnitus, and vertigo), cause of perforation, past medical history, past surgical history, drug history, and smoking history was taken from the patients. Full general and otorhinological examination was carried out, focusing on the ear, including otoscopic, rigid 0-degree endoscopic, and microscopic examination, concentrating on assessment of the size of TM perforation and the status of the middle ear mucosa and the status of the contralateral ear. The patients were divided into four groups depending on the estimated size of TM perforation according to the Griffin grading system: Small ($\leq 25\%$), medium (26% - 50%), Large (51%-75%), and Subtotal ($> 75\%$). Hearing assessment was performed using a 512Hz tuning fork for Rinne and Weber tests. Patients were referred for pure tone audiometry (PTA) to measure both air and bone conduction thresholds. Three frequencies—500, 1000, and 2000Hz—were used to calculate the average air threshold and the mean air-bone gap (ABG) for each ear. Tympanometry was conducted on all patients. Additionally, a CT scan of the temporal bone was performed for all patients to evaluate the middle ear and ossicular chain status, mastoid air cells, sigmoid sinus, dural plate, and surrounding structures. Patients with active discharge received conservative treatment, including suction clearance and topical and systemic antibiotics based on culture and sensitivity testing, for 10 to 14 days to dry the ear. All patients were informed verbally before surgery. The inclusion criteria included age of more than 12 years, central TM perforation, and dry ear for at least one month. Patients were excluded from the study if they had any of the following criteria: age less than 12 years, marginal TM perforation, perforation of the pars faccida, previous tympanoplasty, advanced tympanosclerosis, only hearing ear, or medically unfit patient for GA.

Surgical Procedure: All surgeries were performed under GA and oral endotracheal tube, using hypotensive technique, the patient was positioned in the supine position, and the head was turned to the opposite ear. Scrubbing of skin with Antiseptic Povidone iodine and draping were done. An ear examination under a microscope was done, and then the perforation edge was scraped using a curved needle and scraping the epithelium in the undersurface of the TM. All patients were approached through a postauricular incision, which was about 0.5 cm from the postauricular sulcus, and the temporalis fascia was harvested through the same incision and was dried. An incision was then made by cautery down to the periosteum, creating an anteriorly based musculoperiosteal flap or T-shaped flap. By using a periosteal elevator, the periosteum is elevated anteriorly, reaching the posterior canal wall and identifying the spine of Henley. Cortical mastoidectomy was done in some patients to enlarge air cells and for more ventilation of the middle ear. Then a tympanomeatal flap was elevated using a drum elevator, and canaloplasty was done in some cases. Inspection of middle ear cavity and assessing of ossicular chain integrity was carried out, after that gel foam was put in middle ear cavity to support the temporalis fascia graft which was put under the remnant of TM (underlay technique), then the tympanomeatal flap was returned to its position, gel foam put over the graft then BIPP wick was inserted in the external auditory canal, corrugate drain was applied in patients whose underwent cortical mastoidectomy, the post auricular incision was closed, lastly mastoid dressing.

Postoperative follow-up: Postoperatively, patients were kept on injectable antibiotics and oral analgesia. Stitches and BIPP were removed after seven days. Corrugated drain was removed after 1-4 weeks. Patients were advised to avoid straining and exercise for at least 4 weeks after the operation. Patients were followed monthly for three months by examination of the TM healing, and PTA was performed at the end of 3 months. Complete healing of TM: intact, dry, normally positioned graft with no residual perforation and hearing improvement (Air conduction threshold and ABG) after three months was considered as the success of the surgery.

Statistical Analysis: Data were first entered in an Excel file, and later transported into the Statistical Package for Social Sciences file 24 (SPSS v24) for data analysis. Continuous variables were presented as means, and discrete variables were presented as numbers and percentages. Chi-square test for independence was used to test the significance of the association between discrete variables. Paired t-test for two dependent variables was used to test the significance of the difference in means for measured variables before and after surgery. The Kruskal-Wallis Test was used to test the significance of variation in means between more than two independent samples. The level of significance was set at P value equal to or less than 0.05.

