Prospective Study of Audiological Analysis of Ossiculoplasty in Cases of Chronic Suppurative Otitis Media

Rushika Patel¹, Sumeet Kaur Ghai^{2*}, Shreeya V. Kulkarni³, Chaitanya Bharadwaj¹, Vandana Sancheti⁴ and K. S. Burse⁵

¹Assistant Professor, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; rushikap@gmail.com, drchaitanyab@gmail.com
²PG Resident, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; sumi.pisces@gmail.com
³Professor, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; kshreeya@hotmail.com
⁴Senior Resident, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; kshreeya@hotmail.com
⁵Professor and Head, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; pksancheti@rediffmail.com
⁵Professor and Head, Department of ENT, Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik - 422003, Maharashtra, India; drksburse@gmail.com

Abstract

Background: Ossiculoplasty is defined as reconstruction of the ossicular chain using various graft materials and techniques. **Aim:** Audiological analysis with Pure Tone Audiometry (PTA) of results of ossiculoplasty in cases of safe and unsafe csom and its correlation with preoperative middle ear status using Kartush's Middle Ear Risk Index (MERI). **Methodology:** Non randomized prospective study conducted over 2 years in 34 patients with CHL; ossiculoplasty conducted with cartilage, remodeled autologous incus or malleus, malleostapediopexy and PORP; preoperative and 3 months postoperative PTA done. Kartush's MERI to correlate preoperative middle ear status with postoperative hearing results done. Out of 34 patients operated: 10-cartilage ossiculoplasty, 6-autologous incus, 2-autologous malleus, 4-PORP and 12-malleostapediopexy. **Results and Conclusion:** Hearing improvement was seen in all types of ossiculoplasties using various materials and techniques. However, there was no significant statistical difference between the various types in relation to the postoperative hearing improvement. Kartush's MERI was found to be an indicator of postoperative hearing improvement. It was found that as the value of the index increases, the postoperative hearing improvement decreases.

Keywords: Chronic Suppurative Otitis Media (CSOM), Middle Ear Risk Index (MERI), Ossiculoplasty, Pure Tone Audiometry

1. Introduction

In India, chronic ear disease commonly causes damage to both tympanic membrane and the ossicles. The term ossiculoplasty refers to reconstruction of the ossicular chain. Historically, the primary concern of the surgeon was creation of a "safe" ear. Hence, restoration of sound conduction had largely been ignored. However, when in 1957 Hall and Rytzner introduced the technique of sculpted autograft incus interposition, the goals of chronic ear surgery expanded to both disease removal and hearing restoration¹. Even before this in 1901, Matte's performed his first myring ostapediopexy in the case of the missing ossicle, which was the earliest recorded attempt to re-establish a connection between the tympanic membrane and the oval window^{2.3}. The middle ear environment in chronic

*Author for correspondence

ear disease is a major factor in determining treatment success, so from the past few decades there has been a search for middle ear implants. Also, various attempts have been made since then to re-create the middle ear sound-conducting mechanism using numerous materials. Both biologic and alloplastic materials have been used for ossicular substitution or reconstruction with the biologic materials including autograft or homograft ossicles, cortical bone, teeth, and cartilage. Incus body has been the most commonly used autograft material, which is often reshaped to fit between the manubrium of the malleus and the stapes capitulum. However, autograft materials may not always be available or may have microscopic squamous epithelium infiltration in patients with cholesteatoma that precludes their use. The most commonly used materials for ossicular reconstruction today are the Alloplastic variety, which can be classified as biocompatible, bioinert, or bioactive. Over the past years many materials have been discovered and it has been found that each of the have their own specific advantages and disadvantages. When the surgeon chooses a particular prosthesis, selection must be based on several factors, including experience of the surgeon, compatibility, ease of configuring the prosthesis during surgery and the environment in which the prosthesis is going to be placed.

