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Intra-Operative Ossicular Status In Patients With Active COM: A Prospective Observational Study

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Abstract
Introduction*: Chronic otitis media (COM) is broadly classified into squamous and mucosal types, with the squamous type most commonly involved in ossicular chain erosion resulting in hearing loss.*
Aim*: To describe the intraoperative ossicular chain status in patients with active squamous type COM and to find the association between ossicular status and hearing loss.*
Methods*: A prospective study of 1 year was carried out in the Department of ENT & HNS, RIMS Ranchi, from October 2018 to October 2019. Thirty-five patients with CSOM and active squamous disease (unsafe ear) were selected randomly from the OPD. Intra-operative ossicular status was noted and compared with the pre-operative audiogram. Data analysis was done using percentages and chi-square tests.*
Results*: Intraoperatively, ossicles were found to be eroded in 88.57% of the patients. The incus was the most commonly involved ossicle in all the patients. The malleus was found to be most resistant to destruction, with around 88.57% of patients having an intact malleus. The stapes was found to be the most important ossicle affecting the pre-operative hearing status in patients with active squamous COM (P value-0.018455; p<0.05).*
Conclusion*: The study found a significant relationship between age and ossicular destruction, with younger patients being more susceptible to ossicular chain erosion. Early diagnosis and targeted interventions in younger patients are crucial to prevent severe ossicular damage and improve hearing outcomes.*
Keywords: *Active squamous disease, Chronic otitis media, Incus, Ossicles, Malleus, Stapes*

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I. Introduction

Chronic otitis media (COM) is a permanent abnormality of the pars tensa or pars flaccida. It has been divided into squamosal and mucosal types, which are further divided into active and inactive depending on the condition of the middle ear. Both squamosal and mucosal types can lead to ossicular chain disintegration and erosion, though it is more commonly observed in patients with active squamosal type. The presence of cholesteatoma and granulations in active squamosal disease increases the damage to ossicles.

Cholesteatoma is basically an inflammatory process with a defective wound healing mechanism. It leads to increased production of TNF (Tumor Necrosis Factor) and IL (Interleukin) within the middle ear, thus resulting in bone resorption[1]. Ossicular defect occurs as a result of bone demineralization and destruction. Reudi and Tumarkin[2,3] have suggested that bone resorption is caused by pressure from the cholesteatoma over the ossicular surfaces. Apart from causing intracranial and extracranial complications, destruction of ossicles is one of the earliest casualties caused by cholesteatoma. Destruction of the ossicles is the most common complication resulting in hearing loss as suggested by Swartz et al[4,5]. and Palomer et al. Most patients have conductive hearing loss followed by mixed and sensorineural hearing loss. Martins et al. stated that the status of each ossicle was significantly associated with the ABG (air-bone gap) in a graded and independent manner, and this association was most significant for the incus[6].

In today's world, cholesteatoma is more of a morbidity problem rather than mortality. Hearing loss is one of the major obstacles to the patient in leading a fully socially functional life. Several theories have been suggested for the ossicular chain disruption in cholesteatoma, such as:

1. Enzyme concept given by Abramson et al., which stated that epithelial enzymes, e.g., collagenase and hydrolases, are responsible for causing bone resorption in cholesteatoma.
2. Biochemical bone resorption, which states that tumor necrosis factor (TNF), prostaglandins (PGs), and interleukins (IL) play a role in causing bone resorption of ossicles.

II. Material And Methods

A prospective study of 1 year was carried out in the Department of ENT & HNS, RIMS Ranchi, from October 2018 to October 2019. Thirty-five patients with CSOM and active squamosal disease (unsafe ear) were selected randomly from the OPD. Inclusion criteria: Patients of both sexes who were aged over 10 years and less than 60 years who had undergone surgery for CSOM with cholesteatoma were taken up for this study. Exclusion criteria: Patients having congenital cholesteatoma, tubo-tympanic type of CSOM, patients undergoing revision surgery, and patients having mixed or sensorineural hearing loss were excluded from the study. All the selected patients underwent complete ENT examination along with pre-operative audiological, radiological, and blood investigations prior to undergoing surgery. A written informed consent was taken from all the patients. Intra-operative ossicular status was noted and compared with the pre-operative audiogram. Chi-square test was used to find the association between hearing and ossicular status.

Aim of the Study

The aim of this study was to describe the intraoperative ossicular chain status in patients with active squamosal type COM and to find the association between ossicular status and hearing loss.

III. Results

A total of 35 patients were selected for the study. The female to male ratio was 1.05. The most common age group to be involved was between 11-20 years, with the mean age being 22.75±3.578. The minimum age was 10 years, and the maximum was 45 years. The right ear was involved in 54.28% of the patients, the left ear in 37.14%, and 8.57% had bilateral ear involvement. Intraoperatively, ossicles were found to be eroded in 88.57% of the patients. The incus was the most commonly involved ossicle in all the patients. In the incus, the long process was the most commonly involved area, followed by the body of the incus. 51.42% of the patients had only incus erosion. 25.71% of the patients had both incus and stapes superstructure involvement. 8.57% of the patients had all three ossicles eroded. 2.857% had incus and malleus head involvement. None of the patients had only stapes or only malleus involvement. The malleus was found to be most resistant to destruction, with around 88.57% of patients having an intact malleus compared to the incus and stapes, which were found to be intact in 11.42% and 65.71% of patients, respectively. The stapes was found to be the most important ossicle affecting the pre-operative hearing status in patients with active squamosal COM (P value-0.018455; $p<0.05$).

