

Original Research Article

Tympanoplasty with and without cortical mastoidectomy in treatment of inactive mucosal chronic otitis media

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ABSTRACT

Background: Tympano-mastoidectomy has been found to be an effective method of treatment of chronic ear infection, but the effect of mastoidectomy on patients without evidence of active infectious disease in mastoid remains highly debated and unproven. Analyse the surgical outcomes of repair of uncomplicated tympanic membrane perforations with tympanoplasty alone and tympanoplasty combined with mastoidectomy.

Methods: The present study was a prospective, comparative, randomized controlled trial in which 60 patients 30 in each groups via simple random sampling technique underwent tympanoplasty with cortical mastoidectomy. Temporalis fascia was used as graft in all the cases. All the surgeries were done by post aural route and underlay technique was used in all cases.

Results: The overall graft uptake rate in our study was 88.33%. The graft uptake rate in tympanoplasty group was 87% and 90% in the tympanoplasty with cortical mastoidectomy group. There was no significant difference in the graft uptake rates of the two groups. There was no statistical significance between the two groups as $p > 0.05$, suggesting that mastoidectomy when combined with tympanoplasty offers no benefit over tympanoplasty alone. There was no significant difference in hearing gain between the two groups as p value obtained was > 0.05 .

Conclusions: Tympanoplasty alone is sufficient in patients with chronic inactive mucosal otitis media, as the results of the graft uptake and hearing improvement show no significant difference between the tympanoplasty group and the tympanoplasty with cortical mastoidectomy group.

Keywords: Tympanoplasty, Cortical mastoidectomy, Chronic otitis media

INTRODUCTION

Chronic suppurative otitis media (CSOM) is an inflammatory process of the mucoperiosteal lining of the middle ear space and mastoid. Infection of the middle ear has been a problem encountered in the human race, and is as old as humanity itself. It is one of the most common ear diseases encountered in developing countries because of poor socioeconomic standards, poor nutrition, lack of health education and unhygienic habits. It is a major cause of deafness in India.¹

Tympanoplasty is a commonly performed surgical procedure to close perforations of the tympanic membrane. The results of tympanic membrane repair, although generally favourable, can vary significantly based on multiple factors including infection, eustachian tube dysfunction, and variations in operative technique.² Many otolaryngologists routinely perform mastoidectomy with tympanoplasty, arguing that surgical aeration of the mastoid will improve outcomes by providing a reservoir of air that can buffer pressure changes in the middle ear according to Boyle's law.³ Additionally, mastoidectomy can allow surgical debridement of infected and

devitalized tissues that can lead to persistent middle ear disease. Others argue that performing mastoidectomy in these patients is unnecessary, does not improve surgical outcomes, and subjects patients to increased surgical risks. The contribution of mastoid pneumatization remains controversial, and the role of mastoidectomy in treating tympanic membrane perforations continues to be debated, particularly in cases of CSOM in the absence of cholesteatoma.

It is well accepted that the main purpose of operation is to obtain a permanently dry ear and close the perforation. Tympanoplasty with mastoidectomy has been identified as an effective method of treatment of chronic ear infection resistant to antibiotic therapy, but the effect of mastoidectomy on patients without evidence of active infectious disease remains highly debated and unproven.

There are three opinions in this issue:

- The first is that mastoidectomy is useful for both infected and dry ears.
- The second is that mastoidectomy is useful for infected ears, but not for dry ears
- The third is that mastoidectomy is not useful for either infected or dry ears.

The purpose of this study is to determine the role and usefulness of mastoidectomy as a surgical treatment option in the repair of uncomplicated tympanic membrane perforations.

METHODS

The present study was a prospective, comparative, randomized controlled trial conducted in the Department of Otorhinolaryngology, Northern Railway Central Hospital, New Delhi after the approval of scientific committee and institutional Ethics committee from May-2016 to May 2017.

The study was conducted on patients attending the Outpatient clinic of Department of E.N.T., Northern Railway Central Hospital, New Delhi meeting the following selection criteria.

Inclusion criteria

Inclusion criteria were age more than 15-years; dry perforation for at least 6 weeks; central perforation; tubotympanic disease.

