

# Study of Various Prognostic Factors Affecting Successful Myringoplasty in a Tertiary Care Centre

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## Abstract

**Introduction** Myringoplasty is a commonly performed otologic surgery.

**Objectives** The objective of this study is to evaluate the effect of prognostic factors like - size, site of perforation, status of operating ear, approach, status of contralateral ear, experience of surgeon, primary or revision myringoplasty, and smoking in graft uptake, as well as to evaluate the hearing results after myringoplasty.

**Methods** This is a prospective study. We included in our sample patients aged over 13 years with a Tubotympanic Chronic Otitis Media diagnosis. The patients underwent preoperative evaluation and Pure Tone Audiogram within one week prior to surgery. We performed myringoplasty using temporalis fascia graft with conventional underlay technique. We evaluated postoperative graft uptake and various factors related to the study and did a Pure Tone Audiogram at one year after surgery.

**Results** The graft uptake rate after myringoplasty was 83.1% at one year in 219 patients. Graft uptake with normal opposite ear was 88.2%, and with Tubotympanic Chronic Otitis Media was 75% (statistically significant). We found no statistically significant difference in graft uptake results with other factors. We calculated hearing results of 132 patients with normal ossicular status who underwent myringoplasty. The average Air Conduction Threshold improvement was 11.44dB ( $p < 0.001$ ) and the average Air-Bone Gap closure was 8.89dB, highly statistically significant ( $p < 0.001$ ).

**Conclusion** Diseased contralateral ear was a statistically significant poor prognostic factor for graft uptake after myringoplasty. Other factors studied were not statistically significant determining factor for graft uptake. Hearing improves significantly after myringoplasty if the ossicles are normal.

## Keywords

- ▶ myringoplasty
- ▶ fascia
- ▶ tympanic membrane perforation

## Introduction

Chronic Otitis Media (COM) is the disease of the middle ear cleft with the permanent abnormality of pars tensa or pars flaccida.<sup>1</sup> COM is an important cause of preventable hearing loss, particularly in the developing world.<sup>2</sup> In Nepal, 3.04% of the population above 5 years of age have tubotympanic COM.<sup>3</sup> Tubotympanic Chronic Otitis Media (previously termed as simple or non-cholesteatomatous type of COM) encompasses cases with central perforation in the pars tensa of the tympanic membrane. The

surgical treatment for tubotympanic COM is myringoplasty. Myringoplasty is the simple repair of a tympanic membrane (TM) perforation in which no ossicular reconstruction is involved.<sup>4</sup> The purpose of the surgery is to repair pars tensa perforation and thus eliminate the susceptibility to middle ear infections and improve hearing. Myringoplasty prevents migration of squamous epithelium in the middle ear and thus cholesteatoma formation.<sup>5</sup> It helps to prevent further hearing loss which may occur in a chronically discharging ear due to resorptive osteitis of the ossicles.<sup>1</sup>

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Myringoplasty was first performed by Berthold using full thickness skin graft in 1878 and the operation was called "myringoplastik."<sup>6</sup> Heermann introduced temporalis fascia as a graft in 1958. This is still the most popular grafting material followed by perichondrium and cartilage. The advantages of temporalis fascia include the ease of harvest, availability of large amount of graft, and very high take rates without subsequent problems when used to close simple perforation.

There is a long-standing debate regarding factors that affect successful closure of perforation such as – age, size, and site of perforation, duration of dry period prior to surgery, surgical approach and technique, status of the contralateral ear, status of the middle ear at surgery, experience of surgeon, primary or revision surgery, and the smoking status. The success rate of myringoplasty varies between 35–94% in children with follow-up ranging from 6 months to 1 year.<sup>5</sup> The aim of this study is to evaluate the anatomical (postoperative graft uptake) and functional results (postoperative hearing improvement) after myringoplasty in adults and to find out the possible factors which affect these results.

## Methods

This is a prospective study performed over a period of 18 months from October 2011 to April 2013. Patients of age > 13 years with tubotympanic COM took part in this study. In our institution, patient > 13 years of age are operated in the Otolaryngology Unit and patients < 13 years are operated in the Pediatric Unit. In our center, we perform myringoplasty under local anesthesia because of high case load under general anesthesia. We obtained ethical clearance from the Institutional Review Board. We excluded patients with other middle ear pathology such as cholesteatoma, granulation tissue, extensive tympanosclerotic patch in the middle ear, patient undergoing combined procedure (cortical mastoidectomy, ossiculoplasty), myringoplasty using graft materials other than temporalis fascia, and patients with congenital craniofacial abnormalities. For hearing assessment, we excluded patients with immobile / disintegrated ossicular chain. We calculated the sample size using the Sample Size Calculator after reviewing the number of surgeries performed in previous years.

