

Original Research Article

Evaluation of outcome of ossiculoplasty with and without an intact malleus

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ABSTRACT

Background: CSOM is commonly encountered in the clinical practice as a cause of conductive hearing loss. Preoperative evaluation of hearing becomes mandatory for proper management. Ossiculoplasty is usually done in conductive hearing loss due to ossicular chain abnormality in CSOM. The aim of the evaluation of outcome of ossiculoplasty with and without an intact malleus.

Methods: Total 40 patients greater than 18 years with mucosal type of CSOM with good cochlear reserve and Eustachian tube function, requiring intact canal wall mastoidectomy only were taken. All cases were planned ossiculoplasty with tympanoplasty or tympanomastoidectomy and postoperative follow-up done with measurement of Pure-tone average air-bone gap Ossiculoplasty Outcome Parameter Staging (OOPS) index and complications. Simple random sampling technique is used to calculate the size during the study.

Results: Ossiculoplasty was done in all cases in which 50% of patients (n=20) had malleus and 50% (n=20) with no malleus and AB gap in both group have almost similar result.

Conclusions: Ossiculoplasty techniques using neo malleus struts combined with assembly prostheses, in middle ear reconstruction was studied and was non-significant.

Keywords: Ossiculoplasty, OOPS index, Malleus bone

INTRODUCTION

The ear is one of the most important organ of the human body, which may affect various physiological and pathological conditions. Due to rapid environment changes, urbanization and industrialization the morbidity due to hearing impairment has shown an increasing trend in the community. The ideal scenario in which to perform ossiculoplasty is in a stable well-ventilated middle ear, with an intact tympanic membrane, in the absence of ongoing middle ear infection or cholesteatoma. Absence of any of the above factors increases the risk of failure, as do patient factors such as smoking status.¹ The Middle Ear Risk Index (MERI) was devised by Kartush in 1994

and generates a numeric value which corresponds to severity of disease, and the likelihood of a successful outcome following surgery.² This can be used to guide case selection and counselling of patients pre-operatively but is perhaps most useful for research purposes. It is an amalgamation of the Austin-Kartush classification of ossicular defects, the Belluci classification of otorrhea and takes into consideration the presence of tympanic membrane perforation, middle ear granulation, and cholesteatoma.³ The MERI was originally scored 0–12, and was later modified in 2001 to include smoking and increase the weighting for granulation and cholesteatoma thus giving a score of 0–16.⁴ Alternative risk stratification or scoring systems include the Ossiculoplasty Outcome

Parameter Staging (OOPS) index or SPITE factors (surgical, prosthetic, infection, tissue, Eustachian).^{5,6}

Parameters examined included age, diagnosis, perforation, Bellucci classification score, Austin classification, middle ear mucosa status, preoperative audiogram, canal wall status, surgical procedure, revision status, ossicular status, type of prosthesis used (PORP or TORP), and presence or absence of drainage or fibrosis at the time of surgery. A multivariate analysis of variance was then performed to identify the factors to be most significant in predicting postoperative air-bone gaps. Pair-wise comparisons were made to identify the individual factors that were significant. These significant factors were then placed in a multiple linear regression to assess each factor in its prediction of postoperative air-bone gaps. It is important to note that the multivariate analysis allowed all of the parameters to be examined for any significant correlation among them.

Out of these most significant factors is presence of middle ear fibrosis at time of surgery, defined as any mucosal disruption or adhesion between two adjacent structures.

Objective

Parameters included age, diagnosis, perforation, Bellucci classification, Austin classification, middle ear mucosa status, audiogram, canal wall status, surgical procedure, revision status, ossicular status, type of prosthesis used (PORP or TORP), and presence or absence of drainage or fibrosis during surgery. Pair-wise comparisons were made to identify the individual factors that were significant. These significant factors were then placed in a multiple linear regression to assess each factor in its prediction of postoperative air-bone gaps.

METHODS

Study type

The study type was comparative, single centered, prospective.