Exclusion criteria

Exclusion criteria were wet ear; marginal or attic perforation; cholesteatomatous ear; associated otitis externa (OE); previous mastoid operation, diabetes mellitus, non-patent Eustachian tube; ossicular discontinuity/dislocation; granulomatous ear diseases; smokers.

Sampling

60 patients were recruited for the study who were then divided in two groups of 30 patients each via simple random sampling technique. The sample size for comparing the two groups is determined with Holmquist and Bergstrom study.⁴

An informed and written consent was obtained from all the patients. All the patients were subjected to full history taking including onset, course, and duration of the disease, associated symptoms, previous medications, and operations or trauma. Patients were subjected to full otological examination to exclude scar of previous operation, condition of the tympanic membrane, condition of the middle ear mucosa, tuning fork tests, and also nasal and oral examination to exclude predisposing factors as allergy or causes of recurrence of the condition. All patients were subjected to preoperative pure tone audiometry which was repeated 6weeks post operatively and 3 months postoperatively. Routine preoperative lab investigations were done for all patients. All patients received the initial antibiotic therapy and ears were considered dry after a period of 6 weeks of no ear discharge. Patients were then operated upon.

Preoperative examination

After the confirmation of central perforation and dry ear, following preoperative analysis was done:

- Examination under microscope
- Pure tone audiometry

Relevant laboratory investigations including haemogram, liver and kidney function tests, blood grouping, urine routine and microscopic examination were done for pre-anaesthetic check-up before surgery.

Pre-operative preparation

After placing the patient on the operating table, the auricle and the surrounding area was thoroughly scrubbed with savlon (chlorhexidine) and spirit for 5 minutes. The area was then painted with betadine. After this part was draped in sterile towels.

Technique of cortical mastoidectomy with tympanoplasty

Local anaesthesia, post auricular incision, temporalis fascia graft harvesting is done as described for tympanoplasty. Elevation of the mucoperiosteum, canal wall incision, freshening of margins of perforation, elevation of tympanomeatal flap and entry into the middle ear are done similarly as described for tympanoplasty. At this point, a cotton ball soaked in lignocaine with adrenaline solution is placed in the external auditory canal.

The soft tissue over mastoid cortex is elevated to expose the surface landmarks of Macewen's triangle. The superior boundary is the temporal line extending posteriorly from the zygoma. This line corresponds to the probable level of the tegmen tympani, the bony plate separating the middle cranial fossa from the mastoid air system. The anterior boundary is a vertical line tangential to the posterior bony canal wall. Contained within these boundaries is a collection of bony perforations known as the cribriform area. The mastoid antrum is directly deep to this area. After identifying the surface landmarks, the cortex of the mastoid is opened using a large cutting bur. Dissection proceeded from a lateral to medial direction, beveling all bony overhangs to allow adequate exposure of the cavity. The tegmen tympani and sigmoid sinus were identified and clearly defined to avoid injury. In doing so, the sinodural angle is opened. The petrosquamous septum, also known as Körner's septum, was removed if encountered and all mastoid air cells anteromedial to the sigmoid sinus were opened. At this point, the mastoid antrum, the short process of the incus, and the horizontal semicircular canal were identified. Dissection of the mastoid tip air cells was performed not only to increase the cavity volume but also to remove all mucosal disease that could potentially lead to future infection. On opening the mastoid tip, the digastric ridge was identified medially. Liberal use of irrigation was done during the entire mastoid drilling and final polishing of the tegmen plate with a diamond bur was done to reduce bleeding.

The patency of antrum was checked. Cotton ball in the external auditory canal removed and graft was placed as described for tympanoplasty. The tympanomeatal flap was now repositioned. The mastoid cavity was packed with gelfoam. The under laid fascia and the meatal skin flap was kept in position by the pledgets of gelfoam soaked in antibiotic solution. The hemostatic retractors were removed and the subcutaneous tissue and skin incisions were closed with 3-0 vicryl and 3-0 silk sutures in two layers. The canal was packed lightly with an antibiotic pack. A sterile mastoid bandage was then applied

All the patients were started on IV antibiotics (Inj. amoxicillin plus clavulanic acid 1.2 gm IV 12 hourly) for two after surgery and then oral for the next 7 days, IV analgesics, Oral antihistaminics and continued for 3 weeks. All the patients were instructed to take precautions to avoid water entry in to the ear canal during bathing, avoid lifting of heavy weights and sneezing with mouth open. The patients were discharged 2 days after the surgery. The patients were advised to report if they develop pain or redness around the wound. Post-aural sutures were removed after 7 days.

