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Original Research Article

A COMPARATIVE STUDY OF CARTILAGE OSSICULOPLASTY VERSUS PARTIAL OSSICULAR REPLACEMENT PROSTHESIS, TOTALOSSICULAR REPLACEMENT PROSTHESIS IN CHRONIC SUPPURATIVE OTITIS MEDIA AT TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Aim: To evaluate the outcome of Cartilage Ossiculoplasty and PORP, TORP Ossiculoplasty in CSOM patients.

Materials and Methods: This prospective observational study was conducted over a period of two years at Government ENT Hospital, Hyderabad, a tertiary care centre in Telangana. The study included adult patients aged 20–50 years diagnosed with safe or unsafe CSOM, with or without cholesteatoma, granulation tissue, or aural polyp, who underwent canal wall-up or canal wall-down procedures following informed consent. Patients undergoing ossicular reconstruction with cartilage, PORP, or TORP were evaluated clinically and audiologically. Preoperative and postoperative pure-tone audiometry (PTA) and air-bone gap (ABG) were compared to assess hearing outcomes. Postoperative complications, including prosthesis extrusion, were also evaluated.

Results: In Group A, the majority of patients (36.7%) were aged 30–40 years, whereas in Group B, the majority (43.3%) were aged 20–30 years. Males constituted the majority (53.3%) in Group A, while females predominated in Group B (63.3%). Large perforations were the most common type in both groups, accounting for 80% of cases in Group A and 63.3% in Group B. Medium perforations were observed in 13.3% and 13.3%, while subtotal perforations were present in 6.7% and 23.3% of Groups A and B, respectively. The right ear was more frequently affected in Group A (56.7%), whereas the left ear predominated in Group B (53.3%). Postoperative improvement in pure-tone average was statistically significant ($p=0.006$). A significant reduction in the air-bone gap was also observed following surgery ($p<0.001$). There was no statistically significant difference between the groups with regard to prosthesis extrusion. Significant postoperative hearing gain was observed in the PORP/TORP group ($p=0.002$).

Conclusion: Ossiculoplasty is an effective method for improving hearing in patients with CSOM undergoing tympanomastoid surgery. Both cartilage ossiculoplasty and prosthetic ossicular reconstruction using PORP/TORP resulted in significant postoperative improvement in hearing and reduction in the air-bone gap. The absence of a significant difference in extrusion rates suggests comparable postoperative safety among the reconstruction techniques. Selection of the ossiculoplasty technique should be individualized according to the extent of ossicular erosion, middle-ear status, presence of cholesteatoma, and availability of a suitable ossicular support.

Keywords: Ossiculoplasty, chronic suppurative otitis media, CSOM, cartilage ossiculoplasty, PORP, TORP, cholesteatoma, air-bone gap, hearing gain.

INTRODUCTION

According to the World Health Organization, 63 million people in India have significant hearing impairment. It is about 6.3% of total population in India. Reports of NSSO survey in the year 2001 suggest that there are 291 persons per one lakh population suffering from severe to profound hearing loss.[1]

With such a large number of hearing-impaired young Indians, it amounts to a severe loss of productivity, both physical and economic.[2,3]

Great progress has been achieved in the field of otolaryngology since few decades and the focus has been shifted from not only preventing from complications but to improve the overall condition of the patient including improvement in hearing. Ossiculoplasty is one of the most common oto-surgical procedures aimed at restoring hearing.

Reconstructive surgery of the conductive hearing mechanism is collectively called as tympanoplasty.[4]Ossiculoplasty may be defined as restoring the hearing mechanism between the tympanic membrane and the oval window by re-establishing a functioning ossicular chain. In that case, there is a reduction in the air-bone gap postoperatively, thus improving the hearing of the patient. Operating on an only hearing ear is an absolute contraindication for Ossiculoplasty.[5]Ossiculoplasty using a Partial Ossicular Reconstruction Prosthesis (PORP) is done when the stapes superstructure is intact. Ossiculoplasty with Total Ossicular Reconstruction Prosthesis (TORP) is required when the stapes superstructure is absent, and the footplate is mobile.5