Evaluation of outcome of ossiculoplasty with and without an intact malleus was conducted in Department of otorhinolaryngology in GSVM Medical college, Kanpur from January 2019 to October 2020.

The prospective study was conducted on 40 patients of diagnosed chronic otitis media showing clinical symptoms which affect quality of life. Patients who were fulfilling inclusion criteria after screening were selected for study. All cases are planned ossiculoplasty with tympanoplasty or tympano-mastoidectomy using cartilage tympanic membrane grafts under LA and postoperative follow-up. Pure-tone average air-bone gap [PTA-ABG] measured (with interval of 1, 3 and 6

month), Ossiculoplasty Outcome Parameter Staging (OOPS) index, and complications.

Inclusion criteria

Patient >18 year of age with mucosal type of chronic suppurative otitis media with good cochlear reserve and good eustachian tube function and cases selected are those which required intact canal wall mastoidectomy only. Intra operative findings of ossicular discontinuity in the form of erosion of long process of incus with intact malleus and stapes intact (Austin's type A).

Exclusion criteria

Patient <18 year of age with previous history of ear surgeries having atticofacial disease and cholesteatoma along with sensorineural or mixed hearing loss who require canal wall down mastoidectomy as part of their treatment.

Table 1: Number of patient in their respective risk factor and risk value according to OOPS staging.

Risk factor		Risk value
Middle ear factors		
Drainage	None	0
	Present >/50% of time	1
Mucosa	Normal	0
	Fibrotic	2
Ossicles	Normal	0
	Malleus+	1
	Malleus -	2
Surgical factors		
Type of surgery	No mastoidectomy	0
	Canal-wall-up mastoidectomy	1
	Canal-wall-down mastoidectomy	2
	Canal-wall-down mastoidectomy	2
Revision surgery	No	0
	Yes	2

Ethical committee approval

The Ethics Committee (For Biomedical Health & Research), GSVM Medical College, Kanpur has approved the proposal "Evaluation of outcome of ossiculoplasty with and without an intact malleus".

Statistical analysis

Statistical analyses will be performed using the IBM SPSS version 21. The averages and the frequency distributions will be examined. The normality of the intergroup distribution will be checked. Size of the sample to be decided as per requirement of the study, which is normally distributed.

RESULTS

Most of patient presented with unilateral symptom approximately 65% (n=26) and patient who presented with bilateral ear symptoms contributes about 35% (n=14) and majority of the population belongs to class IV socio economic status i.e lower socio-economic class and contributes about 45% (n=18) and very minimal percentage of population belongs to upper socio-economic class approximately 2.5% (n=1).

Table 2: Distribution on the basis of sex.

S. No.	Sex	No. of cases	%
1.	Male	16	40
2.	Female	24	60

Table 3: Cases of socio economic status according to modified B.G. Prasad social classification scale for S.E.S.

S. No.	Class	Income per month (in Rupees)	No. of Patients	%
1.	Class I	7008 & above	1	2.5
2.	Class II	3504 - 7007	5	12.5
3.	Class III	2102 – 3503	13	32.5
4.	Class IV	1051 – 2001	18	45
5.	Class V	< 1050	3	7.5
Total			40	100

Table 4: Area wise distribution.

Sl. No.	Area	No. of cases	%
1.	Rural	25	62.5
2.	Urban	15	37.5
Total		40	100

The role of ossiculoplasty techniques using neomalleus struts combined with assembly prostheses, in middle ear reconstruction was studied and was found to be non-significant. ossiculoplasty using malleus to stapes reconstruction and incus to stapes reconstruction and found that both type of procedure have more or less similar result. Ossiculoplasty was done in 50% of patient (n=20) who had malleus and ossiculoplasty was done in 50% (n=20) of patient who had no malleus and found that air bone gap in both group of patient have almost similar result. In our study female patients were more common as compared to male patients. Male (n=16) contributes 40% and female (n=24) contributes 60%.

