ORIGINAL RESEARCH ARTICLE

COMPARATIVE STUDY OF PLACEMENT OF GRAFT MEDIAL OR LATERAL TO HANDLE OF MALLEUS IN INLAY TECHNIQUE OF MYRINGOPLASTY: A RETROSPECTIVE AND PROSPECTIVE STUDY

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ABSTRACT

This randomized triple blinded retrospective and prospective study, was studied in terms of graft take-up rate, hearing improvement and complications and get more fruitful way for my rhinoplasty surgery. This study of 180 patients were divided in two groups. Group A (51 patients) in whom graft was placed medial and in group B (129 patients) graft was placed lateral to the handle of malleus in modified inlay technique of my rhinoplasty. The results were compared at 3 weeks, 3- and 6-month follow-up. Pre- and post-operative air conduction (AC), bone conduction (BC) and air-bone gap (ABG) were compared.

KEYWORDS

Chronic otitis media, my rhinoplasty, Inlay technique, Air Bone Gap, Conductive hearing Loss

INTRODUCTION

Myringoplastyis the closure of the perforation of pars tensa of the tympanic membrane to restore its integrity and to improve hearing. 'rhinoplasty' was introduced in 1878 by Berthold[1]using skin graft.

Many techniques of my rhinoplasty have been described in literature like overlay, underlay. Underlay technique were introduced by Austin and Shea(1961) which was later modified by Hough (1970)[2]. This study was conducted to

observe the result of graft placement, medial or lateral to the handle of malleus in my rhinoplasty keeping all other influencing factors constant. The three principal indications for my rhinoplasty are recurrent otorrhea, hearing loss due to chronic perforation and desire to swim without having to water proof the ear [3].

AIMS AND OBJECTIVE

This study is to assess the success rate in inlay technique of my rhinoplasty with placement of graft either medial or lateral to handle of malleus in terms of 1) Graft take up rate, 2) Change in hearing threshold, 3) Complications, if any.

MATERIALS AND METHODS

This was a retro-prospective, randomized triple blinded comparative study conducted in the Department of E.N.T and Head & Neck Surgery on 180 patients of chronic otitis media mucosal disease after due clearance from the Institutional Ethics Committee [Ethics Committee Registration No. ECR/922/Inst/UP/2017 issued under Rule 122DD/of the Drugs & Cosmetics Rule 1945].

Patients included in this study were aged between 18 to 40 years, with medium sized central perforation, dry ear for more than 6 weeks, healthy middle ear mucosa on otoscopy, conductive deafness \leq 40 dB (i.e. air conduction threshold of \leq 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 co-morbidities like diabetes mellitus, hypertension, tuberculosis or auto immune diseases.

Patients who were below 18years old and above 40years old, with small, large or subtotal perforation, evidence of discharge or squamosal type of chronic otitis media, abnormal Eustachian tube function, previously operated ear or active infectious foci in nose, throat or oral cavity were excluded from this study.

Consent: 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 which 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. Operations were performed by experienced surgeons.

OPERATIVE PROCEDURE

In all the selected case, post-aural approach with temporalis fascia graft and Hough's inlay technique of myrhinoplasty 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 predetermined) after keeping abgel in middle ear and Eustachian tube opening.

Group A (prospective+retrospective): 51 Patients in whom graft was placed medial to the handle of malleus after making a 'V' shaped notch in the graft.

Group B (prospective+retrospective): 129 Patients in whom graft was placed lateral to the handle of malleus Tympanomeatal flap was reposited. 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, Antihistaminic and nasal decongestants for 1 week and stitch removal on 7th 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 from baseline of

preoperative level and at 6weeks&at 6 months of follow-up period. 10 dB or more deterioration or loss in hearing from baseline of preoperative level and at 6 weeks & 6 months 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 myrhinoplasty were compared between group A & B utilizing Chi square two tailed test for graft success rate and complications. Paired and unpaired T-test for small n (n<30) otherwise Z test were utilized to compare pre and postoperative air conduction change. Statistical significance was accepted as p<0.05.

