

# **Original Research Article**

# Study of malleus as a prognostic indicator on hearing outcomes after tympanomastoid surgery: A prospective observational study

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# ABSTRACT

**Background:** Tympanomastoid surgery comprises a range of surgeries (cortical, radical, modified radical). Pre-operative auditory deficit in a patient with cholesteatoma may be correlated with ossicular chain status. The incus is often expected to be eroded, which may not be true for the malleus. The presence of malleus and it's significance on the post-operative needs to be studied further.

Aim and Objective: The purpose of our study is to determine the effect of intraoperative status of malleus on the post-operative hearing outcomes of patients undergoing canal wall-down mastoidectomy.

**Materials and Methods:** A prospective observational study of 24 patients was conducted, where preoperatively pure tone audiometry (PTA) was performed. Intraoperatively, the status of malleus was noted. Canal wall down mastoidectomy was done. Post-operative PTA was recorded after 3 months and both audiograms compared.

**Results:** An air bone gap (ABG) of less than 20dB post-operatively was considered significant functional improvement. In patients with a preserved malleus, mean improvement was 25.2dB ( $\pm$ 9.8), whereas patients in whom malleus was remove had mean 16.8dB ( $\pm$ 10.49) improvement. Similar results were found by Lu et al, Blom et al and Haberman et al. Haberman et al theorised the concentration of sound waves and preservation of middle ear volume as a contributing factor to the results.

**Conclusion:** Hence it was concluded that relatively better post-operative audiological outcomes were obtained when malleus was present/preserved intraoperatively.

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# 1. Introduction

Chronic suppurative otitis media (COM) is becoming increasingly prevalent in the community. Defined as a chronically discharging ear for 3 months or more,<sup>1</sup> the most commonly encountered complaints by otorhinolaryngologists include continuous discharge from the ear and a significant hearing deficit (mostly conductive type with or without a sensorineural component). The pathology leading to this is often a perforated tympanic membrane, diseased condition of the ear ossicles (which is responsible for conductive hearing loss) and by extension, the mastoid bone.<sup>1</sup> On failure of medical treatment, the only option is surgical i.e., a tympano-mastoid exploration. This surgery includes clearing the mastoid bone<sup>2</sup> of its pathology as well as assessment of the intraoperative status of ear ossicles (absence/intra-operative removal) for prognosis of post-operative hearing.

The ossicular chain may be either intact, partially eroded or completely eroded, explaining the auditory deficit.<sup>3</sup> Sometimes, it may have to be removed by the surgeon intraoperatively for adequate clearance of the disease. Though the incus is often expected to be eroded because of its precarious blood supply, the same cannot be said about the malleus and stapes.

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Hence, we shall aim to recognise the presence or absence of the malleus in relation to the stapes and establish the significance, if any, on the post-operative hearing outcomes after canal wall down mastoidectomy on intraoperative removal of malleus or its absence due to the disease. The purpose of our study is to record the intraoperative status of malleus and compare the pre-operative and post-operative hearing in the presence or absence of malleus.

## 2. Materials and Methods

This study was conducted in the Department of Otorhinolaryngology and Head & Neck surgery at a tertiary care hospital. It was conducted in a prospective observational design and a total of fifty-six patients diagnosed with squamous type of chronic otitis media (COM) scheduled to undergo canal wall down mastoidectomy were considered through purposive sampling, after taking due informed written consent. Patients above the age of twelve years coming to ENT OPD diagnosed with chronic suppurative otitis media and are complaining of hearing deficit were considered for this study. Patients not willing to give consent to participate in the study, patients less than twelve years of age, patients with sensorineural component associated with hearing deficit, patients failing to follow up and patients having intracranial and extracranial complications of CSOM were excluded from the study.

A detailed history of all patients was taken and clinical examination was performed. Pre-operatively, a pure tone audiometry (PTA) was performed and the results were recorded. Intraoperatively, the status of malleus was noted (whether it was intact/ partially eroded/fully eroded). A canal wall up mastoidectomy was performed keeping in view the primary aim which is disease clearance. The incus was removed and the stapes footplate was preserved in all patients. Malleus which was not ridden with disease was preserved and partially eroded/diseased malleus was delivered. For the second set of patients, a cartilage ossiculoplasty was done using conchal cartilage from the meatoplasty site. All patients were followed up for 3 months in the post-operative period. At 3 months follow up, a PTA was repeated and both pre-operative and post-operative audiograms were compared.

