

Study of Various Factors Affecting Graft Success in Myringoplasty Cases

Jyoti Kumar Verma¹, Rajesh Kumar², Kamlesh Chaudhary³

ABSTRACT

Introduction: Chronic suppurative Otitis media (CSOM) is a potentially dangerous disease capable of causing severe destruction and irreversible sequelae like fatal intracranial complications. The aim of present study is to evaluate the prognostic role of various factors affecting graft success in myringoplasty cases.

Material and methods: Present study was conducted in Department of Otorhinolaryngology, Institute of Medical Sciences, BHU from December 2017 to July 2019. Two hundred cases of middle ear diseases were selected with using random number table in the study. General physical, systemic examination and ontological examination was done. Pure Tone Audiometry was done. Risk categories were derived from MERI's and OOPS index. Supportive treatment was given and patients were called for follow-up after 1 month. Status of graft and hearing evaluation by pure tone audiometry (PTA) was done at 6 weeks, 3months and 6months postoperatively. Chi-square test was used to find out the association between in variables.

Results: For 10-20 years age group, in 36.5% cases graft was accepted while in > 20 years age group graft acceptance rate was 63.5%. In smokers graft was successfully accepted in 8.8% cases and in non-smoker this rate was 91.2%. Maximum graft acceptance (64.1%) was seen in type 1 surgery cases. Graft acceptance was 67.9% in mild MERI index cases while it was 8.18% in severe MERI index cases.

Conclusion: Present study shows significant association of graft success with smoking status, middle ear status and type of surgery performed. Graft success also shows association with MERI Index and OOPS index.

Keywords: Chronic Suppurative Otitis Media, MERI Index, OOPS Index, Prognostic Factor.

than the closed techniques, it is still debatable. Simple repair of a tympanic membrane perforation without ossicular reconstruction is known as myringoplasty. Myringoplasty prevents Squamous epithelium migration in middle ear and cholesteatoma formation.³ Heermann introduced temporalis fascia as a graft material in 1958. Temporalis fascia is still the most popular grafting material used in myringoplasty.

There is a long-standing debate regarding various prognostic factors affecting success of graft material like age profile, unilaterality/bilaterality of disease ear, smoking status, duration of ear discharge, inactivity duration, type of surgery performed, MERI Index, OOPS Index etc. Myringoplasty success rate varies from 35–94% with follow-up ranging from 6 months- 1 year.⁴ The aim of this study was to evaluate the prognostic role of various factors affecting graft success in myringoplasty cases.

MATERIAL AND METHODS

Present study was conducted in Department of Otorhinolaryngology, Institute of Medical Sciences, BHU from December 2017 to July 2019. Two hundred cases of middle ear diseases were selected with using random number table in the study. These patients were admitted and treated surgically and record was kept for 6 months follow-up in post operated period (45 days, 3month and 6 month). Patients with sensorineural hearing loss and congenital deformity for ear, nose or throat were excluded from study. Detailed history was taken. General physical, systemic examination and ontological examination was done. Pure Tone Audiometry was done. Risk categories were derived from MERI's and OOPS index.

All the selected cases underwent tympanoplasty under local anaesthesia with intravenous sedation. Tympanoplasty or tympano-mastoidectomy (CWD & CWU) with or without ossiculoplasty was performed according to the ossicular status found during surgery. Temporalis fascia was harvested

INTRODUCTION

Chronic suppurative Otitis media (CSOM) may result in undue burden on the patient, family and society. CSOM poses serious health problem worldwide especially in developing countries due to lack of specialized medical care. CSOM is an important cause of preventable hearing loss; particularly in the developing world.¹ Tympanic membrane perforations are most commonly occurring due to trauma and middle ear infections and less commonly iatrogenic. In present scenario, due to rising number of trauma cases throughout the world, tympanic membrane perforation cases are increasing.²

The consistent achievement of good hearing results in presence of CSOM is still one of most difficult challenges of otologic surgery. Whether the open techniques of Mastoidectomy with Tympanoplasty are better or worse

¹Senior Resident, Department of ENT, Government Allopathic Medical College Banda, U.P. ²Professor & Head, ³Junior Resident, Department of ENT, Institute of Medical Science, BHU, Varanasi, UP.

