ORIGINAL ARTICLE

WHY MYRINGOPLASTIES FAIL? IMPACT OF RELEVANT CLINICAL FACTORS ON THE SURGICAL OUTCOME; A STUDY FROM PAKISTAN

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Background: Myringoplasty is the reconstruction of the tympanic membrane by grafting. Success varies from 50–100%. A study was conducted to unveil the vital causes for failed myringoplasty with an aim to attenuate graft rejections and augment better outcomes. **Methods:** It was descriptive case series in which data was retrospectively collected at a tertiary care hospital (Rawalpindi, Pakistan) from January 2009 to December 2018. First 600 consecutive patients who qualified for inclusion/ exclusion criteria, underwent myringoplasties were followed-up for 6 months. Graft Take/Failure, the main outcome variable, was correlated with relevant independent variables. Data was collected on a structured *pro forma*, approved by hospital ethical committee. Data was analysed using IBM-SPSS-21.0. **Results:** Out of 600, 164 (27.3%) had graft rejection; failure being significantly enhanced by increasing age (p<0.001), larger perforation (p-0.025), co-morbidities (p<0.001), especially diabetics (p=0.040) and Eustachian tube (p-0.016) dysfunction amongst among systemic and ENT diseases respectively, and discharge-free ear (Dry Ear) for <4 weeks (p<0.001); while best graft take was achieved with end-aural surgical technique (p=0.048). Gender (p-0.897) did not caste a significant impact on graft outcome. **Conclusion:** The results of various surgical approaches of myringoplasty are equitable. Proper socio-demographic and clinical evaluation can improve graft outcome, and this surgery shall be discouraged in patients with diabetes mellitus and defective Eustachian Tube functions.

Keywords: Failed Myringoplasty; Tympanic Membrane (TM); DNS; Deflected Nasal septum

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INTRODUCTION

Persistent tympanic membrane (TM) perforation is a frequently encountered entity in ENT OPDs since early days, which commonly leads to hearing impairment.[1] Most practiced treatment is closure of tympanic membrane perforation through surgery. The earliest attempts to repair tympanic membrane can be traced back to 19th century. In 1878, Berthold successfully closed a perforation with full thickness skin graft and introduced the term 'Myringoplastik'.[2] The term "Myringoplasty" refers to reconstructive surgery limited to TM only without involving removal of disease from middle ear, as it aims primarily at anatomical, not functional restoration.[3]

Advent of surgical microscope brought concept of tympanic reconstruction, which further altered the surgical techniques. In 1951, Wullstein and Zollner introduced tympanoplasty in their reputed classification.[4,5] Since then, myringoplasty evolved a great deal and different persons performed it using diversified approaches, variety of techniques and multitude of graft materials; with thriving outcome.[6,7] Today, it is amongst the commonest ear surgeries globally. Literature documents speckled failure rate with widely heterogeneous data, and graft rejection ranges between 50–100%.[8] Rejection can be linked to a spectrum of factors; site/size of perforation, co-morbidities and presence of discharge at time of intervention. This mandate careful analysis of pre and post-operative factors, in order to evaluate surgical choice tentatively indicated and predict prognostic outcomes. In this study, it was aimed to analyse the rate of recurrence of tympanic perforation after myringoplasty and probable causes of failure. No such study has been carried out in subject hospital, and authors look forward to draw inferences valuable for contemporary clinical practitioners; and medical researchers in future. Hypothesis drawn was; various socio-demographic, clinical and surgical factors temper the graft acceptance in patients who undergo myringoplasty, while the question posed was, which factors are more valuable to generate better post-operative outcomes in subject groups.

MATERIAL AND METHODS

It was descriptive case series in which data was retrospectively collected. It was conducted at a tertiary care hospital (Rawalpindi, Pakistan) from January 2009-December 2018, preceded by formal permission by institutional ethical review committee. Data was collected for cases in the last 10 years, and confidentiality of subjects was ensured. Adults aging from 18–60 years, of both genders, having central perforation and dry ears for at least 2 weeks duration,

