

A COMPARATIVE STUDY OF ROLE OF CORTICAL MASTOIDECTOMY IN MYRINGOPLASTY

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ABSTRACT: BACKGROUND: Chronic suppurative otitis media is an inflammatory process of mucoperiosteal lining of middle ear space and mastoid. Effect of mastoidectomy on patients without evidence of active infectious disease remains highly debated and unproven. In this study the role of cortical mastoidectomy in myringoplasty in patients of CSOM in dry as well as wet ears was evaluated. **OBJECTIVE:** To evaluate the efficacy and role of cortical mastoidectomy in patients with CSOM (safe type) in dry as well as wet ears. **STUDY DESIGN:** Prospective randomized. **METHODS:** Data was collected from the patients undergoing myringoplasty with or without cortical mastoidectomy. Study was carried out on a total of 80 patients undergoing the surgery. Study period was 18 months with 6 months of follow up. Outcome was evaluated in terms of graft rejection, lateralization and change in AB gap. **STATISTICAL ANALYSIS:** The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. **RESULTS:** overall success rate was 77.5%. It was higher in dry ear (87.5%) as compared to wet ear (67.5%) and this difference was significant statistically. On evaluating odds of failure for wet ear, it was observed that group 1 had higher odds of failure for wet ear as compared to that of group 2. **CONCLUSION:** In both myringoplasty alone or with cortical mastoidectomy, failure rates were higher in wet as compared to dry ears, however odds of failure in wet cases were much higher in myringoplasty alone group as compared to myringoplasty with cortical mastoidectomy.

KEYWORDS: Chronic suppurative otitis media (CSOM), Cortical mastoidectomy, Myringoplasty.

INTRODUCTION: Chronic otitis media is an inflammatory process of the mucoperiosteal lining of the middle ear space and mastoid. It is characterized by thickening of mucus membrane owing to edema, sub mucosal fibrosis, and infiltration with chronic inflammatory cells. Almost 6% of Indian population suffers from chronic ear disease.¹

Myringoplasty is an operative technique designed to close tympanic membrane defects. Tympanic membrane perforation can result from physical injury, scalds, burns, pressure effects, head injuries or infection process; out of this chronic suppurative otitis media is the most common cause. The main aim of surgery is to eliminate disease process and reconstruct the hearing mechanism to give the patient a dry safe and functioning ear. The first milestone is reconstruction of tympanic membrane (Krishna and Devi, 2013)² Attempts at reconstruction may seem futile as long as the infection in and around the middle ear cleft and mastoid antrum is lurking. In this context cortical mastoidectomy seems to be an integral part of every tympanoplasty (Krishnan et al., 2002).³

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The effect of mastoidectomy on patients with inactive disease remains highly debated and unproven (Albu et al., 2012; Kamath et al., 2013).^{4,5} However, in cases with active disease process, mastoidectomy has been shown to have significantly better outcome concerning postoperative complications (Mutoh et al., 2007).⁶ In order to resolve the controversies the present study was planned to evaluate the role of mastoidectomy in the surgical outcome of myringoplasty in patients with chronic suppurative otitis media (safe type) in dry as well as in wet ear.

AIMS AND OBJECTIVES: The present study was carried out with an aim to evaluate the efficacy and role of cortical mastoidectomy in patients with chronic suppurative otitis media (safe type).

1. To evaluate the success rate of active and inactive types of chronic otitis media for the two treatment modalities (with cortical mastoidectomy and without cortical mastoidectomy).
2. To evaluate the suitability of cortical mastoidectomy either for active or inactive chronic otitis media in patients undergoing myringoplasty.

MATERIAL AND METHODS: Data for the study was collected from the patients undergoing myringoplasty (safe type) with or without cortical mastoidectomy surgery in the Department of Otorhinolaryngology at Era's Lucknow Medical College and Hospital, Lucknow.

STUDY DESIGN: Prospective randomized.

METHOD OF COLLECTION OF DATA:

SAMPLING PROCEDURE: A predesigned proforma was used to record the relevant information [patient data, clinical findings, investigation reports – pure tone audiometry and X-ray mastoid, examination under microscope (EUM) along with diagnostic nasal endoscopy (DNE)] from the individual patient selected with inclusion and exclusion criteria.

The study was carried out on a total of 80 patients undergoing myringoplasty surgery.

STUDY PERIOD: 18 months starting from January 2013 to June 2014.

FOLLOW UP PERIOD: 6 months.

The subjects were randomly allocated to one of the two groups as follows:

Group I (n=40): Patients of chronic suppurative otitis media (safe type) who were treated with tympanoplasty alone.