The patients were followed up at 7th day, 3 weeks, 6 weeks and 3 months. The patients were assessed for wound healing, any upper respiratory tract infection, postoperative pain, graft uptake or failure. Hearing assessment was done with tuning fork tests and pure tone

audiometry. Any complications at any stage were addressed.

Statistical testing was conducted with the statistical package for the social science system (version SPSS 17.0). Continuous variables will be presented as mean±SD. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups was compared using Chi-square test. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

RESULTS

A total number of 60 patients were included in the study and were divided into two groups. The first study group consisted of 30 patients who had undergone tympanoplasty and the other group of 30 patients, underwent tympanoplasty with cortical mastoidectomy. Temporalis fascia was used as graft in all the cases. All the surgeries were done by post aurial route and underlay technique was used in all cases.

The tympanoplasty group had mean age of 32.20±11.68 years and the Tympanoplasty with Cortical Mastoidectomy group had mean age of 33.07±10.13 years. Both the groups were found comparable (p=0.76).

In present study groups gender, social status, laterality and operative ear in both groups p value showed no statistical significance, thereby suggesting both the study groups comparable.

There is non-significant difference between the two groups as (p=0.557) is more than 0.05, thereby suggesting both the study groups are comparable.

Clinical hearing assessment in pre-operatively 18 (60%) patients had weber lateralised to their left side and in 12(40%) patients, weber was lateralised to right side in the tympanoplasty group. Similarly, in case of tympanoplasty with cortical mastoidectomy group, 19 (63%) patients had weber lateralised to their left side and 11 (37%) patients had weber lateralised to right side. Similar post-op results with weber testing were obtained showing that the two groups are comparable in terms of surgical results (p=0.791).

Sclerotic mastoids on X-ray, type of anaesthesia (LA/GA), presence of tympanosclerotic patch, polypoidal middle ear mucosa and any granulations present. The p values obtained as shown in the last column are greater than 0.05 and so there is non-significant difference between the two groups as far as above mentioned variables are concerned.

Graft uptake was observed at three different time points (3 week, 6 week and 3 months). The overall graft uptake

rate was 88.33%. The graft uptake rate in tympanoplasty group was 87% and 90% in the tympanoplasty with cortical mastoidectomy group. There is non-significant difference at all the time points.

There is non-significant difference in graft uptake with respect to size of perforation (p=0.406), suggesting that success rate does not depend on size of the perforation.

There is non-significant difference in graft uptake with respect to laterality (p=0.768), suggesting that success rate does not depend on the status of the opposite ear.

But, there was significant difference in graft uptake with respect to gender. Graft uptake was more in the males than females (p=0.017), suggesting that gender may be a factor for graft uptake.

Hearing gain in both the groups shows non-significant difference as p=0.963 is greater than 0.05.

The mean postoperative hearing gain in our study was 13.50±5.89 dB in the tympanoplasty with cortical mastoidectomy group and 14.33±6.12 dB in tympanoplasty group. There was no significant difference in hearing gain between the two groups as p-value obtained was >0.05.

To compare mean ABG between the two groups, t-test was applied. The mean and standard deviation are presented in the above table. The p values in last column shows non-significant mean differences between the two groups at all the time points.

Table 1: Demographic distribution.

	Group				Total no. of patients	Pearson Chi-square	P value
	Tympanoplasty		Tympanoplasty with Cortical Mastoidectomy				
	No. of patients	%	No. of patients	%			
Age (in years)							
≤20	6	20	3	10	9	4.06	0.398
21-30	11	37	11	37	22		
31-40	5	17	11	37	16		
41-50	4	13	2	7	6		
51-60	4	13	3	10	7		
Total	30	100	30	100	60		
Mean±SD	32.20±11.68		33.07±10.13			P value	0.76
Gender							
Male	12	40	13	43	25	0.069	0.793
Female	18	60	17	57	35		
Social status							
Rural	15	50	14	47	29	0.067	0.796
Urban	15	50	16	53	31		
Laterality							
Unilateral	24	80	25	83	49	0.111	0.739
Bilateral	6	20	5	17	11		
Operative ear							
Left	18	60	19	63	37	0.071	0.791
right	12	40	11	37	23		

Table 2: Pre and postoperative Weber test.