2. Aims and Objectives

- 1. Audiological analysis with pure tone audiometry of results of ossiculoplasty in cases of safe and unsafe chronic suppurative otitis media using cartilage/remodeled autologous incus/malleus/malleostapediopexy/Partial Ossicular Replacement Prosthesis (PORP).
- 2. To correlate the preoperative middle ear status with postoperative hearing results in cases of safe and unsafe Chronic Suppurative Otitis Media (CSOM) after ossiculoplasty using Kartush's Middle Ear Risk Index (MERI)⁴⁵.

3. Materials and Methods

Type of study: Non-Randomized Prospective Study

Study settings: Department of Ear Nose Throat of a Medical College and Tertiary Health care centre.

Study duration: 2 Years. From July 2015 to December 2017.

Study population: Cases of safe and unsafe CSOM coming to the ENT OPD of Vasantrao Pawar Medical College.

Sample Size: 34

3.1 Eligibility Criteria

Patients of all age groups and sex with safe and unsafe chronic suppurative otitis media.

a) Inclusion criteria:

Patients of chronic suppurative otitis media with conductive hearing loss.

b) Exclusion criteria:

1. Patients with

a) Sensorineural hearing loss and mixed hearing loss affecting diseased ear.

b) Any intracranial complications of ear disease like meningitis, subdural abscess, lateral sinus thrombophlebitis and ottic hydrocephalus.

- c) Malignant neoplasm of external or middle ear.
- d) Fixed stapes footplate.
- e) Normal tympanic membrane.
- f) Revision surgery.
- g) Failure of surgery.
- h) Unsatisfactory follow up (< 3 months).
- 2. Patients not willing to give informed consent.

Written informed consent was obtained from all the study participants and detailed history along with findings of general and ear, nose, throat examination was noted.

All patients were then subjected to pure tone audiometry both pre-operatively and 3 months postoperatively. The air conduction and bone conduction thresholds were measured at frequencies 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz and their mean values were calculated. The mean air-bone gap was calculated both preoperatively and postoperatively.

The patients were then counseled and explained the surgical procedure and after taking consent for the surgery were posted for appropriate surgery.

Management options included tympanoplasty or mastoidectomy with ossiculoplasty using:

- Cartilage- Tragal and Conchal.
- Remodeled Autologous Incus or Malleus.
- Grafts- Alloplasts- PORP.

Each patient in this study was scored using Kartush's MERI to correlate the preoperative middle ear status with the postoperative hearing results.

The data obtained was subjected to statistical analysis, which was done using Statistical Package of Social Science ((SPSS) Version 20; Chicago Inc., USA) with the consult of a statistician.

4. Observation and Results

4.1 Distribution of Study Subjects According to Type of Ossiculoplasty Methods

Table 1 and Figure 1 reveal distribution of study subject according to the type of ossiculoplasty method. Total 34

Type of Ossiculoplasty	Number	Percentage
1. Cartilage	10	29.41%
2. Autologous Incus	6	17.64%
3. Autologous Malleus	2	5.88%
4. PORP	4	11.76%
5. Malleostapediopexy	12	35.29%
Total	34	100%

Table 1. Distribution of study subject according to type of Ossiculoplasty

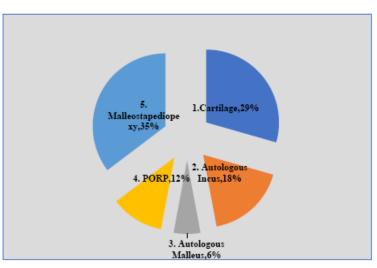


Figure 1. Distribution of study subject according to type of Ossiculoplasty methods.