Group B (n=40): Patients of chronic suppurative otitis media (safe type) who were treated with tympanoplasty with cortical mastoidectomy.

INCLUSION CRITERIA:

- a. Cases of safe CSOM with pure conductive hearing loss.
- b. Age criteria-patients from 15-50 years.
- c. Gender- both male and female.

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EXCLUSION CRITERIA:

- a. Patients with granulation or cholesteatoma and with impending complications of chronic suppurative otitis media making it unsafe type.
- b. Patients below 15 years and above 50 years.
- c. Those having sensorineural hearing loss or mixed hearing loss.
- d. Those having any systemic illness like hypertension, diabetes mellitus or any chronic illness (tuberculosis) or having history of allergic reactions.
- e. All cases with tympanosclerosis, revision or combined procedures (mastoidectomy and ossiculoplasty).
- f. With any deformity or congenital anomaly of external ear.
- g. Unusual infections such as malignant otitis external and complication of chronic ear diseases (Meningitis, Brain abscess, Lateral sinus thrombosis)
- h. Surgically unfit cases (pre anaesthetic check-up unfit cases).

METHODOLOGY: Patients were selected consecutively as and when they presented during the study period considering the inclusion and exclusion criteria.

PROCEDURE: A detailed history and clinical examination of the patients of chronic suppurative otitis media was done according to the proforma.

The cases of chronic suppurative otitis media with hearing loss were first diagnosed by examination (otomicroscopy) and investigations (Pure tone audiometry). Randomization was done by draw of lots.

Pre-operatively all patients had a pure tone audiogram with a four frequency average (0.5/1/2/4 kHz) calculated for both air conduction and bone conduction.

Hearing results were assessed by comparing pre-operative and post-operative pure tone averages over the above four frequencies as well as closure of the air-bone gap.

Myringoplasty was performed using Underlay procedure as detailed in Glasscock-Shambaugh Surgery of the Ear (4th Edition)¹. Cortical mastoidectomy was performed using posterosuperior approach detailed by same author. Figure 1, 2.

POSTOPERATIVE CARE:

- A mastoid dressing is applied for the first 6 postoperative days.
- Stitch removal is done on 7th postoperative day.

FOLLOW UP: Post-operative follow up was performed at the end of 3rd week, 12th week and 24th week.

STATISTICAL ANALYSIS: The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean \pm SD.

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The following Statistical formulas were used:

- 1. Mean:** To obtain the mean, the individual observations were first added together and then divided by the number of observation. The operation of adding together or summation is denoted by the sign Σ .

The individual observation is denoted by the sign X, number of observation denoted by n, and the mean by \bar{X} .

$$\bar{X} = \frac{\Sigma X}{\text{No. of observations (n)}}$$

- 2. Standard Deviation:** It is denoted by the Greek letter σ .

- 3. Chi square test:**

$$\chi^2 = \sum \frac{(O - E)^2}{E}$$

Where O = Observed frequency.

E = Expected frequency.

- 4. Student 't' test:** To test the significance of two means the student 't' test was used

$$t = \frac{\bar{X}_1 - \bar{X}_2}{S \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

where $S^2 = \frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2}{N_1 + N_2 - 2}$

where \bar{X}_1, \bar{X}_2 are means of group 1 and group 2

N_1, N_2 are number of observation group1 and group 2.

SD_1, SD_2 are standard deviation in group1 and group 2.

- 5. Level of significance:** "p" is level of significance

$p > 0.05$ Not significant.

$p < 0.05$ Significant.

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RESULTS: The present study was carried out with an aim to evaluate the efficacy and role of cortical mastoidectomy in patients with chronic suppurative otitis media (safe type). Study and were randomly allocated to one of the two groups as follows:

Sl. No	Group	Description	No. of cases	Percentage
1.	I	Patients of chronic suppurative otitis media (safe type) treated with tympanoplasty alone	40	50.0
2.	II	Patients of chronic suppurative otitis media (safe type) treated with tympanoplasty with cortical mastoidectomy	40	50.0

Table 1: Group wise distribution of patients

AGE DISTRIBUTION:

- Age of patients ranged from 15 to 47 years.
- In Group I, Mean age of patients was 29.23 ± 8.62 years.
- In Group II, Mean age of patients was 29.48 ± 8.64 years.
- On evaluating the data statistically, no significant difference between two groups was observed either for age groups ($p=0.737$) or for mean age ($p=0.897$).

DISTRIBUTION OF PATIENTS IN TWO GROUPS WITH RESPECT TO SIDE INVOLVED:

Majority of patients ($n=69$; 86.2%) had unilateral involvement with right side being more commonly involved (47.5%) as compared to left side (38.8%). Bilateral involvement was observed in 11 (13.8%).