Many types of prefabricated PORPs and TORPs are accessible on the market, and prostheses can also be sculpted from ossicles and cortical bones by a surgeon. Yet, controlled, randomized clinical trials to detect the best options are hard to perform due to a number of variables that are hard to control, such as level of experience, skills of the surgeon, individual anatomical variations, and variable healing process.[3]

Chronic suppurative otitis media (CSOM), with and without cholesteatoma, commonly results in disturbance of the ossicular chain. Chronic suppurative otitis media is a long-standing infection. Among the two types of chronic suppurativeotits media, tubotympanic and atticoantral, the former is characterized by central perforation in the pars tensa surrounded by residual tympanic membrane and the latter involves posterosuperior part of middle ear cleft.[6] Chronic otitis media is a leading cause for deafness, which is due to tympanic membrane perforation and ossicular erosion resulting from chronic inflammation of middle ear cavity.

Bone resorption from the cholesteatomas may occur due to enzyme production by the expanding epithelial lining and lead to bony erosion of the ossicles, oticcapsule and mastoid. Conductive hearing loss from ossicular chain abnormalities can result from either discontinuity or fixation of the ossicular chain.[7] In order of frequency, discontinuity most commonly occurs because of an eroded incudo-stapedial joint, an absent incus, or an absent incus and stapes superstructure. In more than 80% of patients, the cause of ossicular damage i.e., discontinuity, is chronic suppurative otitis media with or without cholesteatoma. Trauma or congenital malformations account for most of the remaining causes of ossicular damage.8

Ossicular abnormalities can result from loss of ossicular continuity due to trauma, surgical correction or middle ear pathology such as cholesteatoma or fixation of the ossicles in cases of otosclerosis and myringostapediopexy or it can be because of both.[8]

Numerous Ossiculoplasty techniques have been used to reconstruct the ossicular chain. Ossiculoplasty material should be ideally biocompatible, stable, safe, affordable and easily available.[8] In our study we used cartilage Ossiculoplasty and partial ossicular replacement prosthesis/Total ossicular replacement prosthesis for ossicular reconstruction.

The present study was done to compare the outcome of Cartilage Ossiculoplasty with partial ossicular replacement prosthesis (PORP) and total ossicular replacement prosthesis (TORP) in suitable patients presenting with chronic suppurative otitis media for middle ear reconstructive surgeries.

Aim

- To evaluate the outcome of Cartilage Ossiculoplasty and PORP, TORP Ossiculoplasty in CSOM patients.

Objectives

- To assess hearing outcome following cartilage Ossiculoplasty and PORP/TORP Ossiculoplasty in patients with chronic otitis media.
- To compare the above results and to assess hearing gain in both condition.
- To assess air bone gap reduction following cartilage and PORP/TORP Ossiculoplasty.
- To compare extrusion rate in both groups

MATERIALS AND METHODS

Study setting

The present study was carried out at Government ENT hospital, Hyderabad, a tertiary care center in Telangana.

Study design: Prospective observational

studyStudy period: 2 years from date of approval

Study population: Study population comprised of adults who attended the OPD at the tertiary care center during the study period.

Inclusion Criteria

- All patients with a diagnosis of safe and unsafe CSOM aged between 20 to 50 years of age with or without cholesteatoma, granulation tissue and

aural polyp undergoing canal wall up and canal wall down procedures, after getting an informed consent.

- All patients who have received treatment with adequate antibiotics and topical antibiotic and steroid ear drops.

Exclusion Criteria

- Those less than 20 years of age
- Those above 50years of age
- Patients with sensorineural hearing loss, meningitis, labyrinthitis, and neurological disorders.
- Those with head and neck injury.

Data collection procedure

The cases selected for the study were subjected to detailed history taking and ENT examination. Routine investigation viz., CBP, CT, BT, RBS, Blood Urea and CUE were done. All patients in active stage of the disease were treated with course of suitable antibiotics. Each patient underwent a systematic EUM and CT Temporal bone after maximum medical therapy. The patients underwent canal wall up or canal wall down procedures after obtaining written informed consent. PTA and other audiological investigations for hearing assessment.