Table 2. Comparison of p	preoperative and	l postoperative r	nean air con	duction am	ong different
Ossiculoplasty methods					
			1		1

Groups	Pre operative	Post operative	Mean Diff. ⁴ Test		ʻp' Value
	Mean ±SD	Mean ±SD		Value	
1. Cartilage	51.50±21.39	46.75±21.10	4.75±6.55	2.291	0.048(S)
2. Autologous incus	46.66±11.03	39.37±8.54	7.29±4.70	3.796	0.013(S)
3. Autologous Malleus	65.62±2.65	55.00±8.88	10.62±6.18	2.429	0.249(NS)
4. PORP	43.12±12.43	30.31±8.91	12.81±3.86	6.622	0.007(S)
5. Malleostapediopexy	43.64±8.36	38.22±6.68	5.83±5.17	3.322	0.007(S)
Total	47.72±14.60	40.99±14.00	6.87±5.78		

cases of CSOM were selected for the study that underwent treatment by five methods of Ossiculoplasty. Out of the 34 cases, 12(35.29%) underwent Malleostapediopexy, 10(29.41%) underwent cartilage ossiculoplasty, 6(17.6%) underwent ossiculoplasty by Autologous Incus technique, in 4(11.76%) patients PORP was inserted and only 2(5.88%) underwent Ossiculoplasty by Autologous Malleus technique.

4.2 Comparison of Preoperative and Post-Operative Mean Air Conduction among Different Ossiculoplasty Methods

Table 2 and Figure 2 reveal comparison of preoperative and postoperative mean air conduction among different Ossiculoplasty methods. In all methods of ossiculoplasty, mean air conduction was reduced post operatively which showed success of the surgery. Maximum reduction or success was seen among PORP (12.81 ± 3.86) and Autologous Malleus methods (10.62 ± 6.18) and it was least in the cartilage group (4.75 ± 6.55). Mean air conduction was reduced from 47.72 ± 14.60 to 40.99 ± 14.00 . Total Mean reduction (Success) in air conduction was 6.87 ± 5.78 dB. There was statistically significant reduction (p<0.05) in mean air conduction post operatively in each group when comparision of air conduction pre and post-operatively was done in each group. However, the mean difference between the post and pre-operative air conduction in the autologous malleus group was not statistically significant. (p>0.05)

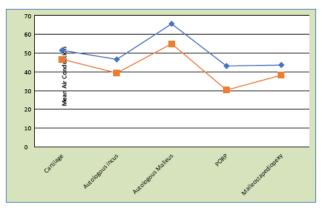


Figure 2. Comparison of preoperative & post-operative mean air conduction among different Ossiculoplasty methods.

4.3 Comparison of Preoperative and Postoperative Mean Air Bone Gap among Different Ossiculoplasty Methods

Table 3 and Figure 3 reveal comparison of preoperative and postoperative mean air bone gap among different Ossiculoplasty methods. In all groups the mean air bone gap was reduced post operatively which showed success of treatment. Maximum reduction was seen among PORP

	Air Bone Gap	D: 14			
Groups	Pre operative	Post operative	Mean Diff.	Paired 't' Test Value	ʻp' Value
	Mean ±SD	Mean ±SD	Mean Dill.		
1. Cartilage	28.50±15.84	24.12±15.73	4.37±5.44	2.543	0.032(S)
2. Autologous incus	26.25±7.78	20.00±5.59	6.25±4.60	3.321	0.021(S)
3. Autologous Malleus	41.87±7.95	31.25±14.14	10.62±6.18	2.429	0.249(NS)
4. PORP	25.00±8.83	11.56±5.24	13.43±4.71	5.695	0.011(S)
5. Malleostapediopexy	23.85±6.06	17.81±5.41	6.04±4.48	4.666	0.001(HS)
Total	26.83±10.82	20.11±10.66	6.72±5.42		

Table 3. Comparison of preoperative and postoperative mean air bone gap among differentOssiculoplasty methods

Table 4. Kartush MERI among study subject

MERI	Severity of	f MERI Index				
Index	Disease	Number	Mean	SD	Median	Range
1-3	Mild	6	2.83	0.408	3.00	2-3
4-6	Moderate	22	4.86	0.834	5.00	4-6
7-12	Severe	6	7.50	0.548	7.50	7-8
Total		34	4.97	1.586	5.00	2-8

 (13.43 ± 4.71) and Autologous Malleus groups (10.62 ± 6.18) and it was least for the cartilage group (4.37 ± 5.44) . Mean air bone gap of all the patients was reduced from 26.83 ± 10.82 to 20.11 ± 10.66 giving a total Mean reduction by 6.72 ± 5.42 . There was statistically significant reduction (p<0.05) in mean air bone gap postoperatively in each group when comparison of air bone gap pre and postoperatively was done in each group. However, the mean difference between the post and pre-operative air bone gap in the autologous malleus group was not statistically significant (p>0.05).