		Group				Total no. of patients	Pearson Chi-square	P value
		Tympanoplasty		Tympanoplasty with cortical mastoidectomy				
		No. of patients	%	No. of patients	%			
Pre op Weber	L	18	60	19	63	37	0.071	0.791
	R	12	40	11	37			
Post op Weber	L	18	60	19	63	37	0.071	0.791
	R	12	40	11	37			

Table 3: Preoperative and intra-operative findings.

Variables		Group				Total no. of patients	Pearson Chi-square	P value
		Tympanoplasty		Tympanoplasty with cortical mastoidectomy				
		No. of patients	%	No. of patients	%			
X-ray mastoids sclerotic	No	14	47	10	33	24	1.111	0.292
	Yes	16	53	20	67			
Anaesthesia	GA	2	7	4	13	6	0.741	0.389
	LA	28	93	26	87			
TS patch	No	26	87	25	83	51	0.131	0.718
	Yes	4	13	5	17			
Polypoidal middle ear mucosa	No	28	93	25	83	53	1.456	0.228
	Yes	2	7	5	17			
Granulations	No	29	97	25	83	54	2.963	0.085
	Yes	1	3	5	17			

Table 4: Graft uptake with reference to size of perforation, gender, laterality of disease.

		Graft uptake 3 months		Total	Pearson Chi-square	P value
		Yes	No			
Perforation	Large	10	3	13	2.906	0.406
	Medium	32	3	35		
	Small	5	1	6		
	Sub total	6	0	6		
Sex	Male	25	0	25	5.66	0.017
	Female	28	7	35		
Laterality	U/L	43	6	49	0.087	0.768
	B/L	10	1	11		
Total		53	7	60		

Table 5: Paired T-test for change in ABG of both groups.

		Mean	N	Std. deviation	t-value	P value
Paired T-test for change in ABG of tympanoplasty group						
Pair 1	Pre-OP ABG	34.00	30	6.49	11.592	<0.001
	Post OP ABG 6 weeks	23.33	30	5.31		
Pair 2	Post OP ABG 6 weeks	23.33	30	5.31	5.809	<0.001
	Post OP ABG 3 months	19.67	30	5.40		
Pair 3	Pre-OP ABG	34	30	6.49	12.825	<0.001
	Post OP ABG 3 months	19.6667	30	5.40		
Paired T-test for change in ABG of tympanoplasty with cortical mastoidectomy group						
Pair 1	Pre-OP ABG	32.83	30	5.36	11.987	<0.001
	Post OP ABG 6 weeks	22.33	30	5.68		
Pair 2	POST OP ABG 6 weeks	22.33	30	5.68	5.835	<0.001
	Post OP ABG 3 months	19.33	30	6.40		
Pair 3	Pre-OP ABG	32.83	30	5.36	12.545	<0.001
	Post OP ABG 3 months	19.33	30	6.40		

To see the significance in decrease of ABG with respect to time in tympanoplasty group, paired t-test was applied. As the table shows the mean ABG of the study group is 34.00dB, 23.33 dB, 19.67 dB preoperatively, 6 weeks post operatively and 3 months post operatively

respectively. P values in last column shows that there is highly significant decrease in ABG from pre-op to 6 week post-op, 6 week post-op to 3 month post-op and when compared preoperatively with 3 months post mean ABG of the study group is 32.83dB, 23.33dB, 19.33dB

pre-operatively, 6 weeks post-operatively and 3 months post-operatively respectively. p-values in last column shows that there is highly significant decrease in ABG from pre-op to 6 week, 6 week to 3 month time and when compared pre-operatively with 3 months post-operatively.