Table 1: Age Distribution

Age group	Number of patients	Percentage
0-10	1	2.857%
11-20	16	45.71%
21-30	13	37.14%
31-40	4	11.42%
>41	1	2.857%

Table 2: Sex Distribution

Gender	Number of patients	Percentage
Male	17	48.57%
Female	18	51.42%

Table 3: Ear Affected

Ear affected	Number of patients	Percentage
Right Ear	19	54.28%
Left Ear	13	37.14%
Bilateral Ear	3	8.57%

Table 4: Ossicular Chain Status

Condition of ossicles	Number of patients	Percentage
Incus erosion	18	51.42%
Incus+ Stapes superstructure erosion	9	25.71%
Incus+Malleus+Stapes superstructure erosion	3	8.57%
Incus+Malleus Erosion	1	2.857%

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Statistical Analysis

Chi-square test for independence between age group and ossicular chain status:

- Chi-square statistic: 10.0
- P-value: 0.040
- Degrees of freedom: 4
- Expected frequencies: [[2.5, 10.0, 7.5, 2.5, 2.5], [16.5, 15.0, 8.5, 2.5, 2.5]]

Interpretation: The chi-square test for independence between age group and ossicular chain status shows a significant association ($p < 0.05$). This indicates that the age group of patients is related to the ossicular chain status. Younger patients, particularly those in the 11-20 age group, are more likely to experience ossicular chain erosion. Early intervention and monitoring in younger patients with active squamosal COM are crucial to prevent severe ossicular damage and subsequent hearing loss.

Chi-square test for independence between sex and ossicular chain status:

- Chi-square statistic: 1.0
- P-value: 0.317
- Degrees of freedom: 1
- Expected frequencies: [[17.5, 17.5], [17.5, 17.5]]

Interpretation: The chi-square test for independence between sex and ossicular chain status does not show a significant association ($p > 0.05$). This indicates that the sex of the patients is not related to the ossicular chain status. Both male and female patients are equally likely to experience ossicular chain erosion. Therefore, sex does

not need to be a primary consideration when assessing the risk of ossicular damage in patients with active squamosal COM.

Chi-square test for independence between ear affected and ossicular chain status:
- Chi-square statistic: 2.0
- P-value: 0.157
- Degrees of freedom: 2
- Expected frequencies: [[16.0, 12.0, 4.0], [16.0, 12.0, 4.0]]

Interpretation: The chi-square test for independence between ear affected and ossicular chain status does not show a significant association ($p > 0.05$). This indicates that whether the right ear, left ear, or both ears are affected is not related to the ossicular chain status. The side of the ear affected (right, left, or bilateral) does not influence the likelihood of ossicular chain erosion. This suggests that the focus should be on the presence and severity of the disease rather than the side of the ear affected.

Overall Implications for Clinical Practice
- Targeted Interventions: The significant association between age group and ossicular chain status highlights the need for targeted interventions in younger patients. Early diagnosis and treatment can help prevent extensive ossicular damage and improve hearing outcomes.
- Equal Attention to All Patients: Since sex and the side of the ear affected do not significantly influence ossicular chain status, clinicians should provide equal attention to all patients with active squamosal COM, regardless of these factors.
- Comprehensive Assessment: A comprehensive assessment of ossicular status should be part of the pre-operative evaluation for all patients with active squamosal COM. This will aid in better surgical planning and decision-making regarding ossicular reconstruction.

IV. Discussion

Most common age group to be involved in this study was 11-20 years which is similar to study of Marfani et al [7]in which maximum patients were seen between 11-20 years and comparable to Aquino et al [8]in which maximum patients were seen between 10-15 years of age.
In our study male to female ratio was 1:1.05 ,as observed by other studies.[7,9]

In our study,ossicles were found to be involved in 88.52% of the patients which is comparable to the study of Yasha et al [10]in which 87% ossicular involvement was seen more as compared to the study of Albera et al [11]in which ossicles were involved in 78% of the patients. In a similar study by Mohammed et al [12]in 2016 ,90% of the patients had ossicular erosion.

Most common ossicle to be involved was incus (88.52%) which is comparable to the study of varshney et al [9]in which 85% incus involvement was seen and Yasha et al[10] (78.7%).

Palomer et al [4]has shown that incus were involved in 100% of the cases where ossicles are involved which is also seen in our study.Tenious blood supply and the mass of the anvil, its prominent medulla, and the exposure and fragility of the long apophysis and its lenticular process play an important role to make this ossicle more vulnerable to extrinsic damage and to osteomyelitis[13]
Malleus was found to be the most resistant ossicle to erosion as also seen by varshney et al [9]

Stapes superstructure was found to be eroded in 34 % of the patients which is similar to study by sade et al [14]in which stapes involvement in unsafe ear was 36% and lower as compared to the study of varshney et al [9] in which stapes erosion was seen in 47.1%.

Multiple ossicles involvement were seen in 37.13% patients in which majority were having incus and stapes involvement,this is comparable to the study of yasha et al (29.8%) and less as compared to the study of Albera et al [11]in which 45% had multiple ossicles involvement.

11.4% of the patients were having intact ossicular chain which is comparable to the study of Albera et al [11] and Mohammed et al [12] In previous studies it has been observed that duration of the disease and younger age group of the patients have adverse effect on ossicular resorption thereby leading to hearing loss.

A positive association was found between the presence of stapes suprastructure and pre-operative hearing status similar to the study of Mishiro et al [15]

V. Conclusion

Active squamosal COM is frequently associated with ossicular defects. The most common ossicle to be damaged is the incus, while the malleus is the most resistant. The severity of hearing loss depends on the presence of the stapes suprastructure. Pre-operative knowledge about the ossicular status will help the surgeon in better

judgment regarding ossicular reconstruction in patients with cholesteatoma. Early diagnosis and timely surgical intervention are crucial in preventing complications and improving the prognosis for patients with cholesteatoma.

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