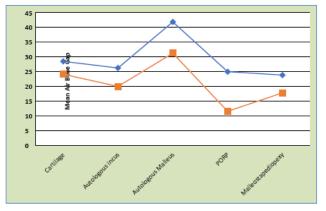


Figure 3. Comparison of preoperative & post-operative mean Air Bone Gap among different Ossiculoplasty methods.

4.4 Kartush MERI Among Study Subjects

Table 4 and Figure 4 reveal Kartush MERI among study subjects. Based on the score of the MERI Index, study subjects were divided into three groups, Mild (1-3), Moderate (4-6) and severe (7-12) disease. Out of the 34 study subjects, 22 had moderate disease and 6 each had mild and severe disease.

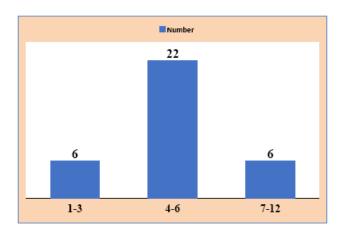


Figure 4. Kartush Middle Ear Risk Index (MERI) among study subjects.

4.5 Comparison of Preoperative and Postoperative (Success) Mean Air Conduction According to MERI Index.

Table 5 and Figure 5 reveal comparison of preoperative and postoperative (Success) mean air conduction according to MERI Index. It shows that as MERI Index/ Severity of disease increases; mean air conduction also increases both pre and post operatively. Maximum hearing improvement (reduction in the mean air conduction threshold postoperatively) was seen in 4-6 MERI index score group (7.61±5.78) and least was seen in 7-12 MERI Index score group (4.16±6.05). However, the hearing improvement was statistically significant in 1st and 2nd group (p<0.05) and the 3rd group did not show statistically significant difference (p = 0.153) when the pre and postoperative values were compared.

Groups	Mea	Mean Air Conduction			
Severity of Disease/MERI	Pre operative	Post operative	Mean Diff.	Paired 't' Test Value	ʻp' Value
Index	Mean ±SD	Mean ±SD			
Mild (1-3)	43.75±6.37	36.87±8.54	6.87±5.68	2.961	0.031(S)
Moderate (4-6)	48.12±15.34	40.73±14.16	7.61±5.78	5.693	0.001(HS)
Severe (7-12)	50.20±18.76	46.04±18.08	4.16±6.05	1.685	0.153(NS)
Total	47.72±14.60	40.99±14.00	6.87±5.78	6.583	0.001(HS)

 Table 5. Comparison of preoperative and postoperative (Success) mean air conduction

 according to MERI index

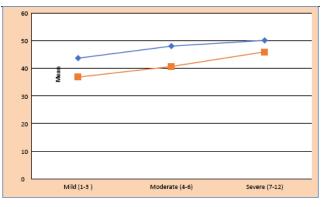


Figure 5. Comparison of preoperative & post-operative (Success) mean air conduction according to MERI Index.

4.6 Comparison of Preoperative and Post Operative Mean Air Bone Gap according to MERI Index

Table 6 and Figure 6 reveal comparison of preoperative and postoperative (Success) mean Air Bone Gap with MERI Index. It shows that as MERI Index/Severity of disease increases; mean Air Bone Gap was also increases both pre & post operatively. Maximum reduction in air bone gap between postoperative and preoperative values (postoperative hearing improvement) was seen in 4-6 MERI index score group (7.27±5.12) and least reduction was seen in 7-12 MERI Index score group (4.58±7.05). However, the hearing improvement was statistically significant in only 1st and 2nd group (p<0.05) and the 3rd group did not show statistically significant difference (p = 0.172) when the pre and postoperative values were compared.