In our study maximum percentage of the patient belongs to class IV (45%) (n=18) compared to class I (2.5%) (n=1) which contributes to minimum percentage.

Total no of rural patients (n= 25) out of 40 patients (62.5%). Total no of urban patients (n=15) out of 40 patients (37.5%). 45 percentage of cases were having dry

ear(n=18) at the time of their first visit, while 50 percentage having discharging ear (n=20). 92.5 percentage of cases have hearing loss (n=37). 70 percentage of cases were having ear pain (n=28). 12.5 percentage of cases were having tinnitus (n=5).

Table 5: Symptomlogy showing varies symptoms

Sl. No.	Symptoms	No. of Cases	%
1.	Discharge	20	50
2.	No discharge	18	45
3.	Difficulty in hearing	37	92.5
4.	Ear pain	28	70
5.	Tinnitus	5	12.5
Total		100	

Table 6: Degree of deafness on the basis of who criteria (1980).

PTA (0.5-4 kHz)	Verbal Descriptor	No of patients	%
26-40 dB	Mild	20	50
41-55 dB	Moderate	17	37.5
56-70 dB	Moderately severe	3	7.5
71-91 dB	Severe	0	0
> 91 dB	Profound	0	0
Total		40	100

Table 7: Pre-op and post-op PTA-AB gap of ossiculoplasty with malleus (Group A).

	Mean±SD (db)		
Pre-op	40.2±5.85		
Post-op	At 1 month	At 3 months	At 6 months
Group A	20.6±3.38	19.8±3.49	19.0±3.15
P value (as compared pre-operatively)	0.0001	0.0001	0.0001
P value (1 st and 3 rd month) =0.47 (statistically not significant). P value (1 st and 6 th month) =0.13 (statistically not significant)			

Audiometry was done in 40 patients out of which most common pattern was patients with mild hearing loss and contributes 50% of all the patients (n=20). In our study ossiculoplasty was done in 50% of patient (n=20) who had malleus and ossiculoplasty was done in 50% of patient (n=20) who had no malleus.

For group A mean value of baseline (pre op), 1 month, 3 month and 6 months AB gap were 40.2±5.85 dB, 20.6±3.38 dB, 19.8±3.49 dB and 19.0±3.15 dB respectively. After applying paired t test between pre

operative and post operative (1 month) in group A $p < 0.05$ which denotes that there was significant difference.

After applying paired t test in group A between postoperative (1 month and 3 month) and post operative (3 month and 6 month) p value was found to be 0.47 and 0.13 respectively which was > 0.05 which denotes that there was statistically no significant difference.

Table 8: Pre-op and post-op PTA-AB gap of ossiculoplasty without malleus (Group B).

	Mean±SD		
Pre-op	42.4±5.4		
Post-op	At 1 month	At 3 month	At 6 month
Group B	22.5±4.63	20.7±3.69	19.3±3.63
P value (as compared pre-operatively)	0.0001	0.0001	0.0001
P value (1 st and 3 rd month) =0.18 (statistically not significant). P value (1 st and 6 th month) =0.25 (statistically not significant)			

For group B mean value of baseline (pre op), 1 month, 3 month and 6 month AB gap were 42.4±5.4 dB, 22.5±4.63 dB, 20.7±3.69 dB and 19.3±3.63 dB respectively. After applying paired t test between pre operative and post operative (1 month) in group B p value was found to be < 0.05 which denotes that there was significant difference. After applying paired t test in group B between post operative (1 month and 3 month) and post operative (3 month and 6 month) p value was found to be 0.18 and 0.25 respectively which was > 0.05 which denotes that there was statistically no significant difference.

After applying unpaired t test between group A and group B pre operative AB gap, $p > 0.05$ denotes that there was no significant difference in baseline value.

After applying paired t test between pre operative and post operative (1 month) in group A $p < 0.05$ which denotes that there was significant difference.