and underwent myringoplasty by end-aural, post-aural or permeatal techniques by ENT consultants were enrolled in this research; while others who have had myringoplasty more than once, had clinical/ intra-operative evidence of cholesteatoma, paediatric clients (under 18 years), patients with air-bone gap >30 db, those with marginal perforations, or being operated by post-graduate residents were excluded. First 600 patients were consecutively selected meeting inclusion/ exclusion criteria and were followed-up for consecutive 06 months were analysed to assess specified graft outcome. Every patient had undergone preoperative and post-operative micro-otoscopy, nasal and nasopharyngeal endoscopy (to visualize the Eustachian tube opening), pure tone audiometry (@ 0.5,1,2,4 kHz), and speech audiometry. The primary post-surgical endpoint was considered complete closure of the tympanic membrane with improved air bone gap by 15 dbs or more, at least 06 months after the surgery. The secondary endpoints were considered as adverse events (i.e., recurrent and residual perforation, and discharging ear. Self-designed structured *pro forma* were filled by consultants themselves, which carried relevant socio-demographic as well as pre and post-operative clinical details of the subjects, including systemic (hypertension/HTN, diabetes mellitus/DM, smoking) and ENT (deflected nasal septum/DNS, recurrent respiratory infections/ARI, defective Eustachian functions and allergic rhinitis) co-morbidities. Graft Take/Failure, the vital dependent variable, was correlated with relevant independent variables. Data were analysed by IBM-SPSS-21, categorical and quantitative variables are described as frequencies and percentages, whereas quantitative variables are described as Mean±Standard Deviation. (Minimum-Maximum) respectively. Level of significance was taken as 0.05.

RESULTS

Age of subjects was 38.00±12.192 (18–59) years, 400 (66.7%) being males, while 436 (72.7%) and 164 (27.3%) had graft success and failure respectively. Table-1 illustrates qualitative variables along with their cross-tabulation with dependent variable; 54 had both systemic and ENT co-morbidity.

Best graft take was achieved with end-aural approach (p-0.048) (42/200, 21%); whereas graft failure significantly aggravated with increasing age (p<0.001), co-morbidities (p<0.001) (n74/170, 43.5%), especially diabetics among systemic ailments (p-0.040) (p<0.040, n-20/50, 40%) and Eustachian tube dysfunction amongst ENT diseases (p-0.016) (n-11/19, 57.9%), larger perforation (p-0.025) (72/214, 33.6%), and discharge-free ear (Dry Ear) for less than 4 weeks (p<0.001) (n-73/173,42.2%). Gender (p-0.897) did not caste a significant impact on graft outcome.

Break-up of graft failure among various surgical techniques was as follows; Permeatal (n-76/248, 30.6%), Post-aural (n-45/152, 29.6%) and End-aural (n-42/200, 21%), with marginally better results with latter technique (p-0.048). Table-2 unveils certain biases in selection of different techniques; permeatal being preferred for middle aged (p<0.001), with no ENT co-morbidity (p<0.001), and small perforation (p<0.001), while end-aural being more practiced amongst those with large perforation, whereas patients with systemic co-morbidities had equitable application of these three surgical techniques (p-0.074). Thus, few inferences characteristic to this variable could be jeopardized.

Table-1: Socio-demographic and clinical characteristics of participants, along with cross tabulation with fate of graft (n-600)

Variable	Sub-Variable	n	%	Taken	Failure	*p*-Value
Age (Years)	18–30	177	(29.5)	148	29	**<0.001**
	31–45	236	(39.3)	173	63	
	46–60	187	(31.2)	115	72	
Gender	Male	400	(66.7)	290	110	.897
	Female	200	(33.3)	146	54	
Co-Morbidity	Yes	170	(28.3)	96	74	**<0.001**
	No	430	(71.7)	340	90	
ENT Co-Morbidity	No	500	(83.3)	374	126	**0.016**
	DNS	22	(3.7)	16	6	
	Nasal Allergy	41	(6.8)	27	14	
	Recurrent RTI[4]	18	(3.0)	11	7	
	Defective Eustachian Function	19	(3.2)	8	11	
Systemic Co-Morbidity	Nil	487	(81.2)	364	123	**0.040**
	DM	50	(8.3)	30	20	
	HTN	44	(7.3)	27	17	
	Smoker	19	(3.2)	15	4	
Perforation Size	Small	208	(34.7)	132	46	**0.025**
	Medium	178	(29.7)	142	72	
	Large	214	(35.7)	162	46	
Technique	End-aural	200	(33.3)	158	42	**0.048**
	Post-aural	152	(25.3)	106	46	
	Permeatal	248	(41.3)	172	76	
Discharge Dryness	> 4 Weeks	427	(71.2)	336	91	**<0.001**
	<4 Weeks	173	(28.8)	100	73	

Table-2: Correlation between surgical technique and relevant variables (n-600)

Variable	Sub-Variable	End-aural	Post-Aural	Permeatal	*p*-Value
Age (Years)	18–30	54	46	77	**<0.001**
	31–45	81	16	139	
	46–60	65	90	32	
Gender	Male	170	141	89	**<0.001**
	Female	30	11	159	
Co-Morbidity	Yes	34	89	47	**<0.001**
	No	166	63	201	
ENT Co-Morbidity	No	182	88	230	**<0.001**
	DNS	6	15	1	
	Nasal Allergy	1	39	1	
	Recurrent RTI[2]	11	7	0	
	Defective Eustachian Function	0	3	16	
Systemic Co-Morbidity	Nil	161	122	204	0.074
	DM	19	13	18	
	HTN	11	17	16	
	Smoker	9	0	10	
Perforation Size	Small	0	11	167	**<0.001**
	Medium	55	78	81	
	Large	145	63	0	
Discharge Dryness	> 4 Weeks				
	<4 Weeks				

DISCUSSION

Many studies have acknowledged myringoplasty as a triumphant procedure for closing TM perforations and improving air conduction hearing.[4–7] It is an established procedure; with varied results from diversified surveys. The quest to advance post-operative accomplishments, an urge to pinpoint clinical attributors of graft failure; mandate further research.