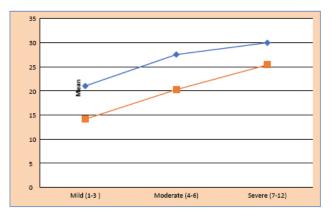


Figure 6. Comparison of preoperative & post-operative mean Air Bone Gap according to MERI Index.

5. Discussion

In the 34 cases of CSOM which were selected for the study, 12 were operated by Malleostapediopexy, 10 by cartilage ossiculoplasty, 6 by Autologous Incus technique, 4 PORP insertion and 2 by Autologous Malleus technique.

Out of 34 patients included in the study between the ages of 8 to 62 years of age the mean age of study subjects was 26 years. Similar demography was also found in a study conducted to evaluate and compare the result of ossiculoplasty using different types of graft materials and prosthesis in cases of ossicular discontinuity in chronic suppurative otitis media cases⁶ where they found the mean age of presentation of patients to be around 31.8 years. 19 of the total patients were female and 15 were male.

Out of 34 cases of CSOM, 29(85.3%) were Atticoantral and 5(14.7%) were tubotympanic. Amongst the tubotympanic type, 2 of the cases belonged to Austin's type B group of ossicular chain defects and were operated by autologous incus technique of ossiculoplasty. One of the cases which were operated by malleostapediopexy belonged to Austin's group A. In a patient with Austin's group C defect, PORP prosthesis was inserted and group D defect was operated by cartilage ossiculoplasty placing the cartilage from the graft to the stapes footplate.

In this study, comparison of mean air conduction among different Ossiculoplasty methods preoperatively and post operatively revealed that the mean air conduction threshold was reduced from 47.72 ± 14.60 to 40.99 ± 14.00 indicating improvement in hearing by 6.87 ± 5.78 dB. This data was similar to that obtained by a study² where the mean AC thresholds improved from 50.7 ± 17.2 to 39.8 ± 19.1 dB.

In the Autologous incus group, the mean air conduction values changed from 46.66 ± 11.0 to 39.37 ± 8.54 giving a statistically significant hearing improvement of 7.29 ± 4.70 dB. These results were similar to the results obtained for the same group in a study⁶ changing from 41.60 ± 8.86 to 33.82 ± 8 giving a hearing improvement of 7.78 dB.

In the PORP group, the mean air conduction values changed from 43.12 ± 12.43 to 30.31 ± 8.91 giving a hearing improvement of 12.81 ± 3.86 dB. These results were similar to those obtained in a study⁶ changing from 42.8 ± 9.19 to 32.97 ± 9.02 giving a hearing improvement of 9.83 dB.

In our study, comparison of preoperative and postoperative mean air bone gap among different Ossiculoplasty methods revealed that the mean air bone gap decreased

Groups	Air Bone Gap			D: 14)	
Severity of Disease/	Pre operative	Post operative	Maar Diff	Paired 't' Test Value	ʻp' Value
MERI Index	Mean ±SD	Mean ±SD	Mean Diff.		
Mild (1-3)	21.04±2.89	14.16±5.34	6.87±5.22	3.220	0.023(S)
Moderate (4-6)	27.55±10.88	20.28±10.28	7.27±5.12	6.654	0.001(HS)
Severe (7-12)	30.00±14.59	25.41±14.20	4.58±7.05	1.591	0.172(NS)
Total	26.83±10.82	20.11±10.66	6.72±5.42	7.229	0.001(HS)

 Table 6. Comparison of preoperative and postoperative (Success) mean air bone gap with MERI index

from 26.83 ± 10.82 to 20.11 ± 10.66 giving an air bone gap closure of 6.72 ± 5.42 which showed success of treatment.