After applying paired t test between pre operative and post operative (1 month) in group B $p < 0.05$ which denotes that there was significant difference.

1st month follow-up

On applying unpaired t test between the mean A-B gap of group A and group B p value was found to be 0.89 which was > 0.05 denotes that statistically not significant.

3rd month follow-up

On applying unpaired t test between the mean A-B gap of group A and group B p value was found to be 0.75 which was > 0.05 denotes that statistically not significant.

6th month follow-up

On applying unpaired t test between the mean A-B gap of group A and group B p value was found to be 0.93 which was > 0.05 denotes that statistically not significant.

As per the scoring of OOPS stage 50% (n=20) of patient fall under the risk value ranging between 0-3 have good outcome and 50% (n=20) of patient fall under the risk value ranging between 4-6 have fair outcome.

Number of patient according to oops staging who fall under risk value of 0-3 having drainage present $> 50\%$ of time, normal mucosa, malleus present and in which no mastoidectomy done are 5, 20, 20, 20 respectively.

In the postoperative period maximum 60% of patient (n=24) presented with complaint of pain and minimum 0% of complaint contributes to discharge and facial asymmetry.

DISCUSSION

In current study the discussion is made on evaluation of the outcome of ossiculoplasty with and without intact malleus. OOPS staging have been taken into consideration for evaluation, its various points include drainage, mucosal condition of middle ear, surgical procedure is included like canal wall up mastoidectomy and whether previous surgery history is present or not. Outcome of ossiculoplasty have been studied shows non-significant outcome when AB gap is compared in pre and post operated patient.

In our hospital, with a comparative, single centred, prospective study. Our study was conducted on 40 patients (> 18 years) presented with various symptoms such as discharging ear, tinnitus, vertigo, pain. This study compared the AB gap between two groups; one with intact malleus and other group without intact malleus. During the follow up phase, patients were selected according to the inclusion criteria and exclusion criteria (Discussed in Material and Methods); then eligible patients were included in the follow up study.

Patients after follow up were divided into two groups and the first 20 patients were with intact malleus and subsequent 20 patients were without malleus. Then patients were followed up at 1 month, 3 month and 6 month to compare the AB gap in the pre and post op period.

Currently while evaluation of outcome of ossiculoplasty with and without intact malleus 60% of the affected patient population were females (n=24) and 40% of the patient were males (n=16) and most of them belong to rural areas contributing about 62.5% (n=25) and urban patient contributes 37.5% (n=15). It has also found in my study that most of patient presented with unilateral symptom approximately 65% (n=26) and patient who

presented with bilateral ear symptoms contributes about 35% (n=14) and majority of the population belongs to class IV socio economic status i.e lower socio-economic class and contributes about 45% (n=18) and very minimal percentage of population belongs to upper socio-economic class approximately 2.5% (n=1). These results of our study is favoured by study done by Shaheen et al who showed that Chronic suppurative otitis media (CSOM) is one of the common community health disorders. It is more common in rural population where poverty, overcrowding, illiteracy, ignorance, poor hygiene, malnutrition and lack of medical facilities i.e in lower socioeconomic status have been suggested as a basis for the widespread prevalence of CSOM. In this cross sectional study among the 1468 rural population, total 77 cases of CSOM were detected and the prevalence of CSOM was 5.2%. Prevalence of CSOM was more among females 46 (5.7%) than the males 31 (4.7%). The relative higher prevalence rate of CSOM among the females can be explained by the social and familial indifference to them. According to our study, 52.6% of the samples were from low income group where CSOM were also more prevalent (7.1%). 71.4% of total CSOM cases were detected from this group. 42 (54.5%) population had right sided, 30 (38.9%) had left sided CSOM and 5 (6.5%) had bilateral CSOM. Thus, in our study, population from lower socio economic strata were found more vulnerable to CSOM.