2. Results:

This study evaluated the outcomes of type I tympanoplasty using the temporalis fascia graft in fifty patients with tympanic membrane perforation. The age ranged from 14 to 60 years, with a mean age of 33.9 ± 11.3 . There were 23 (46%) males and 27 (54%) females. The clinical features accompanying the perforation were hearing loss in 46 (92%), ear discharge in 45 (90%), otalgia in 18 (36%), tinnitus in 11 (22%), and vertigo in 8 (16%). Infection was the primary cause of perforation in 41 patients (82%), while it was due to trauma in the remaining 9 patients (18%). Bilateral ear involvement was in 18 patients (36%) and unilateral in 32 patients (64%). The side of the operated ear was the right side in 22 cases (44%) and the left side in 28 cases (56%). The size of TM perforation out of the total size of the membrane was up to 25% in 13 patients (26%), 26% - 50% in 15 patients (30%), and between 51% - 75% in 10 patients (20%), and more than 75% in 12 patients (24%). Concerning smoking, 11 patients (22%) were smokers (Table 1).

Table 1: Sociodemographic and related characteristics of the study patients

Variable	Frequency. (n= 50)	Percentage %
Age in years (mean \pm SD)	33.9 \pm 11.3	Range (14 – 60)
Gender		
Male	23	46.0

Female	27	54.0
Clinical feature		
Hearing loss	46	92.0
Ear discharge	45	90.0
Otalgia	18	36.0
Tinnitus	11	22.0
Vertigo	8	16.0
Cause of perforation		
Infection	41	82.0
Trauma	9	18.0
Side of perforation		
Bilateral	18	36.0
Unilateral	32	64.0
Side of the operated ear		
Right	22	44.0
Left	28	56.0
Size of operation		
Small	13	26.0
Medium	15	30.0
Large	10	20.0
Subtotal	12	24.0
Smoking		
Smoker	11	22.0
Non-smoker	39	78.0

Out of 50 patients, 42 (84%) got a successful tympanic graft take, while the remaining 8 patients (16%) did not. Smoking was observed to have a significant association with non-take of graft (50% of non-take were smokers, $P < 0.05$). The Size of perforation was significantly associated with the status of graft take in a way that perforation size larger than 50% found to be associated with less take of graft ($P < 0.05$). Age, gender, history of ear discharge, status of the contralateral ear, side of the operated ear, and cause of perforation were not significantly associated with the outcome of graft take (Table 2).

Table 2: Distribution of the study patients according to their response to the graft and to their characteristics

Variable	Category	Graft success				P value
		Yes		No		
		N=42	%	N=8	%	
Age (years)	Mean \pm SD	34.6 \pm 11.7		30.4 \pm 8.5		0.337
Sex	Male	19	45.2%	4	50%	0.804
	Female	23	54.8%	4	50%	
History of ear discharge	Yes	37	88.1%	8	100%	0.304
	No	5	11.9%	0	0%	
Smoking	Yes	7	16.7%	4	50%	0.036
	No	35	83.3%	4	50%	
Side of perforation	Bilateral	15	35.7%	3	37.5%	0.923
	Unilateral	27	64.3%	5	62.5%	
Side of the operated ear	Right	19	45.2%	3	37.5%	0.686
	Left	23	54.8%	5	62.5%	
Cause of perforation	Infection	33	78.6%	8	100%	0.148
	Trauma	9	21.4%	0	0%	
Size of perforation	$\leq 25\%$	13	31.0%	0	0%	0.007*
	26%- 50%	14	33.3%	1	12.5%	
	51%- 75%	7	16.7%	3	37.5%	
	> 75%	8	19.0%	4	50%	
*After merging size categories up to 50% & larger than 50%.						

Out of the 42 patients with successful graft take, the improvement in hearing varied proportionally based on the size of the perforation, with larger perforations showing greater improvement ($P < 0.05$). The mean postoperative improvement in the average ABG increased from 5.25 dB in TM perforations of 25% or less to 20.63 dB in perforations larger than 75%. The mean postoperative hearing gain in the average air conduction threshold increased from 5.77 dB in TM perforations of 25% or less to 24.37 dB in perforations larger than 75% TM perforations. (Table 3).