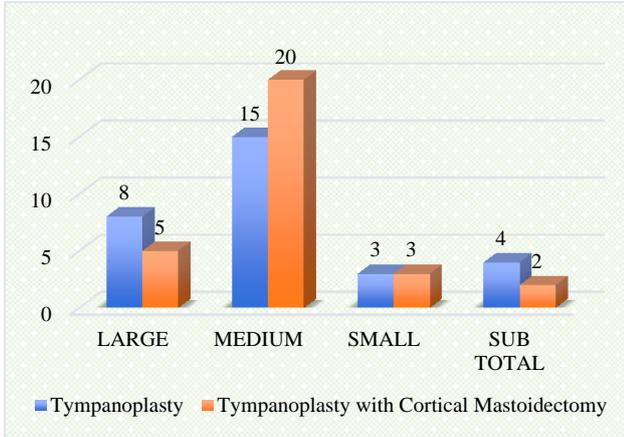


Figure 1: Size of perforation.

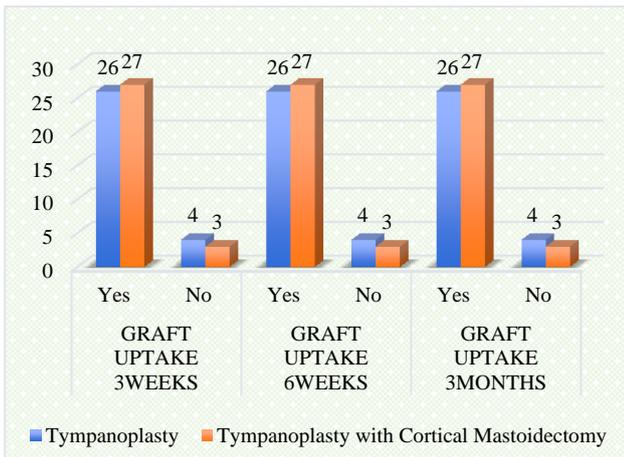


Figure 2: Graft uptake at various time intervals.

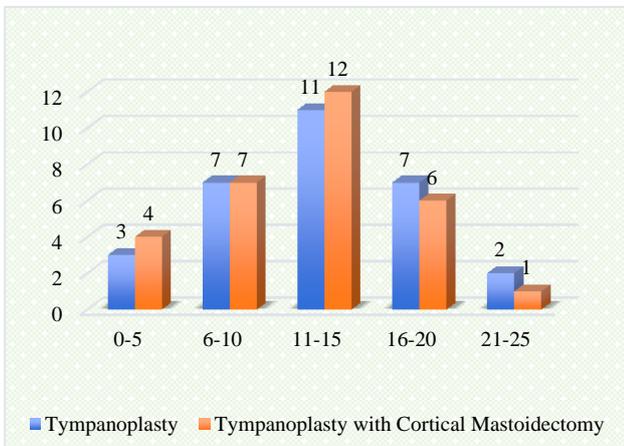


Figure 3: Hearing gain after procedure.

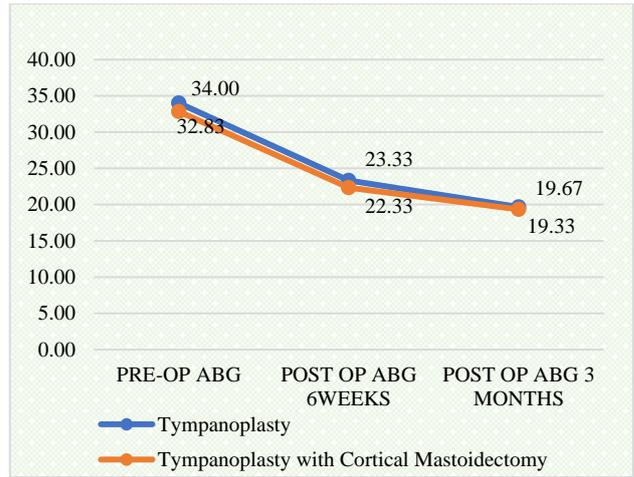


Figure 4: ABG at different time intervals.

