



## “COMPARATIVE STUDY OF THE PLACEMENT OF GRAFT MEDIAL OR LATERAL TO HANDLE OF MALLEUS IN INLAY TECHNIQUE OF MYRINGOPLASTY”

### ENT

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### ABSTRACT

**Background:** The Study entitled “Comparative analysis of graft placement medial or lateral to the handle of malleus in inlay technique of myringoplasty in terms of graft take-up rate, hearing improvement and complications”.

**Methods:** Prospective randomized single blind study on 52 patients (age 18-40 years) who had dry, central, medium sized perforation secondary to Chronic Otitis Media (mucosal disease) were included in our study. The patients were divided into two groups. Group A (23 patients) in whom graft was placed medial to the handle of malleus and group B (29 patients) in whom graft was placed lateral to the handle of malleus in modified inlay technique of myringoplasty.

**Results:** The results of the two techniques were compared in terms of graft take-up rate, hearing improvement and complications at the end of 6 month follow-up. The graft take-up rate and post operative gain in air conduction in group A was 91.30%, 3.57+/-6.61 dB (mean+/-SD) respectively and it was 96.55%, 6.62+/-6.86 dB (mean+/-SD) respectively in group B (p value is >0.05). Which were statistically analysed by Chi-square and T-test.

**Conclusion-** We concluded that there is no difference in graft take-up rate, gain in hearing or complications in both the techniques, in consideration of the duration of surgery, technicality and healing, placement of graft lateral was found to be better than medial to the handle of malleus in modified inlay technique of myringoplasty.

### KEYWORDS

Chronic Otitis Media, Inlay techniques, Myringoplasty.

### INTRODUCTION

**Myringoplasty** is the closure of the perforation of pars tensa of the tympanic membrane to restore its integrity and to improve hearing<sup>1</sup>. It was introduced in 1878<sup>2</sup> using skin graft.

Many techniques of myringoplasty have been described in literature like overlay, underlay, through and reverse through. Underlay technique were introduced by **Austin and Shea** (1961) which was later modified by **Hough** (1970)<sup>3</sup>. This study was conducted to observe the result of graft placement, medial or lateral to the handle of malleus in myringoplasty keeping all other influencing factors constant.

### Patients and Methods

This was a prospective, randomized single blind comparative study conducted in the Department of E.N.T and Head & Neck Surgery on 52 patients of chronic suppurative otitis media after due clearance from the Institutional Ethics Committee.

### Inclusion criteria:

Patients were aged between 18 to 40 years, with medium sized central perforation, having dry ear for more than 6 weeks, with healthy middle ear mucosa on otoscopy. The patients had conductive deafness less than 40 dB (ie air conduction threshold of < 40 dB) on Pure Tone Audiometry, normal Eustachian tube function on Inflation-Deflation test and cellular mastoid on skiagram. Patients had no history of smoking, allergy and any medical comorbidities like diabetes mellitus, hypertension, tuberculosis or autoimmune diseases.

### Exclusion Criteria:

Patients who were below 18 years old and above 40 years old, with small, large or subtotal perforation were excluded from the study, with evidence of discharge or squamous type of chronic otitis media, abnormal Eustachian tube function, previously operated ear or active infectious foci in nose, throat or oral cavity were not considered for the study.

Patients were properly informed regarding the nature of disease process, the surgical procedure including expected outcomes, potential complications and alternative treatments with written informed consent was signed by patients.

### METHOD:

Decision of graft placement, medial or lateral to the handle of malleus in inlay technique of grafting was done by lottery method (random digit) of randomization. Operation was performed by senior surgeon who has experience of more than 10 years in ear microsurgery.

### Operative Procedure:-

In all the selected cases, post-aural approach with temporalis fascia graft and Hough's inlay technique of myringoplasty was used with slight modifications and procedure was performed under local anaesthesia.

Meatotomy was done by giving an incision from 12 O'clock to 6 O'clock position and thereafter, margin were freshened. Next, a curvilinear incision was taken over the posterior wall of external auditory canal about 8 mm lateral to annulus from 7 O'clock to 2 O'clock position.

According to the original Hough's technique tympanomeatal flap was elevated parallel to the handle of malleus and not freed from it, thereby preservation of normal squamous epithelium was ensured, but here in the study slight variation in the technique was done, the tympanomeatal flap was elevated from 7 O'clock to 2 O'clock from posterior wall and freed from the handle of malleus, anterior malleolar fold and adjacent outer wall of attic. Finally the condition of the middle ear ossicles and labyrinthine windows was checked and graft placement was done medial or lateral to the handle of malleus (as pre-determined) after keeping abgel in middle ear and Eustachian tube opening.