Corresponding author: Dr. Rajesh Kumar, Professor & Head, Department of ENT, Institute of Medical Science, BHU, Varanasi, UP., India

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and used as graft material in all the cases. Perforation margins were freshened and tympanomeatal flap was elevated. When required, ossicular chain reconstruction was performed using either conchal cartilage or autologous sculpted incus. Graft was placed with reposition of flap and gelfoam was used to pack the external auditory canal. Incision was closed in two layers and aseptic dressing was done. Postoperatively, all the patients were put on antibiotics, analgesics, antihistaminic and nasal decongestants. All the patients were instructed to take adequate precautions to prevent entry of water into the ear canal.

Patients were called after 10 to 15 days for stitch removal. Abgel placed in the ear canal was also removed then after 20 days. Supportive treatment was given and patients were called for follow-up after 1 month. Status of graft and hearing evaluation by pure tone audiometry (PTA) was done at 6 weeks, 3 months and 6 months postoperatively. Preoperative and 6 months postoperative follow-up PTA air-bone gap average were measured and compared. If at 6 months postoperative graft was found intact and air conduction threshold average was improved by more than 10dB, tympanoplasty was

considered successful.

STATISTICAL ANALYSIS

The statistical analysis was done using SPSS for Windows version 23.0 software. The findings were present in number and percentage and analysed by frequency, percent and chi-square test. Chi-square test was used to find out the association between variables. The critical value of 'p' indicating the probability of significant difference was taken as <0.05 for comparison.

RESULTS

Table 1 shows the various factors affecting graft success in myringoplasty cases. For 10-20 years age group, in 36.5% cases graft was accepted while in > 20 years age group graft acceptance rate was 63.5%. There was no significant association between age and graft success (p value > 0.05). In cases of unilateral disease, graft was accepted in 30.8% cases and in bilateral cases it was 69.2%. As p value is >0.05 it shows there was no significant association between disease status and graft success.

In smokers graft was successfully accepted in 8.8% cases

Factors	Total no. of cases	Graft accepted	P value	Significance
Age profile				
10-20 Yrs	71	58	0.173	Not Significant
> 20 Yrs	129	101		
Disease status				
Unilateral	62	49	0.913	Not Significant
Bilateral	138	110		
Smoking status				
Smoker	28	14	< 0.001	Significant
Non-smoker	172	145		
Duration of ear discharge				
No discharge	3	1	0.499	Not Significant
< 10 Yrs	100	80		
>10 Yrs	97	78		
Inactivity duration				
Dry	3	1	0.027	Significant
Quiescent	172	139		
Active	25	19		
Middle ear status				
Normal	156	133	0.0001	Significant
Unhealthy	44	26		
Type of Surgery				
Type 1	130	102	0.0003	Significant
Type 2	21	17		
Type 3	4	3		
Type 4	4	3		
CWU	8	6		
CWD	33	28		
MERI Index				
1-3 (Mild)	127	108	0.002	Significant
4-6 (Moderate)	49	38		
7-12 (Severe)	24	13		
OOPS Index				
1-3	175	146	0.0003	Significant
4-9	25	13		

Table-1: Various factors affecting graft success in myringoplasty cases

	MERIs index						Total		Statistics
	1-3		4-6		7-12		No.	%	
	No.	%	No.	%	No.	%			
Pre-op PTA									
< 25 db	30	23.6	11	22.4	2	8.3	43	21.5	$\chi^2=20.006$ p=0.003
26-40 db	81	63.8	24	49.0	10	41.7	115	57.5	
>40 db	16	12.6	14	28.6	12	50.0	42	21.0	
Post-op PTA									
< 25 db	87	68.5	26	53.1	7	29.2	120	60.0	$\chi^2=31.406$ p<0.001
26-40 db	37	29.1	17	34.7	9	37.5	63	31.5	
>40 db	3	2.4	6	12.2	8	33.3	17	8.5	