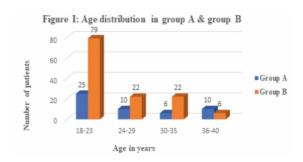
RESULTS

The observations made at the end of the study were, the total no. of 180 (n=180) cases were taken, of which group A having 51 (28.33%) cases in which male and female were 27 (52.94%) and 24 (47.06%) respectively and group B having 129 (71.67%) of cases in which male and female were 51 (39.53%) and 78 (60.46%) respectively. Retrospective and prospective cases in group A were 36 (20%) and 15 (8.33%) respectively while in group B were 84 (46.67%) and 45 (25%) respectively (Table I).

Sex	Group A	(N=51)	Group B	N=129)
	Retrospective	Prospective	Retrospective	Prospective
Male	19	8	36	15
Female	17	7	48	30
Total	36	15	84	45

Table I: Sex distribution in both the groups (n=180) Mean age of patients in group A and group B was 26.13 ± 8.19 and 23.67 ± 6.05 years (mean \pm SD) respectively, which ranged between 18-40 years (p value > 0.0178). Themaximum no of patients (57.78%) in both age groups were in the age group of 18-23 years (Figure I).

Figure I: (Age distribution) This study included patients who were divided randomly into two groups.

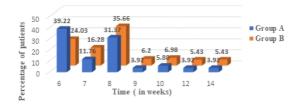


Average operating time in group A and group B were 81 ± 11 minutes and 73 ± 11 minutes (mean \pm SD) respectively (Table II), while graft took more or less equal time in both the groups i.e. about 6 to 8 weeks to heal (Figure II).

Table II: Operative time taken in both the groups (n=180)

Operative Time (minutes)	Group A (N=51)	Group B (N=129)
60-70	13	49
71-80	15	49
81-90	11	22
91-100	12	9
Mean ± SD	81 ± 11 minutes	73 ± 11 minutes

Figure II: Healing time of graft in both the groups



On observing pre-operative hearing threshold on Pure Tone Audiometry, 2 patients in either groups had ≤ 20 dB conductive hearing loss. Air conduction threshold were between 21 and 30 dB in 3 and 18 patients in group A and group B respectively. Air conduction threshold were between 31 and 40 dB in 46 and 109 patients in group A and group B respectively.

The preoperative average air conduction in group A was 36.27 ± 5.50 dB (mean \pm SD), whereas it was 36.19 ± 5.33 dB (mean \pm SD) in group B and P value 0.9293 (p value >0.05); difference was considered to be statistically

insignificant. The average postoperative change in air conduction at 6 weeks was 7.71 ± 7.05 (mean \pm SD) in group A & 8.19 \pm 5.99 (mean \pm SD) in group B and at 6 months in group A was 7.75 ± 7.05 dB (mean \pm SD), whereas it was 8.29 ± 6.04 dB (mean \pm SD) in group B and P value 0.6301; by conventional criteria, this was statistically insignificant. Average Air bone gap (ABG) preoperative was 20.29 \pm 6.13 dB (mean \pm SD) in Group A, whereas it was 21.02 ± 5.81 (mean \pm SD) dB in Group B. Average ABG postoperatively at 6 months in Group A was $16.08 \pm 6.31 \, dB$ (mean \pm SD), whereas it was 15.73 \pm 5.47 dB (mean \pm SD) in Group B. The average gain in ABG at 6 months postoperative in Group A was $4.22 \pm 7.18 \text{ dB}$ (mean \pm SD), whereas it was 5.29 \pm 5.64 dB (mean ± SD) in Group B. There was statistically insignificant difference (p>0.05) between Group A and Group B regarding gain in ABG postoperative (Table III).