Table 3: Hearing improvement in patients with successful graft take according to size of the TM perforation

Perforation size of TM	N	Improvement in Average ABG (dB)		Hearing Gain in Average Air conduction threshold (dB)	
		Mean	SD	Mean	SD
$\leq 25\%$	13	5.25	3.40	5.77	3.01
26%- 50%	14	14.05	3.68	14.88	4.26
51%- 75%	7	21.24	8.51	22.19	5.38

> 75%	8	20.63	5.11	24.37	5.26
Total	42	13.68	8.03	15.09	8.39
P value		< 0.001		< 0.001	

For the overall graft success patients, there is a significant closure of average ABG from (25.62 ± 8.70 dB) preoperatively to (11.94 ± 3.82 dB) postoperatively with a mean improvement in average ABG (13.68 ± 8.03 dB). Hearing gain (in Air conduction threshold) for graft success patients ranges from zero to 31.67 dB, with a mean increase of (15.09 ± 8.39 dB). (Table 4).

Table 4: Outcome of hearing after the success of graft take for tympanic perforation in forty-two patients

Variables	Statistics	Magnitude (dB)
Preoperative Average ABG	Min-Max	6.63 - 40.66
	Mean± SD	25.62 ± 8.70
Postoperative Average ABG	Min-Max	5.0 - 18.33
	Mean± SD	11.94 ± 3.82
Improvement in Average ABG	Min-Max	-0.03 - 33.66
	Mean± SD	13.68 ± 8.03
Hearing Gain	Min-Max	0 - 31.67
	Mean± SD	15.09 ± 8.39
P value for the difference in means in average ABG pre- & post-operatively < 0.001		

4. Discussion:

In this study, 42 patients (84%) achieved successful tympanic graft take, comparable to results from many other studies. In a survey by Arindam Das et al. on 60 patients, the success rate was 80% (48 patients). 5 Rodrigues et al. (2017) observed that surgical closure of the eardrum occurred in 42 out of 52 ears, with a success rate of 80.8%. 8 Al-Khatib et al. (2016) found that complete closure of the perforation in type 1 Tympanoplasty occurred in 82.9% of patients (9). Ali Khan et al. showed that the graft was intact in 87.5%. 11 KM Nurul Alam et al. (2013) showed that the overall success rate was 86.67% (52 out of 60). 12 Md. Zakaria Sarker et al. (2011) found that the average graft-taking rate was 81.67%. 13 In this study, the mean age of patients with graft take was 34.6 ± 11.7 years, and 30.4 ± 8.5 years for patients with graft failure. Therefore, in adults, age was not a significant factor for graft success. This result agrees with data in the literature: Rodrigues et al. (2017), 8 Al-Khatib et al. (2016), 9 Hatice Emir et al. (2007), 13 José Carlos Bolini de Lima et al. (2011), 14 J. H. Black, P. J. Wormald (1993), 15 Muhanned M. Alwan and Naser E Naser (2013), 16 all of whom showed no relation between the patients' age and the anatomical success of tympanoplasty.

In the present study, gender was not a significant factor for graft success. This result is in line with data in literature: Rodrigues et al. (2017), 8 KM Nurul Alam et al. (2013), 12 Muhanned M. Alwan and Naser E Naser (2013). 16 On the contrary, some studies showed a significant difference in graft take in relation to gender. Al-Khatib et al. (2016) found that males had a higher success rate of 93.3% compared to female patients (70%), $p = 0.016$. 9 Hatice Emir et al. (2007) found that males had higher rates of graft success ($P=0.031$). 13 There was no significant relation between the history of ear discharge and the graft take rate. Hatice Emir et al. (2007) and Muhanned M. Alwan and Naser E Naser (2013) showed no significant relation between the ear discharge and the success rate of graft take (P value 0.820 and 0.7, respectively). 13, 16

In this study, the cause of TM perforation was not a significant factor for graft success ($P = 0.148$). This is concurrent with Rodrigues et al. (2017), Al-Khatib et al. (2016), 9, and K.K. Abdul-Lateef and Tahseen Najem Aldeen. 17