Failed myringoplasty can have multiple contributory factors. In this research, overall, 164/600 (28%) patients had a failed outcome. Ashfaq M *et al* claimed a failure rate of 27% among 105 patients[9], while Vartiainen E *et al*[10] and Das A *et al*[11] quoted failure to be around 12% and 20% respectively. This study conferred the long-standing belief of better healing among younger clients; Age group 18–30 years exhibited failure of 17% as opposed to 39.6% in age group of 46–60 years. Similar were the results of Dispenza *et al*[12], who analysed a failure rate of 30% amongst patients above 50 years age, as opposed to 15.4% among patients aging 16–30 years.

Co-morbidities (local or systemic) affect any surgical outcome in general, as was established in this study. Myringoplasty being a pure process of self-regeneration and healing of the tympanic membrane along with the graft is affected adversely by diseases like diabetes mellitus; 20/40 (40%) diabetics and 17/44 (38.64) in hypertension have had graft failure, and presence of multiple co-morbidities escalated the failure rate to 43% (74/170). This data depicted a 22% graft failure among smokers, while Dangol K *et al* documented similar failure rate was among smokers and non-smokers.[13]

Amongst ENT diseases, failure was highest in patients with Eustachian Tube Dysfunction, 8/19 (42%), followed by recurrent upper respiratory tract infection 7/18 (39%), Allergic Rhinitis 14/41(35%) and DNS 6/22 (28%). Dispenza F *et al* also noticed that ear with Eustachian tube dysfunction is almost at 2.9 times more risk of failure of surgery as compared with ears with working Eustachian tube. Niazi SA *et al* found that failure rates were 40% in patients with ENT related co morbidity as compared to 14.67% in patients who underwent myringoplasty without any ENT co-morbidity.[14]

Another important factor that can dynamically affect the outcome of myringoplasty is size of perforation. This study exhibited a failure rate of 22% (46/208) and 33.7% (72/214) in small and large perforations respectively. Lee P *et al*[15] in their study 'Myringoplasty: does the size of the perforation matter?' have shown failure rate of 26% and 56% in small and large perforations respectively. Sajid T *et al*[16] established a 100% graft take in small perforation, where 41.7% of large perforations failed post-operatively.

Traditionally it was thought that for successful outcome of surgery, ear should be dry and free of infection preoperatively for some time, followed by a further debate on required duration of discharge-free ear for better outcomes. This study ascertained that failure was more among subject-group with dry ears for less than 4 weeks 73/173 (42.2%), as compared to those with dry ear for more than four weeks 91/427(22%). Pignataro L *et al*[17] and Denoyelle *et al*[18] have vet similar inference. Denoyelle proclaimed that the inflammatory changes within middle ear mucosa independently influenced

the risk of abnormal postoperative tympanic membrane.[19]

Multiple approaches can be used performing this delicate surgery. Researches in subject survey analysed effects of Endaural, Postaural and Permeatal regimes, minimal failure was faced after endaural technique (21%), with almost similar outcome with other two options; permeatal (31.65%) and post-aural (31.27%). Niazi SA *et al*[19] and Dangol K *et al*[13] found similar results with Endaural and Permeatal surgeries.

Although a unique and pioneer study of its type, this research was not free of limitations. Surgical approaches could not be equally distributed among all sub-variable groups as that could jeopardize graft safety, and was therefore, ethically not justifiable to the patients. Data from more hospitals and varied areas of country can further yield interesting results. It is an operator-based surgery, so, data of surgeries done by other consultants may qualify for varied outcomes.

Nevertheless, it is considered as a fruitful research, which may guide ENT surgeons in their future operations, and provide researchers for way forward to attenuate graft failure in myringoplasty patients.

CONCLUSION

Myringoplasty is not a lifesaving procedure and should be discouraged in patients with Diabetes and defective Eustachian Tube functions. Though success rates cannot always be elevated to 100%, nevertheless, demographic and clinical parameters shall be optimally catered for to reduce graft rejection.

AUTHORS' CONTRIBUTION

SAN: Conceptualization of study design, data collection, write-up. SFK: Literature search, proof reading. KA: Data analysis, data interpretation, proof reading. AR: Data interpretation, write up, literature search. MSG Data collection, proof reading.

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