Table-2: Comparison of pre-operative and post-operative PTA with MERIs index

	MERIs index				Total		Statistics
	1-3		4-9		No.	%	
	No.	%					
Pre-op PTA							
< 25 db	41	23.4	2	8.0	43	21.5	$\chi^2=22.338$ p <0.001
26-40 db	106	60.6	9	36.0	115	57.5	
>40 db	28	16.0	14	56	42	21.0	
Post-op PTA							
< 25 db	113	64.6	7	28.0	120	60.0	$\chi^2=25.164$ p<0.001
26-40 db	53	30.3	10	40.0	63	31.5	
>40 db	9	5.1	8	32.0	17	8.5	

Table 3: Comparison of pre-operative and post-operative PTA with OOPS Index

and in non-smoker this rate was 91.2%. p value (<0.001) indicates significant association between smoking and graft success. In cases where duration of ear discharge is less than 10 years, graft acceptance rate was 50.3% and in more than 10 years cases it was 49.1%. There was no significant association between duration of ear discharge and graft success. In 11.9% cases of graft acceptance, disease ears were actively discharging and p value (0.027) shows significant association between inactivity duration and graft success.

In above table also shows significant association between middle ear status and graft success. Maximum graft acceptance (64.1%) was seen in type 1 surgery cases followed by 17.6% in CWD cases. There was significant association between type of surgery and graft success. In present study, MERI index showed significant association with graft success. Graft acceptance was 67.9% in mild MERI index cases while it was 8.18% in severe MERI index cases. OOPS indexed also showed significant association with graft success as p value was 0.0003.

Table 2 shows comparison of pre-operative and post-operative PTA with MERI index. Before surgery, among patients with MERI 1-3 (mild disease), 23.6% cases had A-B gap of less than 25 db, 63.8% and 12.6% had 26-40 db and more than 40 db A-B gap; among those with MERI 4-6 (moderate disease), 22.4%, 49.0% and 28.6% cases had A-B gap less than 25 db, 26-40 db and more than 40 db, respectively; with MERI 7-12 (severe disease), 8.3%, 41.7% and 50.0% cases had A-B gap of less than 25 db, 26-40 db and more than 40 db, respectively.

After surgery, among patients with MERI 1-3, 68.5% cases had A-B gap less than 25 db, 29.1% and 2.4% had 26-40 db

and more than 40 db A-B gap; among those with MERI 4-6, 53.1%, 34.7% and 12.2% cases had A-B gap less than 25 db, 26-40 db and more than 40 db, respectively; with MERI 7-12, 29.2%, 37.5% and 33.3% cases had A-B gap of less than 25 db, 26-40 db and more than 40 db, respectively.

Table 3 shows comparison of pre-operative and post-operative PTA with OOPS index. Before surgery, patients with OOPS score 1-3 (low risk) had A-B gap of <25db in 23.4% cases, 26-40 db in 60.6% cases and >40 db in 16.0% cases. While those with OOPS score 4-9 (intermediate and high risk) had A-B gap of <25 db, 25-40 db and >40db in 8.0%, 36.0% and 56.0% cases.

After surgery, patients with OOPS score 1-3 (low risk) had A-B gap of less than 25db in 64.6% cases, 26-40 db in 30.3% cases and greater than 40 db in 5.1% cases. While those with OOPS score 4-9 (intermediate and high risk) had A-B gap of <25 db, 25-40 db and >40db in 28.0%, 40.0% and 32% cases.

DISCUSSION

Myringoplasty was the most common otologic surgery done in our department. The success rate of myringoplasty varies from 35% to 95%.⁴ The reason behind wide range of graft success rate is due to non-standardized definitions of success, study designs, selection criteria, and lengths of postoperative follow-up. In present study of 200 patients, 178 patients (89.0%) had intact graft after 6 months follow-up while 22 patients (11.0%) had graft failure. The graft success rate in present study is comparable with the study done by Wasson et al.⁵(80.8% success at minimum three months follow-up), Gersdorff et al.⁶(success rate of 87.7%

after three years follow-up) and Dangol K et al.⁷ (success rate of 83.1% after one year follow-up).