DISCUSSION

This prospective study of tympanoplasty with and without cortical mastoidectomy in treatment of inactive mucosal chronic otitis media consisted of a 60 patients in total. The patients were divided into two groups of 30 patients each, one group consisted of patients who underwent tympanoplasty alone and the other group had patients in whom tympanoplasty was combined with cortical mastoidectomy.

In this study, we have analysed the graft uptake, the post-operative air-bone gap (ABG) and hearing improvement in both the groups. Intraoperative middle ear finding such as tymoanosclerotic patch, polypoidal middle ear mucosa, granulations have also been documented. The sample size is comparable to the studies of Ramakrishnan et al, Habib et al and Bhat et al whose sample size was 62, 60 and 68 respectively. The follow-up period was 3 months which was similar to studies conducted by Ramakrishnan et al and Habib et al.⁵⁻⁷

Age distribution

In our study, maximum number of patients in both the groups were distributed between the age 20-30 years (22 patients). This was followed by patients in the age group 31-40 years (16 patients). Patients in the age group less than 20 yrs were 9. The least number of patients were found to be in the 41-50 age group (6 patients). The mean age of tympanoplasty group is 32.20 years and the tympanoplasty with cortical mastoidectomy group is 33.07 years. The mean age group in study conducted by Albu et al was 26.7 years and Toros et al was 26 years.^{8,9}

Gender distribution is as follows

In our study, 58.3% were females and 41.6% were males. The graft uptake rate in the males is more than that of females (p=0.017), suggesting gender might be a determining factor for the graft uptake rate.

Status of the opposite ear

In the univariate analysis of study conducted by Albu et al, three factors were found to be significant in predicting the success rate: healthy opposite ear, a long dry period preceding the operation and non-smoker status.⁸ In our study both the groups are comparable in terms of number of patients with unilateral and bilateral disease. There were a total of 49 patients with unilateral disease and 11 patients with bilateral disease. There was no significant difference in graft uptake with respect to laterality ($p=0.768$), suggesting that success rate does not depend on the status of the opposite ear.

Size of perforation

Lee et al analysed 423 cases in 2002 to study the effect of size of perforation on the graft uptake rate.¹⁰ They found that the perforation closure rate was higher in small perforations (success rate 74%) than in large perforations (success rate 56%). The overall closure rate was 64%.

In our study, both the groups were comparable in terms of size of perforation ($p=0.556$). There were a total of 6 patients with small perforation, 35 with medium perforation, 13 with large perforation and 6 with sub-total perforation in the whole study population. The results obtained in our study were in contrast to the above study and implied that graft uptake does not depend on the size of perforation ($p=0.406$).

Graft uptake

The overall graft uptake rate in our study was 88.33%. The graft uptake rate in tympanoplasty group was 87% and 90% in the tympanoplasty with cortical mastoidectomy group. There was no significant difference in the graft uptake rates of the two groups.

Our results were similar to the studies conducted by Krishnan et al, Albu et al, Toros et al, Mc Grew et al who concluded that there was no significant difference in the graft uptake rate by combining cortical mastoidectomy with tympanoplasty over tympanoplasty alone in patients with mucosal CSOM without complications.^{5,8,9,11}

The graft uptake rate in the study conducted by Krishnan et al was 93% in tympanoplasty group and 96.7% in tympanoplasty with cortical mastoidectomy group.⁵ The graft uptake rate in the study conducted by Albu et al was 76% in the tympanoplasty group and 82.8% in the tympanoplasty with mastoidectomy group.⁸

The graft uptake rate in the study conducted by Toros et al was 76.1% in the tympanoplasty group and 7.38% in the tympanoplasty with mastoidectomy group.⁹ The graft uptake rate in the study conducted by Mc Grew et al was 90.6% in the tympanoplasty group and 91.6% in the tympanoplasty with mastoidectomy group.¹¹

Our results differed with the study conducted by Nayak et al, who had achieved 100% graft uptake rate in the tympanoplasty with mastoidectomy group and only 60% graft uptake rate in the tympanoplasty group.¹² They suggested that mastoid exploration is necessary in all cases of mucosal CSOM.

Postoperative air-bone gap

In our study, the mean post-operative ABG was 19.67 ± 5.40 dB in the tympanoplasty group and 19.33 ± 6.40 in the tympanoplasty with cortical mastoidectomy group. There was no statistical significance between the two groups as $p>0.05$, suggesting that mastoidectomy when combined with tympanoplasty offers no benefit over tympanoplasty alone.