We obtained a detailed history and performed otoscopy and pure tone audiometry one week prior to surgery. We calculated average hearing threshold from 0.5, 1, 2, 3, and 4KHz frequencies and measured Air Bone Gap (ABG). Size of perforation was labeled as small if less than one quadrant of tympanic membrane was involved, medium if one to two quadrants of tympanic membrane was involved, and large if more than three quadrants of tympanic membrane were involved.<sup>7</sup> In this study, we labeled the site of pars tensa perforation as anterior if perforation was anterior to line passing along the handle of malleus, posterior if perforation was lying posterior to this line, and subtotal if perforation involved both anterior and posterior portions of the pars tensa.<sup>8</sup> We labeled tubotympanic COM as inactive if there was no otorrhea, active if there was discharge in the middle ear,

and quiescent if there was absence of otorrhea for six weeks but middle ear inflammation had not settled completely.

We performed all surgeries under local anesthesia using 2% Xylocaine with 1:2,00,000 adrenaline, infiltrated as four quadrant block in the external auditory canal and at the graft site. We pre-medicated patients using Pethidine 0.5-2 mg/kg and Promethazine 10–25 mg injections intramuscularly in the deltoid region 30 to 60 minutes before surgery. We used the conventional underlay technique, harvesting the temporalis fascia as the graft material. Senior faculties (> 5yrs experience), junior faculties (< 5yrs experience), and residents performed myringoplasties. Residents performed the surgical procedure under supervision of either senior or junior faculty who guided them orally, watching the monitor. Approach was either permeal, postaural, or endaural. Patients were followed-up at one year for the graft uptake results. We reported any residual perforation ranging in size from pin-point perforation to total rejection as failure. Pure Tone Audiogram was done. We analyzed results for graft uptake in relation to different variables. Results for hearing was calculated in those who had normal ossicular status. We applied the chi-square test, Pearson's' correlation test, and logistic regression test for categorical variable and Paired *t*-test to analyze the hearing results on SPSS statistical package version 17.0. The level of statistical significance was set at  $p < 0.05$ .

## Results

The total number of patients enrolled for the study was 230, out of which 11 (4.7%) patients were lost to follow-up. Therefore, total number of patients included was 219. Graft uptake was observed in 182 out of 219 (83.1%). Patients ranged in age from 13 to 62 years, with the mean age of  $26.14 \pm 10.41$  years. There were total 99 (45.2%) males and 120 (54.8%) females. Ninety-eight (44.7%) underwent right myringoplasty and 121 (55.3%) underwent left myringoplasty.

The graft uptake results in relation to various factors are shown in **Table 1**. Size and site of perforation, primary or revision myringoplasty, experience of surgeon, approach for surgery, status of middle ear during surgery, and smoking status were not found to be significant determining factor for successful myringoplasty. There were 54 patients between 13 to 18 years who underwent myringoplasty. Among them, 46 patients had graft uptake. We observed graft uptake in 136 out of 165 patients over 18 years of age. There was no significant difference in graft uptake in patients from the age group between 13–18 years and over 18 years. Graft uptake was higher in cases operated during summer season than in the winter, but the result was not statistically significant.

We found that 127 patients who underwent myringoplasty, had normal contralateral ear. Graft was taken up in 112 (88.2%). 56 patients had tubotympanic chronic otitis media (COM) in the contralateral ear and graft was taken up in 42 patients (75%). Graft uptake was significantly poor

**Table 1** Factors affecting success rate of myringoplasty

Factors	Total patient	Graft taken up	p value	Significance
Age of patient				
13–18yr	54	46	0.638	NS
Adults (>18yr)	165	136		
Season				
Summer	153	128	0.739	NS
Winter	66	54		
Size of perforation				
Large	165	136 (82.4%)	0.566	NS
Medium	52	44 (84.6%)		
Small	2	2 (100%)		
Site of perforation				
Subtotal	198	165 (83.3%)	0.709	NS
Anterior	12	10 (83.3%)		
Posterior	9	7 (77.7%)		
Primary/ Revision				
Primary	197	163 (82.7%)	0.669	NS
Revision	22	19 (86.3%)		
Experience of surgeon				
Senior faculty	51	44 (86.2%)	0.177	NS
Junior faculty	102	87 (85.2%)		
Resident	66	51 (77.2%)		
Approach				
Permeatal	166	136 (81.9%)	0.406	NS
Postaural	44	38 (86.3%)		
Endaural	9	8 (88.8%)		
Status of middle ear				
Dry	179	150 (83.7%)	0.773	NS
Quiescent	32	26 (81.2%)		
Active	8	6 (75%)		
Smoking status				
Smoker	20	16 (80%)	0.447	NS
Non smoker	199	166 (83.4%)		
Status of contralateral ear				
Normal	127	112 (88.2%)	0.046	S
COM Mucosal	56	42 (75%)		
Past Myringoplasty	23	18 (78.2%)		
Sequelae of OME	13	10 (76.9%)		