Table no. III: Pre-operative and post-operative change in hearing threshold and air bone gap

Group	Group A (n=51) [mean ± SD]	Group B(n=129) [mean ± SD]	p-Value
Preoperative air conduction	36.27 ± 5.50 dB	36.19 ± 5.33 dB	0.9293
Postoperative air conduction (6 weeks)	28.57 ± 8.02 dB	28.01 ± 7.27 dB	0.45282
Postoperative air conduction (6months)	28.53 ± 8.03 dB	27.90 ± 7.32 dB	0.6269
Change in air conduction (between preoperative and at 6 months)	7.75 ± 7.05 dB	8.29 ± 6.04 dB	0.6301
Pre-operative ABG	20.29 ± 6.13 dB	21.02 ± 5.81 dB	0.9301
Post-operative ABG (at 6 months)	16.08 ± 6.31 dB	15.73 ± 5.47 dB	0.728
ABG Difference	4.22 ± 7.18 dB	5.29 ± 5.64 dB	0.68

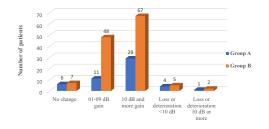
(ABG) in group A and B (n=180)

The significant change in air conduction of 10 dB or more was found in 29 (56.86 %) of patients in group A while it was 67 (51.94 %) patients in group B. When both groups were compared it was found that difference was statistically insignificant (p value- 0.163), (TableIV& Figure III).

Table no. IV: Post-operative status of hearing in Group A and B (n=180)

Change in air	No. of C	ases (%)
conduction (in dB)	Group A (N=51)	Group B (129)
No change	6 (11.76 %)	7 (5.43 %)
01-09 dB gain	11 (21.57%)	48 (37.21 %)
10 dB and more gain	29 (56.86 %)	67 (51.94 %)
Loss or deterioration <10 dB	4 (7.84 %)	5 (3.88%)
Loss or deterioration 10 dB or more	1 (1.96 %)	2 (1.55 %)
Total no of patients	51	129

Figure III: Post-operative status of hearing in group A and B



The graft take-up rate in group A and group B were 94.12% and 96.89% respectively. The Chi square statistic is 0.7566. The p-value is 0.3844. (Table V)

Table no. V: Graft take up rate in group A and B (n=180)

Status of graft	Group A (N=51)	Group B (N=129)
Graft take up	48 (94.12%)	125 (96.89%)
Graft rejection	3 (5.88%)	4 (3.10%)

Comparison of various parameters (including complications) in group A & group B technique of myringoplasty are summarized in Table VI.

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

Different parameters and results were compared

Parameters	Group A (N=51)	Group B (N=129)	P value
Operating time	81 <u>+</u> 11minutes	73 <u>+</u> 11 minutes	
Healing time	6-8 weeks	6-8 weeks	0.3543
Success rate:			
Graft take-up rate	94.11%	96.89%	0.384392
Hearing improvement	7.75 <u>+</u> 7.05 dB	8.29 <u>+</u> 6.04 dB	0.6301
Change in air conduction threshold postoperatively	56.86% patients show significant gain	51.94% patients show significant gain	
Complication			
Lateralization of graft	No	No	
Cholesteatoma pearls	No	No	
Tympanosclerosis	1.96% (1 out of 51cases)	3.10% (4 out of 129cases)	
Retraction of graft	1.96% (1 out of 51cases)	0.77% (1out of 129 cases)	
Deterioration in hearing	1.96 % (1 out of 51 cases)	1.55% (2 out of 129 cases)	
Residual perforation	5.88 % (3 out of 51 cases)	3.10% (4 out of 129 cases)	

of previous studies with our study. (Table VII)

DISCUSSION

The two most widely accepted techniques of myringoplasty are overlay and underlay techniques. Underlay technique is technically easier, less time-consuming and has higher success rate ^[4]. Due to these advantages, it is the most commonly performed technique. The over-underlay myrhinoplasty (underlay myrrhinoplasty 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 retro-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 perforationkeeping all other factors constant. Most of the similar studies [12-17] (as shown in table VII) 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 rhinoplasty [7,12-16]. We had included patients with good Eustachian tube function as tested by reliable inflation-deflation test in our study. In previous studies [7,12,13] authors did not test Eustachian tube function, hence postoperative complication like atelectasis or medialization were more common.

On Pure Tone Audiometry all cases showed a conductive deafness of \leq 40 dB. Most of studies had not specified the preoperative hearing threshold. 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 which is supported by the results of our study.