Group A: 23 Patients in whom graft was placed medial to the handle of malleus after making a 'V' shaped notch in the graft.

Group B: 29 Patients in whom graft was placed lateral to the handle of malleus

Tympanomeatal flap was repositioned. The external auditory canal was packed with abgel & BIPP (Bismuth Iodine Paraffin Paste), incision line was closed in single layer and patient was shifted to post-operative room.

**Postoperatively:** IV Antibiotics for 3 days, orally for 12 days, Antihistaminics and nasal decongestants for 1 week and stitch removal on 7<sup>th</sup> post-operative day was done.

Patient was discharged and called up to O.P.D for follow-up at weekly interval for 1 month, every 15 days for the next 2 months and once in month for next 3 months.

Abgel was cleaned on 15th post-operative day.

The two techniques of myringoplasty were compared in terms of graft success rate (partial or full take, medialization or lateralization) and hearing improvement. At every visit, ear was examined with otoscope to see the graft uptake (any medialization or lateralization of graft, residual perforation or discharge). "Graft take-up was defined as full and intact healing of tympanic membrane graft after 6 months postoperatively". Hearing improvement was defined as the change in air conduction of 10 dB and baseline of preoperative level at 6 week and at 6 month of follow-up period. 10 dB or more deterioration or loss in hearing from baseline of preoperative level at 6 week and 6 month of follow up was considered as significant. Air conduction was calculated as the average of air conduction at 0.5, 1 and 2 kHz. Results were statistically analyzed using SPSS (statistical package for social sciences). Results of the two techniques of myringoplasty were compared between group A & B utilizing Chi square test for graft success rate and complications. Paired and unpaired T-test were utilized to compare pre and postoperative air conduction change. Statistical significance was accepted as  $p < 0.05$ .

## RESULTS

The observations made at the end of the study were, 57.69% (30) of patients are males while 42.30% (24) are females. Mean age of patients in group A is 26.7 +/- 8.78 years (mean +/- SD) and in group B it is 23.24 +/- 6.46 years. Most of the patients (46.15%) in both groups belong to <20 years old age group, 19.23% in age group 20-25 years old, 9.62% in 26-30 years old, 11.54 % in 31-35 years old and 13.46 % in 36-40 years old age group. (figure 1)

On observing pre-operative hearing threshold on Pure Tone Audiometry, only 1 patient in group A while none in group B had < 20 dB conductive hearing loss. 3 patients in group A and 5 in group B had air conduction threshold between 21 and 30 dB. 19 patients in group A and 24 patients group B had their losses in the range of 31-40 dB (Figure 2)

Average operating time in group A and group B were 70 minutes and 60 minutes respectively.

While healing time was found to be of 8-10 weeks in group A, whereas 6-8 weeks in group B. This difference in healing time was compared at 6 & 8 week and was found to be statistically significant (p value .0016). (Figure 3)

Graft take-up rate in group A was 91.30% and 96.55% in group B. The difference is statistically insignificant (p value .8358). (Figure 4)

The average preoperative air conduction threshold in group A was 35.35 +/- 5.64 dB, whereas 36.10 +/- 4 dB in group B. The difference was statistically insignificant (P value 0.57747). The postoperative change in air conduction threshold at 6 week in group A was 3.57 +/- 6.61 dB, whereas 6.62 +/- 6.86 dB in group B, however this difference was statistically insignificant by conventional criteria (P value -.1114). Change in air conduction threshold of 10 dB or more was found in 34.78% patients in group A and 58.62% patients in group B. This difference between the 2 groups was statistically insignificant (p value-.1114). (Figure 5)

Comparison of various parameters (including complications) in medial (group A) or lateral (group B) placement of graft in inlay technique of myringoplasty is summarized in Table 1.

## DISCUSSION

The two most widely accepted techniques of myringoplasty are overlay and underlay techniques<sup>4</sup>. Underlay technique is technically easier, less time-consuming and has higher success rate<sup>5</sup>. Due to these advantages, it is the most commonly performed technique. The over-underlay myringoplasty (underlay myringoplasty in which graft was placed lateral to the handle of malleus but medial to remnant ear drum and annulus) is relatively a new technique.