Multivariate statistical analysis determined the effect of mucosal status, ossicular chain status, and type of reconstruction techniques on hearing. The PTA-ABGs were 13.4 ± 8.1 dB and 14.0 ± 8.4 dB for the PORPs (n=114) and TORPs (n=86), respectively, which was not statistically different. When the malleus handle was present (n=126), the PTA-ABG was 11.6 ± 6.2 dB, compared with 16.9 ± 10.1 dB when it was absent (n=74), which was statistically significant ($p < 0.05$). Mucosal fibrosis, drainage, revision ear surgery, and type of surgical procedure had a significant detrimental impact on hearing. The type of pathologic process (perforation versus cholesteatoma) had no significant impact on hearing results. The revised staging system, the Ossiculoplasty outcome parameter staging index, more adequately predicts hearing outcome in this series of 200 cases.

This study correlates with the study performed in our hospital on patients (n=40) in which similar points of ossiculoplasty outcome parameter staging index (Mucosal fibrosis, drainage, revision ear surgery, and type of surgical procedure) had been compared.

In our study the role of ossiculoplasty techniques using neomalleus struts combined with assembly prostheses, in middle ear reconstruction was studied and was found to be non-significant and was supported by similar study shows that ossicular reconstructions using an autograft strut to replace an absent or malposition malleus, combined with Spanner assembly prostheses. Two

months postoperatively, neomalleus cases returned favourable results in comparison with those of previous techniques, in equivalent situations. The technique appeared to be durable in the longer term. Neomalleus techniques offer enhanced success rates when the malleus handle is displaced, diseased, or absent.

A study on fifty seven patients who underwent bone cement ossiculoplasty and had appropriate follow up were included in the study. Bone cement reconstruction of the ossicular chain was performed 1) from incus to stapes (I-S) in the absence of long arm or lenticular process of the incus and 2) from malleus to stapes (M-S) in the absence of the incus. Pre- and postoperative PTA of all patients were compared, which showed a significant improvement in air PTA ($p < 0.001$) while bone PTA did not change ($p > 0.05$). In I-S and M-S groups, successful hearing restoration could be achieved in 78.6.1% and 87.5% of the patients, respectively.⁷

In our study we performed ossiculoplasty using malleus to stapes reconstruction and incus to stapes reconstruction and found that both type of procedure have more or less similar result. Ossiculoplasty was done in 50% of patient (n=20) who had malleus and ossiculoplasty was done in 50% (n=20) of patient who had no malleus and found that air bone gap in both group of patient have almost similar result, non significant which is supported by the above mentioned study.

In our study canal wall up procedure conducted on 40 patient and followed up at 1 month 3 month and 6 month in group of patient in which the malleus was present and incus eroded and the result found to be non-significant which was favoured by study that compared the results obtained with canal wall up (CWU) tympanoplasty for cholesteatoma using cartilage or an hydroxyapatite (HA) PORP positioned on the head of the stapes and to analyse the impact of malleus removal and total reinforcement of the tympanic membrane with cartilage.

Retrospective study of 128 cases (99 adults, 29 children) operated between 2003 and 2012 for cholesteatoma by CWU tympanoplasty with use of a cartilage graft (90 cases) or a PORP (38 cases) on the head of the stapes. Audiometric results were analyzed according to the International Bureau for Audio phonology (BIAP) criteria and were submitted to statistical analysis. All ossiculoplasties were performed during the first operation and only 39% of patients required surgical revision. The malleus was preserved in 79 cases and sacrificed in 49 cases.

With a follow-up of 2 years, the residual mean air-bone gap was 16.8 dB in the cartilage group (gain of 7.6 dB; $p = 0.001$) and 15.8 dB in the PORP group (gain of 8.5 dB; $p = 0.002$). The air-bone gap was less than 20 dB in 67.6% of cases in the cartilage group and 70.4% of cases in the PORP group. No significant difference was observed between the 2 techniques and no significant difference

was observed according to whether or not the malleus was preserved in either the cartilage group or the PORP group.