There was no significant difference in graft uptake with age in this study. Similar results were also observed by Adkins W et al.⁸ and Berry S et al.⁹ However study done by Rahman et al.¹⁰ found that the success rate of myringoplasty is affected by age.

Smokers presented with long duration of ear discharge, middle ear mucosa changes like granulation and polypoidal changes, abnormal eustachian tube function, and necrosis of ossicular chain. In our study, graft failure is 15.6% in non-smokers while 50% in smokers; p-value <0.05 shows significant association between smoking and graft uptake. In the study conducted by Onal and Uguz et al.¹¹ smoking status of the patient was found statistically significant prognostic factor influencing success rate of operations (p=0.008). However study done by Dangol K⁷ shows that the graft uptake in non-smoking group was 83.4% and that in the smoking group was 80%. This difference was not statistically significant and these results are different from present study. Wasson et al.⁵ also did not find smoking to be a significant factor in success of graft.

With p-value <0.05, our study shows status of ear discharge (dry/wet) and duration of its inactivity has association with success of tympanoplasty. Zakaria Sarker et al.¹² in their study showed that graft take rate was 89.36% in dry perforations while 53.85% in wet perforations. Graft take rate and hearing improvement was greater in dry perforation. Similarly Saeed et al (1994) and Noh et al (2012) found active ear discharge have poorer success. While Adkins W et al.⁸ found that presence of infection at the time of surgery and the length of time the ear had been dry had no influence on success rate of tympanoplasty. Similar results were found in studies conducted by Raj A et al.¹³ and Nagle et al.¹⁴ In a multivariate analysis of ontological, surgical and patient-related factors in determining success in myringoplasty conducted by Onal and Uguz et al.¹¹ by multiple logistic regression analysis found longer duration of dry period of diseased ear to be insignificant to success of tympanoplasty.

With p-value >0.05, chronicity of disease showed no significant association to graft take rate. Onal and Uguz et al.¹¹ in their study found longer duration of diseased ear to be insignificant to the success of tympanoplasty.

With p-value >0.05 no significant association is found between size of perforation and graft success rate. Al-Ghamdi (1994) analysed various factors liable to influence the success rate such as middle ear, size and site of perforation, surgical approach and presence of tympanosclerosis. Only middle ear and presence of tympanosclerosis at the time of surgery were found to have a major effect on final outcome of surgery. Berry S et al.⁹ found no significant difference in hearing improvement across gender (p=0.164), size (p=0.198) or site of the perforation (p=0.447).

Lee et al.¹⁵ showed that size does influenced the success; success rate for small perforation was 74.1% compared with 56% for large perforations. Similarly Onal and Uguz et al.¹¹, James L et al.¹⁶ Sade J et al.¹⁷, and Rehman NA¹⁰ found size

of perforation to be significantly associated with success rate of tympanoplasty.

With p-value >0.05 no significant association was found between presence of bilateral disease and success rate. In the study conducted by Onal and Uguz et al.¹¹ they found smoking status of the patients (p=0.008), status of opposite ear (p=0.01), size of perforation (p=0.009) and experience of surgeon (p=0.002) were statistically significant prognostic factors influencing the success rate of operations. Similarly Adkins W et al.⁸ found status of opposite ear to be significantly influencing success rate.

In our study patients with normal middle ear mucosa had 85.25% graft acceptance, while patients with middle ear pathology like granulation, polypoidal changes had 59.09% graft acceptance. Thus p-value = 0.001, shows significant association between status of middle ear mucosa and graft acceptance. Al-Ghamdi (1994), analysed various factors liable to influence the success rate such as status of middle ear, size and site of perforation, surgical approach and presence of tympanosclerosis were analyzed. Only status of middle ear and presence of tympanosclerosis were found to have a major role in final outcome of surgery. Similarly Chopra et al in 2001 showed 100% success with healthy mucosa, 87.5% with edematous mucosa and 58.83% with hypertrophied mucosa respectively. Fukuchi I et al.¹⁸ observed that condition of middle ear mucosa was not significant in repair of tympanic membrane perforation; closure rate was 85%. Debora et al.¹⁹ also found similar results in their studies.