The state of the contralateral ear may constitute an indirect way to predict the Eustachian tube function. In this study, there was no significant difference in the success rate of graft take between patients with bilateral or unilateral ear involvement (p value=0.923). This is concurrent with KM Nurul Alam et al. (2013), in which the surgical success rate was equal in both unilateral and bilateral cases. 12 On the contrary, Rodrigues et al. (2017) found that the closure rate of patients with disease in the contralateral ear was significantly lower than that of patients with a normal contralateral ear (68% and 96%, respectively), with a p -value of 0.011. 8 K. Onal et al. found that the success rate of myringoplasties of the patients with a pathological opposite ear was 52%, whereas it was 80% in the group of patients whose opposite ear was normal at the time of operation ($P = 0.01$). 18 In our results, smoking was a significant factor affecting the graft take rate, where the non-smoker patients showed a graft take rate of 89.7% while in smoker patients, the graft take rate was 63.6%, $P = 0.036$. K. Onal et al. reported that while the graft take rate in the non-smoking group was 78.7%, it was 47.4% in the smoking group, and this difference was statistically significant ($P = 0.008$) (18). Swain et al. showed that there was a worse outcome of postoperative tympanoplasty among smokers in comparison to non-smokers (graft uptake is 68% and 93%, respectively). 19 On the contrary, José Carlos Bolini de Lima et al state that smoking was not statistically significant for surgical success. 14

In this study, the size of the TM perforation was found to be a significant factor for the success of graft taking. This finding is in line with Arindam Das et al, 5 Hatice Emir et al. (2007), 13 KM Nurul Alam et al, J. H. Black, and P. J. Wormald (1995). 15 On the other side, Al-Khatib et al. (2016) noted a higher success rate of 87% in perforations smaller than 50% and a lower rate of 72.7% in perforations larger than 50%. However, it was not statistically significant to make such an association in that study. 9 Ilana Fukuchi

et al. showed no statistically significant relation between the size of perforation and the success rate. 20

In the current study, preoperative average ABG increased proportionally with the size of TM perforations. The same figure was reported in Sood AS et al, 4 Bianca Niculescu, Doina Vesa and E. Tomescu, 21 M.R. Dawood, 22, and Nayak PD et al. 23

In this study, there was a significant closure of ABG from 25.62 ± 8.70 dB preoperatively to 11.94 ± 3.82 dB postoperatively with a mean improvement in ABG of 13.68 ± 8.03 dB. José Carlos Bolini de Lima et al found that the mean preoperative ABG decreased from 27.1 dB HL to 10.3 dB HL postoperatively. 14 KM Nurul Alam et al. state that the mean pre- and postoperative air conduction threshold in the successful grafting cases were 31.43 dB and 21.43 dB, respectively, with a mean audiological improvement of 10 dB, and the improvement of the mean ABG was 10.83 dB. 12 M.R. Dawood concluded the mean air conduction hearing gain was 22.37 dB, and the mean ABG reduction was 20.73 dB. 22 Nayak PD et al. (2017) found a significant difference between preoperative PTA average and postoperative PTA average, as well as preoperative ABG and postoperative ABG. Mean PTA average gain was 8.9dB, and ABG was 8.3dB. 23 Finally, M.S. Shukur and Sami Matloob (2011) found that the mean pre-operative air conduction threshold in the successful cases was 25.5 dB, and the postoperative air conduction threshold was 11.2 dB, with a mean audiological improvement of 14.3 dB, and an improvement of the mean ABG was 14.5 dB. 24

5. Conclusion:

It was concluded that the anatomical success rate correlated inversely with the preoperative size of tympanic membrane perforation. The hearing loss correlated proportionally with tympanic membrane perforation size, increasing as the perforation grew. The hearing gain was directly associated with the preoperative size of the tympanic membrane perforations, with greater gain observed in larger perforations. Smoking is an important factor affecting the success of type I tympanoplasty. It was recommended that the tympanic membrane perforations should be accurately determined and estimated according to their sizes for a correct estimation of their successful closure and hearing outcome in type I tympanoplasty.

Conflicting interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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