Data Analysis

Data was entered and analyzed in M.s Excel (Office 365). Descriptive analysis was done for describing the study population and its socio-demographic characteristics.

Mean and Standard deviations were used wherever necessary. Chi-Square test was used to test the significance for associations between dependent and independent variables. Independent t-test was used to test the significance of difference between means, wherever necessary. p-value<0.05 was considered to be significant in this study.

Oprerative Procedure

An informed consent was obtained from all patients following which all our patients were operated under general anesthesia.

Mastoidectomy

- A William Wilde post aural incision was made and extended up and temporalis fascia graft was harvested.
- The incision was deepened and then a T shaped incision was made and periosteum was elevated. Spine of Henle was identified.
- A meatotomywas done and pinna retracted forwards.
- Tympan meatal flap was elevated.
- Bone work was started in the MacEwan's triangle and the mastoid antrum reached which was usually located at a distance of 1-1.5cm from the mastoid cortex.

The following were analyzed:

- Extent of the disease determining whether to do an intact canal wall or canal wall down procedure.
  - The ossicular status according to Austin's classification.
- In an intact canal wall procedure, the canal wall was preserved.
- In canal wall down procedures, the bridge was removed and the ridge was reduced while reducing the anterior and posterior buttresses, thereby making the mastoid and middle ear into a single cavity.
- After disease clearance, an ossiculoplastywas done using TORP or PORP depending on the ossicular status.
- If the incus alone was eroded, PORP was used. If incus and superstructure was eroded, a TORP was used.

The TORP and PORP were altered for length before being used. A cartilage cap was then In kept canal between wall the prosthesis and tympanic membrane. downmastoidectomy, concha cartilage was used and in intact canal wall mastoidectomy, tragal cartilage was harvested.

Porp Ossiculoplasty

Partial ossicular replacement prosthesis done for the other half of patients.

- The prosthesis used for Ossiculoplasty was from Decibel's Partial Ossicular Replacement Prosthesis made of Teflon and of size 3mm. Partial ossicular replacement prosthesis Ossiculoplasty done for the other half of cases. The prosthesis was measured for distance between tympanic membrane and suprastructure of stapes and fitted on the head of stapes.
- The Ossiculoplastywas completed with a cartilage cap over the prosthesis as interface between prosthesis and tympanic membrane.
- The harvested temporalis fascia graft shaped to the size appropriate for the perforation and placed medial to elevated drum remnant and to malleus handle over gel foam bed. Tympan meatal flap repositioned; ear wick placed in the external auditory canal. After achieving complete hemostasis, post auricular wound closure done in layers and mastoid dressing applied. Patient weaned from anesthesia.

TORP OSSICULOPLASTY

The TORP prosthesis is placed on footplate of stapes and temporalis graft is placed over it. This is done when malleus, incus and stapes superstructure are eroded due to disease process.

POST OPERATIVE FOLLOW UP

All the patients were started on Intravenous broad-spectrum antibiotics in the immediate postoperative period for 1 week. The patients were discharged on Postoperative day 7 after suture removal. Medicated wick from the external auditory canal was removed at review on Postoperative day 14.

Patients were advised to avoid sneezing, and to keep a dry ear. Patients were followed up with otoscopic examination weekly for the first one week followed by monthly interval for the subsequent 2 months. Patients were asked about the improvement in hearing, upper respiratory tract infection, ear discharge at follow up.

A thorough examination of ear, nose and throat was performed to look for any ear discharge, residual perforation and infection of throat or nose. A pure tone audiometry was done postoperatively at 3 months.

Observation

Among the 60 patients that underwent Ossiculoplasty, the following observations were made:

UnderwentcartilageOssiculoplastyunderwentPORT/ TORPOculoplasty.

The Teflon prosthesis which was used in all the cases had to be altered in length and cartilage was harvested separately, if not during meatoplasty and took considerable time.

Ethical clearance

Ethical clearance was obtained on 8th may 2019 from the Institutional Ethics Committee.