In our prospective study of one year, we have tried to compare the graft placement either medial or lateral to the handle of malleus in inlay technique of myringoplasty in dry, medium sized central perforation keeping all other factors constant. Most of the similar studies<sup>1,6,7,8,9,10,11,12</sup> (as shown in table no. 2) previously done, had not kept other influencing factors constant.

We studied these two techniques regarding graft take-up rate, complications, hearing improvement and tried to find out the better technique. There is no uniform agreement in literature about the status of Eustachian tube function and results of myringoplasty<sup>1,6,7,8,10,11,13,14</sup>. We had included patients with good Eustachian tube function as tested by reliable inflation-deflation test in our study. In previous studies<sup>1,9-11</sup> authors did not test Eustachian tube function, hence postoperative complication like atelactasis or medialization were more common.

On Pure Tone Audiometry all cases showed a conductive deafness of <40 dB. Most of studies had not specified the preoperative hearing threshold.<sup>1,6,10,11</sup> Placement of graft, lateral to the handle of malleus but medial to remnant tympanic membrane and annulus acts as a good alternative in perforations involving the area anterior to handle of malleus<sup>15</sup> which is supported by the results of our study.

Most of the patients in our study, in whom graft was placed lateral to the handle of malleus, took 6-8 weeks for complete healing, whereas healing took 8-10 weeks in whom the graft was placed medial to the handle of malleus. This difference is statistically significant. It can be concluded that healing was faster in lateral placement of graft. Healing time was not considered factor in previous studies<sup>1,6,7,8,9,10,11,12</sup>.

On comparing between the two groups there was no difference in graft take-up rate and hearing improvement. However, when preoperative and post-operative hearing levels were compared between both the groups showed significant improvement (> 10dB gain post-operatively).

Most of the previous studies<sup>1,6,7,8,9,10,11,12</sup> had not taken into account all the influencing factors like status of medical co-morbidity, pre-operative hearing threshold, stage of disease, size of perforation, status of middle ear mucosa, tympano-sclerosis, type of anaesthesia given, experience of surgeon etc., which modified the results of myringoplasty. So, our study is unique because we had kept all the influencing factors constant. Only variable factor was placement of graft either medial or lateral to the handle of malleus in modified inlay technique of myringoplasty.

Thus, our study and relevant literature showed that placement of graft, medial to the handle of malleus in inlay technique of myringoplasty had more technical problems at the time of operation in the form of more operating time, difficulty in placement of graft and lengthy post-operative healing time. Hence placement of graft, lateral to the handle of malleus is better than the graft medial to the handle of malleus because it takes lesser time, is technically easier, has faster healing, although there is no difference in graft take-up rate, gain in hearing or complications.

Another significant inference is that it is better to check Eustachian tube function before myringoplasty to avoid postoperative complication in the form of retraction of graft.

**Conclusion-** We concluded that there is no difference in graft take-up rate, gain in hearing or complications in both the techniques, in consideration of the duration of surgery, technicality and healing, placement of graft lateral was found to be better than medial to the handle of malleus in modified inlay technique of myringoplasty.

## DECLARATIONS

*Funding: none*

*Conflict of interest: no*

*Ethical approval: yes*

**Table – 1 : Comparison of various parameters in medial (group A) or lateral (group B) placement of graft in inlay technique of myringoplasty**

Parameters	Group A	Group B	P value
Operating time	1 hour 10 minute	1 hour	
Healing time	8-10 weeks	6-8 weeks	.0016

Success rate- A) Graft take-up rate B) Hearing improvement (change in air conduction threshold postoperatively)	91.30% 3.57+/-6.67 dB (34.78% patients show significant change)	96.55% 6.66+/-6.86dB (58.62% patients show significant change)	.8358 .1114
Complication			
A)Lateralization of graft B) Cholesteatoma pearls C) Tympanosclerosis D) Retraction of graft E) Deterioration in hearing F) Residual perforation	No No 4.35% (1 out of 23 cases) 4.35% (1 out of 23 cases) 8.69% (2 out of 23 cases)	No No No 3.45% (1 out of 29 cases) 3.45% (1 out of 29 cases) 3.45% (1 out of 29 cases)	