Although proportion of patients with unilateral involvement was higher in Group II (92.5%) as compared to Group I (80%) yet the difference between two groups was not significant statistically ($p=0.064$).

DISTRIBUTION OF PATIENTS IN TWO GROUPS WITH RESPECT TO AB GAP: In both the groups, majority of cases had AB gap >25 dB ($n=22$; 55% in Group I and $n=31$; 77.5% in Group II). Mean AB gap in Group I was 24.50 ± 6.28 as compared to 26.88 ± 5.51 dB in Group II. Statistically, this difference was not significant either for categorical difference ($p=0.315$) or for mean difference ($p=0.076$) between the two groups.

No new case of rejection was observed at 24 weeks. Majority of cases irrespective of their group had involvement of right side as compared to left side. Statistically, there was no significant difference between two groups ($p=0.773$).

Overall, majority of patients had an AB gap of 15 and 20 dB (55%). Mean AB gap of Group I was 13.18 ± 3.26 dB as compared to 13.33 ± 4.39 dB in Group II. Statistically, difference between two groups was not significant.

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FINAL OUTCOME:

Sl. No	Finding	Total (n=80)		Group I (n=40)		Group II (n=40)		Statistical significance
		No.	%	No.	%	No.	%	
1.	Graft rejection	18	22.5	11	27.5	7	17.5	$\chi^2=1.147$; $p=0.284$
2.	Change in AB Gap	9.94±6.29 (0-20)		9.75±5.99 (0-20)		10.13±6.65 (0-20)		$t=0.265$; $p=0.792$
3.	Change in laterality	-		-		-		-

Table 2: Comparison of outcome between two groups

Graft rejection rate was higher in Group II as compared to Group I, however, this difference was not significant statistically ($p=0.121$).

No change in laterality was observed in either of two groups.

Mean change in AB Gap was slightly higher in Group II as compared to Group I yet this difference was not significant statistically ($p=0.792$).

DISCUSSION: Cortical mastoidectomy is performed with myringoplasty in cases of active chronic suppurative otitis media in order to clear the mastoid reservoir of infection. But its role in quiescent and inactive disease is questionable. Hence, the present study was carried out with an aim to evaluate the efficacy and role of cortical mastoidectomy in patients with chronic suppurative otitis media (safe type).

For this purpose, a prospective randomized clinical trial was done in which 80 patients with chronic suppurative otitis media (safe type) who were randomly allocated to two groups – Group I comprising of 40 patients in whom myringoplasty alone was performed whereas Group II comprised of 40 patients in whom myringoplasty was performed along with cortical mastoidectomy.

Majority of our patients were aged <30 years of age. Mean age of patients was 29.35 ± 8.58 years. CSOM is prevalent in all age groups; however, patients in the pediatric and younger age groups are most commonly affected (WHO, 2004). In a study by Yaor et al. (2006)⁷, age of patients undergoing myringoplasty ranged from 9 to 84 years with a mean age of 37 years and 24% of their patients being children aged 9 to 15 years. In present study, mean age was slightly lower which might mainly be attributed to the inclusion criteria where the age range was restricted only between 15 and 50 years. Yoon et al. (2007)⁸ in their series of 111 patients undergoing myringoplasty had all the patients aged 15 years or less. Magsi et al. (2012)⁹ reported a study in which patients were aged 5 to 50 years and had maximum number of patients aged 11-20 years as against present study in which maximum number of patients were aged 21 to 30 years. Age has been identified as a possible confounding factor having an impact on the outcome (Webb and Chang, 2008; Gupta, 2009),¹⁰ hence in present study both extreme ends – pediatric age group as well as elderly were excluded from the study to rule out any such confounding effect.

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In present study, majority of patients irrespective of the group to which they were allocated were males.

Although some western studies (Webb and Chang, 2008) have reported a higher prevalence amongst females yet gender wise differences could be purely incidental and could generally be attributed to gender biased healthcare seeking practices in our settings.

Preoperatively, AB gap ranged from 15 to 35 dB. Majority of cases in both the groups had AB gap of 25 dB or above. Mean AB gap in Groups I and II was 24.50 ± 6.28 and 26.88 ± 5.51 dB respectively. Contrary to our results, Shivakumar et al. (2014)¹² reported only 25% of patients in two groups to have preoperative AB gap of >25 dB.

Mean pre-operative AB gap values in present study were close to that reported by Balyan et al. (2007) and McGrew et al. (2004) (for the cortical mastoidectomy group).