In our study, overall graft acceptance rate was 89%. Beals (1957), study of success rate of Type 1 and type 3 were 70% and 62%. Wullstein (1958) study of success rate of Type 1, Type 3 and Type 4 were 87%, 76% and 78%. Success rate of Type 1 and Type 3 were 84% and 86% in Austin (1962) study. Baumann, Dierichs (1997), study of success rate of Type 3 was 62.5%. Garcia Ibanez (1959), study of success rate of Type 3 and Type 4 were 86% and 92%. On comparative analysis, the results of different type of tympanoplasty in the present series are found to be similar to that obtained by above studies.

The term middle ear risk index is used to predict the success rate of middle ear reconstruction procedures. For accurate prediction of the surgical results the status of middle ear and its ossicles must be ascertained. The MER index was calculated. The total number of patients with score 1-3 (mild disease) were 63.5%, with score 4-6 (moderate disease) were 24.5% and with score 7-12 (severe disease) were 12%. Patients with score 1-3 had graft acceptance of 85.03%, with score 4-6 had graft acceptance 77.55% and with score 7-12 had 54.16% success. Before surgery, hearing loss >40db was found in 12.6% cases with MERI 1-3, in 28.6% cases with MERI 4-6 and in 50% cases with MERI 7-12. After surgery, hearing loss >40db was found in 2.4%, 12.2% and 33.3% cases with MERI 1-3, 4-6 and 7-12, respectively. Previous study by Kumar N et al.²⁰ observed that maximum number of ears 72% fall under MERI 1-3, followed by 24% ears with MERI score of 4-6 and then by 4% ears with MERI score of 7-12. He found that ear that are staged into MERI 1-3 i.e.

mild disease have a graft acceptance of 86%, and ear termed to have a severe disease i.e. MERI 7-12 have a 100% chance of graft rejection. In study conducted by Pinar et al.²¹ MERI score ($p=0.000$) was found to be statistically significant prognostic factor that affects success rate. Hence from the present study it can be concluded that MERI scoring can be useful in predicting the outcome of tympanoplasty (p -value <0.05).

In our study, 83.42% cases with OOPS score 1-3 (low risk) had intact graft while those with OOPS score 4-9 (intermediate and high risk) had graft acceptance in 52.00% cases ($p<0.05$). Pre-operatively, hearing loss >40 db was found in 16.0% and 56% cases with OOPS score 1-3 and 4-9, respectively. While post-operatively, it was found in 5.1% and 32.0% cases with OOPS score 1-3 and 4-9 respectively. In study by Matthew C et al.²² the average hearing result observed was plotted as a function of OOPS index score in the postoperative period and long-term. Spearman's rank-order correlation (r) identified a strong positive correlation between OOPS index score and average postoperative PTA-ABG ($r=0.983$; $p<0.001$; two-tailed), as well as average long-term PTA A-B Gap ($r=0.950$, $p<0.001$; two-tailed).

CONCLUSION

89% cases had successful graft uptake after 6 months follow-up while rest 11% had graft rejected or residual perforation. Age of the patient had no association with success of tympanoplasty. Smokers had an adverse affect on graft acceptance. Duration of inactivity of disease had significant association with graft acceptance. Graft acceptance was 77.6%, 89.3%, 60.0% and 93.7% among those who had dry ear for less than 3 months, for 4-6 months, for 7-12 months and for more than 1 year, respectively. Status of middle ear mucosa during surgery had significant association with graft acceptance. Involvement of the opposite ear had no significant association with graft acceptance rate. Duration of ear discharge and size of perforation had no association with graft acceptance rate. MERI score was found to have statistically significant association with success of tympanoplasty, in form of graft uptake rate and hearing improvement. OOPS score is significantly associated with success of tympanoplasty. Pre-operatively, hearing loss >40 db was found in 16.0% and 56.0% cases with OOPS score 1-3 and 4-9, respectively. While post-operatively, it was found in 5.1% and 32% cases with OOPS score 1-3 and 4-9 respectively.

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