The primary variable of study was the pure tone audiogram, where a loss of 25-40dB was considered mild haring loss, 40-70 dB moderate hearing loss, 70-90 dB severe hearing loss and >90 dB profound hearing loss.<sup>1</sup> For the purpose of our study, an air bone gap (ABG) of less than 20dB post-operatively was considered significant functional improvement.<sup>3</sup>

The ossicular chain status was recorded in accordance with the Austin Kartush classification of Ossicular chain status (Table 1).<sup>4,5</sup>

 Table 1: Austin-Kartushclassification for ossicular chain status

 Statistical analysis

Туре	Ossicular chain status
0	M+I+S+
А	M+S+
В	M+S-
С	M-S+
D	M-S-
Е	Ossicular chain
	fixation
F	Stapes footplate
	fixation

Statistical analysis is done using Paired-t test and Wilcoxin Signed rank Test via SPSS Version 20. At power 80% and Z=1.96, a p value of less than 0.05 was considered statistically significant.

# 3. Result

Fifty-six patients were considered for the study, but statistical analysis was only performed on fifty-four patients. Two patients were excluded from the study as they were lost to follow up. These fifty-four patients were divided into Austin Kartush type A and type C. Incus was absent and stapes was intact in both these groups. In group A, which comprised thirty-seven patients, malleus was present, intact and preserved. The remaining seventeen patients were of Austin Kartush type C, wherein intraoperatively a diseased malleus was found and hence removed.

In the first group, a mean pre-operative PTA was recorded at 51.8 dB with a standard deviation (SD) of 8.3 dB. Post operatively, at three months they were found to have improved hearing and a mean post-operative PTA of 26.6 dB with an SD of 8.3 dB. The mean of differences in PTA in this group was 25.2dB  $\pm$ 9.8 dB. Statistically, p value=0.0001 which was statistically significant.

In the second group, mean pre-operative PTA was 52 dB with an SD of 5.7 dB and three months post-operatively, mean PTA was 35 dB with an SD of 7.4 dB. The mean of differences in this group was 16.8dB  $\pm$ 10.49 dB. Statistically, a p value=0.11 was obtained which was statistically not significant (Table 2).

A Wilcoxin signed rank non-parametric test was performed to check for statistical significance and p value=0.046 was obtained. It was thus established that the presence of malleus has superior results on post-operative hearing outcomes.

## 4. Discussion

The role of malleus in hearing is a terrain which is not fully explored. Although multiple studies have been done on the improvement of post-operative hearing after preservation Ibji et al. / IP Journal of Otorhinolaryngology and Allied Science 2024;7(3):51-55

Austin Kartush Class	Sample size	Pre-op mean (SD)	Post-op mean (SD)	Mean of differences (SD)	P value	Significant p value
	2			Not included		
А	37	51.8 dB (8.3)	26.6 dB (8.3)	25.2 dB (9.8 dB)	0.001	< 0.05
С	17	52 dB (5.7)	35 dB (7.4)	16.8 dB (10.49)	0.11	>0.05
Wilcoxin signed rank test	54				0.046	Reject null hypothesis

Table 2: Pre-operative and post-operative results



Figure 1: Showing a diseases malleus



Figure 2: A healthy malleus which was preserved

of malleus, both positive and negative results have been found. Stankovic<sup>6</sup> and Felek<sup>7</sup> - in two individual studies of their own - have found that post-operative hearing in Austin Kartush group A is significantly better than Austin Kartush group C. A p-value of <0.05 was obtained, inferring that a retained malleus gives better closure of air bone gap. Bared and Angeli recorded that an intact malleus handle intraoperatively was useful in obtaining a smaller postoperative air bone gap with a mean pre-operative ABG of 34 dB and post-operative ABG of 20 dB.<sup>8</sup>

Yung and Vowler<sup>9</sup> stated that a postoperative ABG of less than 20 dB was considered a surgical success in their study whereas an ABG of greater than 20 dB was regarded as surgical failure.