Funding: As it a government institution, no funding was done.

Citing of References: Vancouver's style was used for listing and citing of references.

RESULTS

Table 1: Distribution of study population according to Age

AGE (in years)	CARTILAGE OSSICULOPLASTY	PORP /TORP OSSICULOPLASTY
20-30	12(40%)	13(43.3%)
31-40	11(36.7%)	9(30%)
41-50	7(23.3%)	8(26.7%)
Total	30(100%)	30(100%)

The above table shows the age distribution of the study population.

Table 2: Distribution of study population according to Sex

SEX	**CARTILAGE OSSICULOPLASTY N (%)**	**PORP/TORP N (%)**
Male	16(53.3%)	11(36.7%)
Female	14(46.7%)	19(63.3%)
Total	30(100%)	30(100%)

The above table illustrates the sex distribution of the study population.

Table 3: Distribution of study population according to type of perforation

TYPE	**CARTILAGE OSSICULOPLASTY N (%)**	**PORP/TORP N (%)**
Large	24(80%)	19(63.33%)
Medium	4(13.3%)	4(13.33%)
Sub-total	2(6.7%)	7(23.33)
Total	**30(100%)**	**30(100%)**

The above table shows the distribution of study population according to type of perforation.

Table 4: Distribution of study population based on the side of the disease

SIDE	**CARTILAGE OSSICULOPLASTY N (%)**	**PORP/TORP N (%)**
Left	13(43.3%)	16(53.3%)
Right	17(56.7%)	14(46.7%)
Total	30(100%)	30(100%)

The above table shows the side of the effected ear.

Distribution of study population according to type of CSOM

TYPE	**N (%)**
Squamosal	38(66.3%)
Mucosal	22(33.7%)
Total	**60(100%)**

Table 5: Pre-Operative Pure Tone Audiometry

Pre-Op PTA	**CARTILAGE OSSICULOPLASTY N (%)**	**PORP/TORP N (%)**
<25	2(6.7%)	1(3.3%)
26-40	9(30%)	8(26.7%)
41-55	11(36.7%)	13(43.3%)
56-70	6(20%)	3(10%)
71-90	2(6.7%)	5(16.7%)

>91	0(0%)	0(0%)
Total	30(100%)	30(100%)

The above table compares the Pre-Operative Pure Tone Audiometry

Table 6: Mean and SD of Pre-Operative Pure Tone Audiometry

	CARTILAGE OSSICULOPLASTY	PORP/TORP
PRE-OP PTA	MEAN ± SD	MEAN ± SD
	41.8± 10.35	43.81±6.25

The above table illustrates the Mean and SD of Pre-Operative Pure Tone Audiometry.

Table 7: Post-Operative Pure Tone Audiometry

POST-OP PTA	CARTILAGE OSSICULOPLASTY N (%)	PORP/TORP N (%)
<25	0(0%)	2(6.7%)
26-40	8(26.7%)	10(33.3%)
41-55	15(50%)	8(26.7%)
56-70	4(13.3%)	1(3.3%)
71-90	1(3.3%)	6(20%)
>91	2(6.7%)	3(10%)
Total	**30(100%)**	**30(100%)**

The above table compares the Post-Operative Pure Tone Audiometry

Table 8: Mean and SD of Post-Operative Pure Tone Audiometry

POST-OP PTA	CARTILAGE OSSICULOPLASTY	PORP/TORP
	MEAN ± SD	MEAN ± SD
	38±6.6	37.16±5.51

The above table compares the Mean and SD of Post-Operative Pure Tone Audiometry.

Table 9: Improvement in Pure Tone Audiometry

IMPROVEMENT IN PTA	CARTILAGE OSSICULOPLASTY	PORP/TORP	p-value
	MEAN ± SD	MEAN ± SD	0.006
	3.8±3.75	6.65±0.74	

The above table compares the improvement in PTA in post-operative period among the two groups.