Abbreviations: COM, Chronic Otitis Media; NS, Not significant; S, Significant.

when the contralateral ear had tubotympanic COM ( $p < 0.05$ ).

We assessed a total of 132 patients with normal ossicular chain for hearing improvement after myringoplasty. The average pre-operative Air Conduction Threshold was 45.62 dB and the

average post-operative Air Conduction Threshold improved to 34.17 dB, which was statistically significant ( $p < 0.001$ ). The average pre-operative Air Bone Gap was 30.08 dB and the post-operative Air Bone Gap was 21.18 dB, which was statistically significant ( $p < 0.001$ ), as shown in ► **Table 2**.

**Table 2** Hearing results after myringoplasty

	Pre-operative	Post-operative	p value
Air Bone gap	30.08 dB	21.18 dB	<0.001
Air Conduction Threshold	45.62 dB	34.17 dB	<0.001

During the study, we observed two cases of postaural wound infection and there were no cases of post-operative sensorineural hearing loss.

## Discussion

Myringoplasty is the commonest otologic surgery performed in our center, with cases referred from all regions of the country. We included 230 myringoplasties using fascia graft with underlay technique for the study.

The success rate of myringoplasty ranges from 35% to 95%.<sup>5</sup> The reason for such a wide array of reported success rates is mostly due to the large variety of non-standardized definitions of success, selection criteria, study designs, and lengths of postoperative follow-up; variables that make it very difficult to compare the different published success rates.<sup>9</sup> In our study, we had a success rate of 83.1% at one year follow-up. The success rate in our study is comparable to that of Wasson et al who had 80.8% success at minimum three months follow-up in 130 cases.<sup>10</sup> The study by Gersdorff et al of 320 myringoplasties had a success rate of 87.7% after three years follow-up.<sup>11</sup>

There was no significant difference in graft uptake with the size of perforation in this study. Similar results has been shown by Calyan et al, Wasson et al, Gersdorff et al, Pignataro et al, and Denoyelle et al, where the size of perforation was not an important factor for successful myringoplasty.<sup>5,10-13</sup> On the contrary, Lee et al achieved a success rate of 74% for small perforations (size less than 50%) and 56% for large perforations (size greater than 50%).<sup>14</sup> Study by Kotecha et al and Onal et al have shown better graft uptake in small size perforation as compared with large perforation.<sup>15,16</sup>

There was no difference in graft uptake with the site of perforation in this study. This may be due to disproportionate patient distribution between the subgroups. A study by Kotecha et al and Kumar et al found poorer success rate of myringoplasty in anterior perforation.<sup>15,17</sup> This has been attributed to technical challenge to repair due to poor visibility of anterior margin of perforation, more difficult access, inadequate graft support, and relatively poorer perfusion in anterior portion of tympanic membrane.<sup>15</sup> A study by Koch et al found results of the posterior perforation poorer than the anterior one.<sup>18</sup> Most of the recent studies have found that the site of perforation is not a determining factor for successful myringoplasty.<sup>5,12,19-21</sup>

The graft uptake for myringoplasty done by the senior faculty was 86.2%, by the junior faculty was 85.2%, and by residents was only 77.2%. The result was however not statistically significant. This may be because the number of cases done by junior faculty (102) is double that done by senior

faculty (51) and residents (66). Onal et al, Vartiainen et al, and Black & Wormald have reported inferior success rates for junior surgeons as compared with senior surgeons.<sup>16,19,22</sup> Emir et al, in his 607 patients with at least 12 months of follow-up found that the graft uptake for residents was 86.2%, whereas, for the senior faculty, it was 94.8% ( $p = 0.007$ ).<sup>23</sup> In our institution, myringoplasty is the first middle ear surgery allowed to be performed by the resident under the guidance of faculty from the Otology Unit. Studies by Wasson et al, Lee et al, Kumar et al, and Palva et al have not found the experience of surgeon to be an important factor for successful myringoplasty.<sup>10,14,17,24</sup>