In the autologous incus group of 6 patients, it was found that the air bone gap changed from 26.25 ± 7.78 to 20.00 ± 5.59 giving an air bone gap closure of 6.25 ± 4.60 dB. Similar results were obtained in a study⁶, where the air bone gap closure achieved was 8.47 dB; and by O'Reilly *et al.*,⁸ who obtained a gain of 8.2 dB.

In the PORP Ossiculoplasty group of patients, the mean preoperative ABG changed from 25.00 ± 8.83 dB to 11.56 ± 5.24 dB giving an air bone gap closure of 13.43 ± 4.71 dB, which was similar to the data⁶ with air bone gap closure being 10.48 ± 4.87 dB and to a study², where it was 15.22 dB.

In the 2 patients undergoing Ossiculoplasty using autologous malleus, the mean preoperative ABG was 41.87 ± 7.95 dB and the postoperative ABG was 31.25 ± 14.14 giving a hearing gain of 10.62 ± 6.18 dB which was similar to the 11 dB gain obtained by a study¹⁰.

In the cartilage Ossiculoplasty group of patients, the air bone gap closure was found to be 4.37 ± 5.44 dB in our study similar to a study¹¹ being 7.6 dB.

According to the AAO-HNS guidelines, success of Ossiculoplasty is defined as a closure of postoperative air bone gap to less than 20 dB^{12} .

In our study in the cartilage Ossiculoplasty group success was seen in 50% patients which was similar to several studies $70\%^{13}$, $50\%^{14}$, $60\%^{3}$, and $67.6\%^{11}$.

In the autologous incus group, success was seen in 50% patients, which was similar to 66.7% obtained in a study¹. If in the same group we calculated the percentage of patients with ABG less than 25 dB, it was found to be 83.3% in our study similar to the 88% obtained in a study⁵.

In the malleostapediopexy group of patients, 75% had successful hearing outcomes following surgery in our study similar to the 86% success rate demonstrated¹⁵.

In the autologous malleus group, we obtained a success rate of 100% in our study which was probably due to only 2 patients being operated in this group. In a study¹⁰ the success rate in the same group was found to be 65%.

In the PORP group of 4 patients, 100% success rate was seen in our study. Each patient was inserted with a cartilage interface between the graft and PORP. In a study³, the success rate was found to be 56.25% with an extrusion rate of 25% and in a study¹¹ it was found to be 70.4%.

On comparison of preoperative and postoperative (Success) mean air conduction and mean air bone gap according to MERI Index we found that as MERI Index/ Severity of disease increases; mean air conduction and air bone gap also increases both pre- and post-operatively. Maximum hearing improvement (reduction in the mean air conduction threshold and air bone gap post-operatively) was seen in 4-6 MERI index score group and least was seen in 7-12 MERI Index score group. However, the hearing improvement was statistically significant in 1st and 2nd group and the 3rd group did not show statistically significant difference when the pre and postoperative values of air conduction and air bone gap were compared.

These findings were similar with the study¹⁶ stating that the the preoperative middle ear status is an indicator of the degree of hearing improvement postoperatively.

6. Summary and Conclusion

Amongst all methods of ossiculoplasty, values of mean air conduction and mean air bone gap were reduced post operatively in each individual group of Ossiculoplasty which showed success of the procedure. However, there was no statistical difference in the improvement amongst the groups showing that no technique is better off than the other.

According to the AAO-HNS guidelines, our study concluded that success was seen in 60% patients in

Cartilage Ossiculoplasty group, in 50% patients in the Autologous Incus group, in 75% patients in the malleostapediopexy group and 100% in the autologous malleus and PORP group.

On correlating the Kartush MERI with mean difference in the air conduction and Air bone gap pre and post operatively, it was observed that as the MERI index increases, the hearing improvement and improvement in air conduction thresholds postoperatively decreases.

Hearing improvement and improvement of air conduction thresholds was seen to be least among patients with 7-12 MERI Index value and highest in patients with 4-6 MERI Index value.

MERI index is a good indicator of the post operative hearing improvement.

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