Table 10: Preoperative - Air Bone Gap

PREOPERATIVE - AIR BONE GAP	CARTILAGE OSSICULOPLASTY N (%)	PORP/TORP N (%)
0-10	4(13.3%)	2(6.7%)
11-20	8(26.7%)	11(36.7%)
21-30	15(50%)	13(43.3%)
>30	3(10%)	4(13.3%)
Total	30(100%)	30(100%)

The above table compares the Preoperative - Air Bone Gap

Table 11: Mean and SD of Preoperative - Air Bone Gap

	CARTILAGE OSSICULOPLASTY	PORP/TORP
PRE-OPERATIVE - AIR BONE GAP	MEAN ± SD	MEAN ± SD
	24.57±8.23	22.5+5.5

The above table compares the Mean and SD of the Preoperative - Air Bone Gap.

Table 12: Post-operative - Air Bone Gap

POST-OPERATIVE AIR BONE GAP	CARTILAGE OSSICULOPLASTY N (%)	PORP/TORP N (%)
0-10	3(10%)	1(3.3%)
11-20	13(43.3%)	17(56.7%)
21-30	11(36.7%)	9(30%)
>30	3(10%)	3(10%)
Total	30(100%)	30(100%)

The above table compares the Post-operative - Air Bone Gap between the two groups.

Table 13: Mean and SD of Post-operative - Air Bone Gap

POST-OPERATIVE AIR BONE GAP	CARTILAGE OSSICULOPLASTY	PORP/TORP	p-value
	MEAN ± SD	MEAN ± SD	0.03
	21.33±6.45	18.23±4.3	

The above table compares the Mean and SD of Post-operative - Air Bone Gap between the two groups.

Table 14: Comparison of ABG reduction

ABG Reduction	CARTILAGE OSSICULOPLASTY	PORP/TORP	p-value
	MEAN ± SD	MEAN ± SD	<0.001
	3.24±1.78	5.27±0.9	

The above table shows the Comparison of ABG reduction among the two groups.

Table 15: Comparison of Extrusion

Extrusion	CARTILAGE OSSICULOPLASTY	PORP/TORP	p-value
	MEAN ± SD	MEAN ± SD	0.26
	1.95 ±0.224	2 ±0.1	

The above table shows the mean extrusion of the comparison groups

Table 16: Comparison of hearing gain

Hearing gain	CARTILAGE OSSICULOPLASTY	PORP/TORP	p-value
	MEAN ± SD	MEAN ± SD	0.002
	6.5 ±4.6	9.6 ±2.8	

The above table shows hearing gain among the two groups

DISCUSSION

Over the years, number of surgical modifications and refinements had been developed in the techniques of Ossiculoplasty, which have been suggested by specialists from time to time with a view to further enhance its results.

This study was an attempt at evaluating the hearing improvement following ossicular reconstruction with cartilage Ossiculoplasty and PORP/TORP.

n our study, patients with similar clinical presentations and diagnosed with chronic suppurative otitis media were randomly designated into two groups.

Group A: CARTILAGE OSSICULOPLASTY

Group B: PORP/TORP OSSICULOPLASTY

In the present study, majority (36.7%) of the Group A belong to 30-40 years age group, while that of group B, majority (43.3%) belong to 20-30years age group. In a study done by Morris et.al,[9] mean age was 32 years (range from 15-61 years). 81 This was similar with that of the other studies done by McGrew et.al,[10]Murbe D et al,[10] and Jha et al,[11] with age ranging mostly from 20-35 years.82,83,84. In the present study, in group A majority were males (53.3%) and females were 46.7%. In group b, Majority were females (63.3%) and males were 36.7%). In a study by Vassbotn FS et.al.[12] This patient cohort group consisted of 9 male and 7 female patients (age range = 18–52 years; average = 29.88 ± 11.9).8557% were female patients and 43% were male patients81. In the studies by Hales NW al,[13]of the 150 patients,64% were males and 36% were females.86 In Prasad et al. study , out of 86 patients, 52% males and 48% were females. In Corso et al. study of 142 patients male preponderance of 56% was observed and 44% were females.87