In a multivariate analysis of patients who had undertaken surgery for chronic otitis media, they found that the status of the malleus definitely affected the hearing outcome, with the presence of malleus having a considerable positive outcome and a p value of .02. They also noted that the presence of the stapes did not significantly influence their findings, leading us to believe that the results of hearing provided with the retention of malleus was independent of the presence or absence of stapes.<sup>9</sup> This was also in line with the results found by a meta-analysis conducted by Blom et al.,<sup>10</sup> in which significant post-operative ABG was found in patients in whom the malleus was preserved, i.e, Austin Kartush groups A and B than groups C and D, concluding that malleus has a significant effect on improvement on postoperative hearing of the patient. Lu et al also gave similar finding of better post operative results on the preservation of malleus.<sup>11</sup>

A very important finding was observed and theorised by Haberman, who claimed that planning the removal of malleus and subsequent ossicular chain reconstruction (OCR) gave favourable results in comparision to simple preservation of malleus. For reconstruction, materials like titanium and hydroxyapatite were used as either total ossicular prosthesis or partial ossicular prosthesis.<sup>12</sup> The results between patients in whom malleus was removed with an OCR performed and patients with an intact malleus and anterior malleolar ligament were not statistically significant.<sup>12</sup>

Habermann based his proof of preservation of malleus giving better post-operative results on a theory proposed by Merchant et al.,<sup>13</sup> He suggested that the preservation of malleus is important in concentration of sound energy at one point, in order to be transmitted throughout the entire length of the ossicular chain. Even with a cartilage prosthesis for OCR, a preserved malleus is said to accentuate the transmission of sound waves through the malleus-cartilage coupler. Nott only this, but it also helps in stabilizing the new tympanic membrane thus formed and maintains middle

ear volume by preventing lateralisation of the graft. By both these mechanisms, middle ear ventilation is re-established in a diseased ear.

While the above findings are known to be the way classical thinking is led, there have been studies which have found opposing results to ours. Brackman did a study on the use of TORP and PORP in tympanoplasties and garnered information that preserving handle of malleus gave no statistically significant results in the post-operative period and that the use of artificial prosthesis was superior in achieving said results.<sup>14</sup> Shimizu and Goode concluded the presence of malleus provided neither statistically significant nor clinically good results.<sup>15</sup> Radaelli de Zinis found similar nonsignificant difference in the group of patients in whom malleus was intact.<sup>16</sup>

Querat et al performed modified radical mastoidectomies with malleus preservation and the use of PORP in patients with cholesteatoma and found ossicular reconstruction was superior to preservation of malleus in improvement of post-operative hearing results.<sup>17</sup> In 2021, Maquet et al revisited this terrain and found that an intact malleus had little to no role in the post-operative hearing in patients who were primarily operated for cholesteatoma. There was some improvement observed in a particular group but the overall results were insignificant.<sup>18</sup>

The study has limitations, the most specific one being the heterogenous nature of the study group. Secondly, our study only included patients in whom a canal wall down mastoidectomy was warranted. Owing to the difference pathogenesis of the disease (ossicular erosion versus ossicular necrosis).<sup>12</sup> only patients with cholesteatoma (erosion) were included in the study and any patients with mucosal disease or aggressive granulations or needing just a canal wall up surgery were excluded. High resolution computed tomography (HRCT) of the temporal bone was only studied for confirming the presence and extent of disease pathology and not for the status of ossicles. Lastly, our study had a mean follow up of 3 months for all patients to assess the post-operative hearing, future studies of the same may help us look at long term results in these patients.

#### 5. Conclusion

In our study, it was observed that relatively better post-operative audiological outcomes were obtained when malleus was either present intraoperatively or preserved, making it a critical indicator in the prognosis of postoperative hearing.

#### 6. Ethical Standard

In this study, human participants were used and all procedures performed in the study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed Consent Informed and written consent was taken from all the participants. Data is not displayed due to reasons pertaining to confidentiality of the participants.

## 7. Source of Funding

None.

## 8. Conflict of Interest

Authors have no conflict of Interest.

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