**Table 2 : Comparison of different parameters and results of previous studies**

S No.	Name of authors	Success rate				Complications	
		Group A (UT)		Group B (OUT)		Group A (UT)	Group B (OUT)
		GTR	HI	GTR	HI	Medialization/lateralization Atelactasis/cholesteatoma	Medialization/lateralization Atelactasis/cholesteatoma
1.	Aslam MA et al. 1 in 2015	92.8%	11.3+/-5.84dB	94.1%	10.8+/-5.56dB	Lateralization-00% Medialization-2.9%	Lateralization-00% Medialization-17.8%
2.	MehradRougha et al. 6 in 2014	96.42%	16.10+/-4.89dB	92.85%	15.78+/-3.40dB	Re-perforation-3.57%	Re-perforation-3.57% Blunting-3.57%
3.	Panchal V et al. 7 in 2015	90%	14.5+/-7.236dB	95%	18.75+/-5.35dB	Not mentioned	Not mentioned
4.	Mylanahalli Doddarangiah prakash et al.8 in 2014	92%	4.78dB	96%	8.50dB	Not mentioned	Not mentioned
5.	Kuldec E et al.9 in 2015	89.1%		90.5%		Lateralization-00% Retraction-8.2%	Lateralization-5.6% Retraction-3.8%
6.	Yigit O et al. 10 in 2005	91.5%	16.55dB	94.9%	16.96dB	Lateralization-00% Atelactasis-19.5%	Lateralization-00% Atelactasis-12%
7.	She W et al. 11 in 2008	89%	4.9dB	87.5%	9.7 dB	Lateralization-00% Atelactasis-17.8% Re-perforation-5.9% Anterior blunting-6.8%	Lateralization-00% Atelactasis-15% Re-perforation-6.25%
8.	Imran S et al. 12 in 2014	83.3%	11.7+/-7.2dB	90%	12.2+/-7dB	Lateralization-00% Blunting-00% Infection -00%	Lateralization-00% Blunting-00% Infection-00%

9.	Stage J et al. 15 in 1992			97%			Lateralization-00% cholesteatoma pearl-00%
10.	Our study 2015 India	91.3%	3.57+/-6.61dB	96.55%	6.62+/-6.86dB	Retraction-4.35% Tympanosclerosis-4.35% Deterioration in hearing-4.35% Residual perforation-8.70%	Retraction-3.45% Tympanosclerosis-00% Deterioration in hearing-3.45% Residual perforation-3.45%

**Abbreviations-** UT-conventional underlay technique, OUT-over-underlay technique, GTR- graft take-up rate, HI-hearing improvement.

**Figure 1: Age and sex distribution in group A and B**

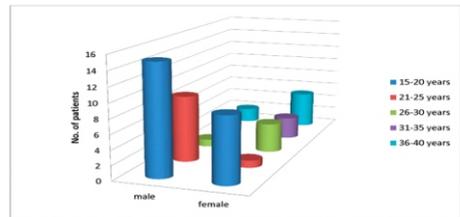


Figure 1

**Figure 2: Air conduction threshold in 52 patients of group A and B**

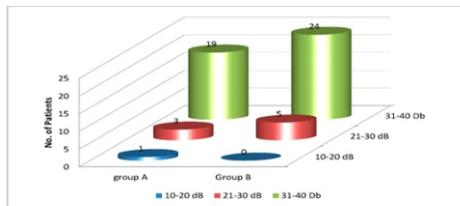


Figure 2

**Figure 3: Healing time of graft placement in group A and group B**

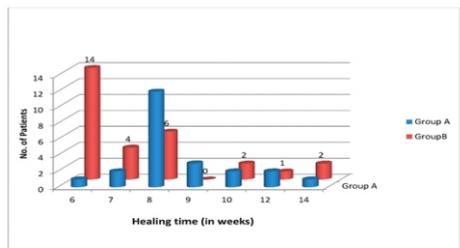


Figure 3

**Figure 4: Graft take-up rate and graft failure in group A and B**

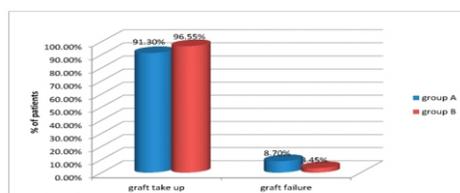
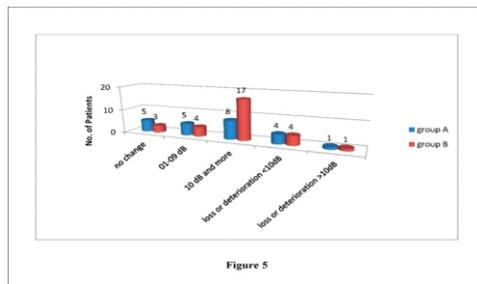


Figure 4

**Figure 5: Pre and post-operative status of hearing level in group A and B****REFERENCES**

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