We operated 166 cases by permeal approach. Graft uptake was 136 (81.9%). We operated 44 cases by postaural approach and graft uptake was 38 (86.3%). We operated 9 cases by endaural approach and 8 had graft uptake (88.8%). The graft uptake with various approaches was not statistically significant. Most of myringoplasty in our setup is done via permeate/transcanal approach. Cases with poor visibility of anterior margin of perforation, narrow canal, and large size perforation undergo the postaural approach. Studies by Pignataro et al and Fransisco et al have not found statistically significant differences in the success rate in terms of the surgical approach, as in this study.<sup>12,20</sup>

The graft uptake was 83.7% in dry ear, 81.2% in quiescent ear, and 75% in actively discharging ear. The result was, however, statistically not significant because of disproportionate case distribution between the subgroups. Studies by Pignataro et al, Denoyelle et al, and Lau & Tos have shown graft uptake results better in dry ears as compared with wet ears.<sup>12,13,25</sup> Denoyelle found that the inflammatory changes within the middle ear mucosa independently influenced the risk of abnormal postoperative tympanic membrane.<sup>13</sup> However, study by Calyan et al claim better graft take rates in wet ears as compared with dry ears because of increased vascularity.<sup>5</sup> Many studies like Knapik M., Kotecha et al, Onal et al, and Vartiainen et al, have not considered the perioperative condition of the middle ear as a prognostic factor in myringoplasty.<sup>9,15,16,19</sup>

In this study, we found the status of the contralateral ear to be an important prognostic factor for graft uptake. Graft uptake was significantly poor when the contralateral ear had tubotympanic COM ( $p < 0.05$ ). We found similar results in the studies by Calyan et al, Gersdorff et al, Onal et al, Koch et al, Fransisco et al, and Ophir et al.<sup>5,11,16,18,20,26</sup> This finding might indicate an Eustachian tube dysfunction and the tendency of chronic otitis media to present as a bilateral disease.<sup>16</sup> The status of contralateral ear is important in two aspects: first, in its contribution for understanding the pathogenesis of otitis media, and second, in its implications in

treatment and counselling. However, other studies by Pignataro et al, Koch et al, and Albera et al have not found the diseased contralateral ear to be an important prognostic factor for successful graft uptake in myringoplasty.<sup>12,18,27</sup>

Studies have shown no significant impact on surgical success in primary or revision myringoplasties by Wasson et al, Lee et al, and Vartiainen et al.<sup>10,14,19</sup> The higher graft uptake rate in revision cases in this study may be because of cases being performed by the faculties.

In this study, 199 patients were non-smokers and 20 patients were smokers. The graft uptake in non-smoking group was 83.4% and that in the smoking group was 80%. This difference was not statistically significant, likely due to a disproportionate population within the subgroup. However, we did not take into account details of amount and duration of smoking in this study. In a study by Onal et al in 80 myringoplasties, they had a success rate of 78.7% in the non-smoking group and 47.7% in the smoking group ( $p = 0.008$ ).<sup>16</sup> Smoking changes the amount and viscosity of mucous and destroys the ciliated epithelium of the Eustachian tube and middle ear mucosa.<sup>16</sup> Nicotine causes cutaneous vasoconstriction, promotes thrombosis, and carbon monoxide inhaled in cigarette smoke also reduces the oxygen-carrying capacity of the blood, which in turn causes inadequate oxygenation of the graft. These factors may impair the graft vascularization. The systemic effects of smoking are the chemoallergic and immunosuppressive properties that may cause increased susceptibility to the infectious agents and thereby lead to graft failure.<sup>16</sup> However, a study by Wasson et al did not find smoking to be a significant factor for successful myringoplasty.<sup>10</sup>

Hearing improvement after myringoplasty is statistically significant if the ossicles are normal. We found similar results in a study done by Wasson et al and Vartiainen et al.<sup>10,19</sup>

Most of the studies have shown short term graft uptake results of myringoplasty. In this study, we followed up the patient for one year to study the long term uptake result of the fascia graft. A larger and proportionate sample size would yield a stronger study.

## Conclusion

Diseased contralateral ear was a statistically significant poor prognostic factor for successful myringoplasty. Other factors such as site and size of perforation, smoking status, revision surgery, status of middle ear, experience of surgeon, and surgical approach were not statistically significant prognostic factors for successful myringoplasty.

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