In most of the cases graft took more or less equal time in both the groups i.e. about 6 to 8 weeks to heal. Healing time was not considered factor in previous studies^[12,13,16,17].

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 postoperatively).

Most of the previous studies [12-17] 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, tympanosclerosis, type of anaesthesia given, experience of surgeon etc., which modified the results of

Table No VII: Comparison of different parameters and results of various studies

ઝં	Name of authors		Succ	Success rate		Complications	ations
Š.	(Year)	Gro	Group A (UT)	Grot	Group B (OUT)	Group A (UT)	Group B (OUT)
		GTR	H	GTR	Ŧ	Medialization/ lateralization Atelectasis/ cholesteatoma	Medialization/ lateralization Atelectasis/ cholesteatoma
-	Singh M et al. [4] (2003)	93.3%	92.8%	93.3%	57.1%	Lateralization/ blunting- 0%, Pin-hole perforation-6.6%	Lateralization-6.6%, Blunting-6.6%. 6.6%. Pin-hole preforation-3.3%
2	Bluestone CD et al. [9](1979)	49%	ı	%29	ı		ı
С	P.Packer et al. [10](1982)	%86	1	91%	1	1	1
4	M. W. Yung [11] (1995)	92.5%	1	1	1	Not mentioned	Not mentioned
2	Yigit O et al. [12] (2005)	91.5%	16.55dB	94.9%	16.96dB	Lateralization-00% Atelactasis-19.5%	Lateralization-00% Atelactasis-12%
9	Aslam MA et al. ^[13] (2015)	92.8%	11.3 <u>+</u> 5.84dB	94.1%	10.8 ± 5.56dB	Lateralization-00% Medialization-2.9%	Lateralization-00% Medialization-17.8%
7	Mehrdad Rogha et al. ^[14] (2014)	96.42%	16.10 ± 4.89dB	92.85%	15.78 ± 3.40dB	Re-perforation-3.57%	Re-perforation-3.57% Blunting-3.57%
8	Panchal V et al. ^[15] (2015)	%06	14.5 \pm 7.236dB	95%	18.75 ± 5.35dB	Not mentioned	Not mentioned
6	Mylanahalli Doddarangaiah Prakash et al. ⁽¹⁶⁾ (2014)	%76	4.78dB	%96	8.50dB	Not mentioned	Not mentioned
10	Kulduk E et al. ^[17] (2015)	89.1%	-	90.5%	-	Lateralization -00% Retraction-8.2%	Lateralization-5.6% Retraction-3.8%
11	Jan Stage & Kristian Bak-Pederson ⁽¹⁸⁾ (1990)	1	-	97%	-	-	Residual perforation- 2.56%
12	Rahul Kawatraet al. ⁽¹⁹⁾ (2014)	%2'98	1	83.3%	1	No complication noticed	
13	Our study (2019) [India]	94:11%	7.745 <u>+</u> 7.045dB	96.89%	8.295 <u>+</u> 6.045 dB	Tympanosclerosis - 1.96 % Residual perforation - 5.88 % Retraction of graft -1.96 % Deterioration in hearing -1.96 %	Tympanosclerosis - 3.10 % Residual perforation - 3.10 % Retraction of graft - 0.77 % Deterioration in hearing- 1.55 %

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

myringoplasty^[5]. 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 postoperative 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 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 myrhinoplasty to avoid postoperative complication in the form of retraction of graft^[6]. A significantly better healing rate was found in the groups classified as "good" ET- function ^[7] The Eustachian tube has a primitive function in ventilation & clearing the middle ear without which the normal or reconstructive tympanum cannot perform its 'transformer function'. ^[8] while in Bluestone CD etal. ^[9] study assessed that Eustachian tube function using the modified inflation-deflation test failed to predict the success of tympanoplasty and clinical obstruction pre-operatively did not increase failure rate. ^[10]

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 myrhinoplastyand grafting technique may also depend on the experienced of the surgeons.

DECLARATIONS

Funding: Nil

Conflicts of interest: There is no conflicts of interest.

Ethical approval: The study was approved by the Institutional Ethics Committee.

Consent: Written and informed consent were taken while doing study. No animal or person were harmed during the study.

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