These results confirm the value of cartilage graft placed on the head of the stapes as ossiculoplasty technique in cholesteatoma operated by CWU tympanoplasty, giving comparable results to those obtained with a PORP. Malleus removal did not induce any reduction of the quality of hearing obtained. Total reinforcement of the tympanic membrane with cartilage appeared to decrease the cholesteatoma recurrence rate (8.5%).⁸

In our study there were total 40 patients which were divided into two group, group A (malleus present) and group B (malleus absent). Preoperative PTA-ABG was 40.2 dB for group A and 42.4 dB for group B ($p=0.66$). 1 month postoperative PTA-ABG was 20.6 dB for group A and 22.5 dB for group B ($p=0.89$). PTA ABG in both groups between preoperative and 1 month $p<0.05$ which was found to be significant. 6 month postoperative PTA-ABG was 19.0 dB for group A and 19.3 dB for group B ($p=0.93$). It was observed that malleus is not significant for the final outcome of audiometric finding, which was favoured by study showing that malleus is not statistically significant with regard to its impact on final audiometric outcome following ossiculoplasty. There were 46 patients in the M+ group and 80 in the M- group. Preoperative PTA-ABG was 23.8 dB for M+ and 34.5 dB for M- ($p=0.00001$). Short-term postoperative PTA-ABG was 19.3 dB for M+ and 18.5 dB for M- ($p=0.727$). Long-term postoperative PTA-ABG was 18.2 dB for M+ and 19.6 dB for M- ($p=0.500$). The OOPS index was 4.11 and 6.41 for M+ and M-, respectively, ($p=0.00001$). Thirteen patients (10.3%) experienced complications. This has implications in that the use of the OOPS index as a prognostic tool and will likely lead to its revision. These data may further support the coupling theory of acoustic gain and weaken the catenary lever theory.⁹

Limitations

Patient <18 year of age with previous history of ear surgeries having atticotomical disease and cholesteatoma along with sensorineural or mixed hearing loss who require canal wall down mastoidectomy as part of their treatment.

CONCLUSION

Ossiculoplasty techniques using neo malleus struts combined with assembly prostheses, in middle ear reconstruction was studied and was non-significant.

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Conflict of interest: None declared

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

REFERENCES

1. Bahmad FMS. Histopathology of ossicular grafts and implants in chronic otitis media. *Ann Otol Rhinol Laryngol*. 2007;116(3):181-91.
2. Kartush J. Ossicular chain reconstruction: capitulum to malleus. *Otolaryngol Clin North Am*. 1994;27(4):689-715.
3. Belluci R. Selection of cases and classification of tympanoplasty. *Otolaryngol Clin North Am*. 1989;22:911-29.
4. Becvarovski Z. Smoking and tympanoplasty: implications for prognosis and the middle ear risk index (MERI). *Laryngoscope*. 2001;110(10):1806-11.
5. Black B. Neomalleus ossiculoplasty. *Otol Neurotol*. 2002;23(5):636-42.
6. Black B. Ossiculoplasty prognosis: the spite method of assessment. *Am J Otol*. 1992;13(6):544-51.
7. Bayazit YA, Ozer E, Kanlikama M, Durmaz T, Yilma M. Bone cement ossiculoplasty: incus to stapes versus malleus to stapes cement bridge. *Otol Neurotol*. May 2005;26(3):364-7.
8. Quérat C, Martin C, Prades JM, Richard C. Canal wall up tympanoplasty for cholesteatoma with intact stapes. Comparison of hearing results between cartilage and PORP on stapes and impact of malleus removal and total reinforcement of the tympanic membrane by cartilage. *Eur Ann Otorhinolaryngol Head Neck Dis*. 2014;131(4):211-6.
9. Page JC, Cox MD, King D, Allsopp T, Dornhoffer JL. Long-term Outcomes of Ossiculoplasty with and Without an Intact Malleus. *Otol Neurotol*. 2019;40(1):73-8.

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