In the present study. Type of perforation was divided into large, medium and small. In group A, 80% had large,13.3% had medium and 6.7% had sub-total perforation. While in group B they were 63.33%,13.33% and 23.33% in each type respectively. In a study by Jackson CGet al,[14] subjects with small, medium, large and sub-total perforations were 2,7,15 and 5 respectively. Small and medium size perforations had 100% graft uptake; whereas large and subtotal perforations had 75% and 71.43% respectively.88

In the present study, in group A right ear was affected in majority (56.7%) of the subjects. In group B, left ear was affected in most of them (53.3%). In another study, Ossiculoplastywas performed in the right ear side in 50 patients (48%) and in the left ear side in 55 (52%).81

In the present study, in group A, Pre-operative PTA was 41-55 in majority (36.7%) and none had >91. In group B, majority had 41-55 and none had >91.In group A Pre operative Mean and SD was 41.8± 10.35, while in group B it was 43.81±6.25. In the present study, in group A, Post-operative PTA was 41-55 in majority (50%) and none had PTA was 56-70.

In Begall K et.al,[15] study, almost half of the patients appreciated a 20 dB or greater PTA improvement in their hearing. There was no significant difference between primary and revision surgery outcomes.89 In the present study, in group A Post-operative Mean and SD was 38±6.6, while in

group B it was 37.16±5.51. Improvement in PTA was significant in this study(p=0.006).

In the present study, in group A Preoperative - Air Bone Gap was 21-30 in majority (50%) and 10% had >30. In group B, 43.3% had 21-30 and 6.7% belong to 0-10 category. Mean and SD of Pre-operative - Air Bone Gap was 24.57±8.23 in group A and 22.5+5.5 in group B. In group A Post-operative - Air Bone Gap was 11-20 in majority (43.3%) and 3.3%% belong to 0-10 category. In group B, 43.3% had 21-30 and 6.7% belong to 0-10 category. Mean and SD of Post-operative - Air Bone Gap was 21.33±6.45 in group A and 18.23±4.3 in group B.

In a study by Krueger WW et.al,[16] Pre-operative mean ABG was 39.3 dB whereas 6 months post-operative mean ABG was 31.6 dB with mean ABG improvement of 7.7 dB which was statistically significant.

In the present study, ABG reduction was significant (p<0.001) with Mean and SD of 3.24 ± 1.78 in group A and 5.27 ± 0.9 in group B.

In the present study, extrusion rate (Mean± SD) was 1.95 ±0.224 in group A and 2 ±0.1 in group B. The difference was not significant(p=0.26) between the two groups.

In Stupp CH et.al,[17]study, Average postoperative air-bone gap (ABG) was 19.2 dB with closure of the ABG to within 20 dB in 62.9% of the subjects. Extrusion was known to occur in 4%.74 In subjects with sclerotic mastoid, graft rejection was 36%. But there was only 15% rejection in cellular mastoids. Mishiro Y et.al,[18] study showed, improvement in graft uptake proportionate to the size of the mastoid.

In the present study, hearing gain was compared between the two groups. It was found to be significant after operation in PORP/TORP group (p=0.002) with (Mean± SD) of 6.5 ±4.6 in group A and 9.6 ±2.8 in group B. In a study done by Timothy et.al, there was no significant postoperative hearing loss compared with preoperative hearing. More than 70% hearing improvement of 0-40 dB (0-10 dB in 19% of ears, 11-20 dB in 44%, 21-30 dB in 7%, and 31-40 dB in 4%) even without Ossiculoplasty.

CONCLUSION

Ossiculoplasty is an effective method for improving hearing in patients with CSOM undergoing tympanomastoid surgery. Both cartilage ossiculoplasty and prosthetic ossicular reconstruction using PORP/TORP resulted in significant postoperative improvement in hearing and reduction in the air-bone gap. The absence of a significant difference in extrusion rates suggests comparable postoperative safety among the reconstruction techniques. Selection of the ossiculoplasty technique should be individualized according to the extent of ossicular erosion, middle-ear status, presence of cholesteatoma, and availability of a suitable ossicular support.

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