Our study results are consistent with previous studies done by Krishnan et al, Albu et al, Toros et al, Mc Grew et al, Krishnan et al.^{4,8-11}

The mean post-operative ABG in study conducted by Krishnan et al was 18.9 ± 9.5 dB in the tympanoplasty with cortical mastoidectomy group and 17.9 ± 7.0 dB in the tympanoplasty group.¹³ The mean post-operative ABG in study conducted by Krishnan et al was 12.6 ± 13 dB in the tympanoplasty with cortical mastoidectomy group and 12.7 ± 11.5 dB in the tympanoplasty group.⁴

The mean post-operative ABG in study conducted by Albu et al was 12.4 ± 6.1 dB in the tympanoplasty with cortical mastoidectomy group and 11.2 ± 6.8 dB in the tympanoplasty group.⁸

The mean post-operative ABG in study conducted by Toros et al was 16.8 ± 11.1 dB in the tympanoplasty with cortical mastoidectomy group and 10.5 ± 9.0 dB in the tympanoplasty group.⁹ The mean post-operative ABG in study conducted by Mc Grew et al was 14.4 ± 11.1 dB in the tympanoplasty with cortical mastoidectomy group and 16.4 ± 12.4 dB in the tympanoplasty group.¹¹

Hearing gain

The mean postoperative hearing gain in our study was 13.50 ± 5.89 dB in the tympanoplasty with cortical mastoidectomy group and 14.33 ± 6.12 dB in tympanoplasty group. There was no significant difference in hearing gain between the two groups as p-value obtained was >0.05 .

Our study results are similar to the studies conducted by Krishnan et al, Albu et al, Toros et al, Mc Grew et al.^{5,8,9,11} The mean postoperative hearing gain in the study conducted by Albu et al was 13.30 dB in the tympanoplasty with cortical mastoidectomy group and 12.2 dB in tympanoplasty group.⁸ The mean postoperative hearing gain in the study conducted by Ramakrishnan et al was 14.7 dB in the tympanoplasty with cortical

mastoidectomy group and 16.9 dB in tympanoplasty group.⁵

The mean postoperative hearing gain in the study conducted by Toros et al (2010) was 9.7±9.0 dB in the tympanoplasty with cortical mastoidectomy group and 10.5±10.5 dB in tympanoplasty group.⁹ The mean postoperative hearing gain in the study conducted by Mc Grew et al was 11.4±16.0 dB in the tympanoplasty with cortical mastoidectomy group and 17.6±21.1dB in tympanoplasty group.¹²

Our study results differed from the study conducted by Habib et al, where the mean postoperative hearing gain in the tympanoplasty with cortical mastoidectomy group was 20.6±6.3 dB and 9.3±2.9 dB in the tympanoplasty group. P<0.01 suggested that there is significant difference in both the groups and cortical mastoidectomy is beneficial in terms of hearing improvement in patients of mucosal CSOM.⁶

Limitations of the study

- The sample size of our study is the relatively small.
- The follow up period of the study is 3 months, may not give the actual long term results and the need for future surgeries in some the patients.
- The fact that the study group consisted only the patients who are railway beneficiaries having a standard source of income and better access to health care the study may not entirely reflect the outcome in low income groups.
- Another limitation is that it was restricted to a genetically relatively homogeneous group of patients (i.e., those of Indian descent).

CONCLUSION

Tympanoplasty alone is sufficient in patients with chronic inactive mucosal otitis media, as the results of the graft uptake and hearing improvement show no significant difference between the tympanoplasty group and the tympanoplasty with cortical mastoidectomy group. It is conclude that cortical mastoidectomy can be considered a useful adjunct to tympanoplasty in selected cases of inactive chronic suppurative otitis media of mucosal type. The decision for the surgery should be made by surgeon after careful middle ear evaluation through otoscopy, pre-operative examination under microscope and X-ray mastoids. As such, tympanoplasty alone is sufficient for majority of cases having healthy middle ear mucosa.

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Conflict of interest: None declared

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

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