In present study an equal number of patients in both the groups had wet (active) and dry (inactive) type of CSOM. This was a systematic purposive allocation in order to evaluate the validity of cortical mastoidectomy in both wet and dry situations and to resolve the debate related with the effect of mastoidectomy on patients without evidence of active infectious disease (Albu et al., 2012; Kamath et al., 2013). In present study, graft rejection rate by first follow up itself was 10% (4 cases each) in both the groups. Between third post-operative week to 12th post-operative week 7 new graft rejections took place in Group I whereas in Group II, a total of 3 new rejections took place during the same period. No new rejection took place in subsequent follow up intervals. Overall graft rejection rate was 27.5% in cases undergoing myringoplasty alone as compared to 17.5% in cases undergoing myringoplasty with cortical mastoidectomy, thus showing a better success rate for myringoplasty with cortical mastoidectomy (82.5%) as compared to myringoplasty alone group (72.5%), however, this difference was not significant statistically ($p=0.284$).

As far as graft take up rate is concerned, our results are comparable to Bhat et al. (2009) and Albu et al. (2012) who observed success rate of 75% and 76% for myringoplasty alone group as compared to 82.85% and 82.8% respectively for myringoplasty with cortical mastoidectomy group. Most of the studies above have reported between 70 to 80% for Myringoplasty alone and between 80 to 90% for myringoplasty with cortical mastoidectomy. However, none of the studies was able to depict a statistically significant difference between two groups. In present study, mean AB gap correction in two groups was 9.75 ± 5.99 and 10.13 ± 6.65 respectively for myringoplasty alone and myringoplasty with cortical mastoidectomy. Similar to our results, Habib et al. (2011) and Kaur et al. (2014) have also shown that gap closure was higher for Myringoplasty with cortical mastoidectomy as compared to myringoplasty alone. Statistically, difference between two groups was not significant.

In present study no change in laterality status was observed comparing the odds of failure in wet ears as compared to dry ears, they were found to be much higher in myringoplasty alone group (OR=2.15) as compared to myringoplasty with cortical mastoidectomy group (OR=1.42), thus implying that cortical mastoidectomy substantially reduces the risk of failure in wet ears. On overall assessment we found that cortical mastoidectomy did not offer any additional benefit as compared to myringoplasty alone. These views are shared by a number of researchers (Balyan et al., 1997; Mishiro et al., 2001; Krishnan et al., 2002; McGrew et al., 2004; Rickers et al., 2006;

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Yoon et al., 2007; Bhat et al., 2009; Gupta, 2009; Mishiro et al., 2009; Ramakrishnan et al., 2011; Albu et al., 2012; Kamath et al., 2013; Elliades and Limb, 2013; Shivakumar et al., 2014; Tawab et al., 2014; Kaur et al. 2014).^{13,17,3,14,18,8,15,11,19,20,4,5,21,12,22,17} However, we found that in case of wet ear, cortical mastoidectomy has a better graft take up rate and lower odds of failure as compared to myringoplasty alone group.

CONCLUSION: On the basis of observations made and their critical evaluation the following conclusions have been drawn from the present study.

1. Overall, failure rate was significantly higher in wet type (32.5%) as compared to dry type (12.5%), showing the odds of failure to be 3.37 in wet type as compared to dry type.
2. In both Myringoplasty alone and Myringoplasty with cortical mastoidectomy failure rates were higher in wet type (35% and 20% respectively) as compared to dry type (20% and 15%), however, odds of failure in wet cases were much higher in myringoplasty alone group (OR=2.15) as compared to myringoplasty with cortical mastoidectomy (OR=1.45).

On the basis of above evaluation, it was observed that despite cortical mastoidectomy group showing a higher success rate proportionally, there was no significant difference between two groups with respect to improvement in hearing status and overall success rate. However, proportional difference in graft take up rate in both dry and wet types indicated the results to be favouring cortical mastoidectomy especially in wet cases where it reduced the odds of failure substantially. Owing to limitation of sample size the trends obtained in present study need further validation and verification.

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Fig. 1: Showing temporalis fascia graft placement by underlay technique.

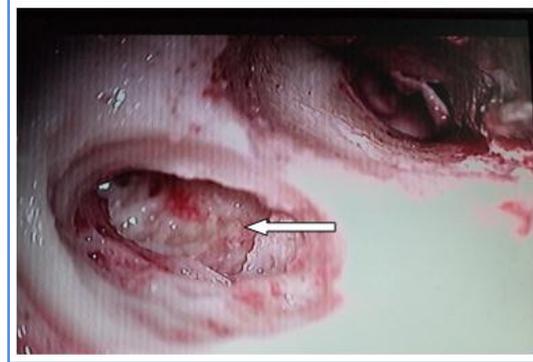


Fig. 2: Showing cortical cavity

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