

A Comparative Study Of Ossicular Pathology In Safe And Unsafe CSOM In A Teaching Hospital Of Rural Bihar

Dr. Suman Maurya, Dr. A.K. Singh, Dr. Md Akbar Ali, Dr. Md Shahabuddin

(Postgraduate Resident 3rd Year, ENT Department, Katihar Medical College, Bihar, India)

(Professor, HOD, ENT Department, Katihar Medical College, Bihar, India)

(Professor, ENT Department, Katihar Medical College, Bihar, India)

(Professor, ENT Department, Katihar Medical College, Bihar, India)

Abstract:

Background: Chronic Suppurative Otitis Media (CSOM) is one of the most common otological diseases, particularly in developing countries like India. It contributes significantly to preventable hearing loss. Based on clinical and pathological features, CSOM is classified as safe (tubotympanic) and unsafe (atticoantral). The distinction is critical because unsafe CSOM is often associated with cholesteatoma and carries a higher risk of complications, including ossicular destruction. The study was conducted to compare the pattern and prevalence of ossicular chain erosion in patients with safe and unsafe types of CSOM, based on intraoperative findings, in a tertiary care teaching hospital serving rural Bihar.

Materials and Methods: A prospective observational study was conducted on 150 patients diagnosed with CSOM (96 with safe type and 54 with unsafe type), who underwent middle ear surgery. Ossicular status was evaluated intraoperatively, focusing on the presence, erosion, or absence of the malleus, incus, and stapes.

Results: Ossicular erosion was observed in 28% of safe CSOM cases and in 82% of unsafe CSOM cases. The incus was the most commonly eroded ossicle in both types, particularly in the unsafe type (85%), followed by the stapes (21%) and the malleus (12%).

Conclusion: Ossicular damage is significantly higher in unsafe CSOM, indicating a more aggressive disease course. Early surgical intervention can preserve hearing and prevent complications, especially in rural populations where delayed presentation is common.

Key Words: CSOM, ossicular erosion, cholesteatoma, tubotympanic, atticoantral, rural India, middle ear surgery

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I. Introduction

CSOM, a common condition in otorhinolaryngology, is characterized by chronic, intermittent or persistent discharge through a perforated tympanic membrane. Poor living conditions, overcrowding, poor hygiene and nutrition have been suggested as the basis for the widespread prevalence of CSOM in developing countries (1,2). Globally, it affects over 65 million people annually, with a disproportionately high burden in low- and middle-income countries (LMICs). India, particularly its rural areas, continues to bear a significant share of this morbidity due to poor hygiene, overcrowding, inadequate healthcare access, and limited awareness.

CSOM is clinically categorized into:

- Safe CSOM (tubotympanic): Associated with central perforation and mucosal disease. It is termed 'safe' due to its relatively benign course and lower risk of complications.
- Unsafe CSOM (atticoantral): Typically involves marginal or attic perforation, often accompanied by cholesteatoma. This type is termed 'unsafe' because of its potential to erode bony structures, including the ossicles, and cause life-threatening complications like brain abscess, facial nerve paralysis, and labyrinthitis.

Both types of CSOM, tubotympanic which is considered safe, as well as atticoantral which is considered unsafe, may lead to erosion of the ossicular chain. This propensity for ossicular destruction is much greater in cases of unsafe CSOM, due to the presence of cholesteatoma and/or granulations (3). The proposed mechanism for erosion is chronic middle ear inflammation as a result of overproduction of cytokines—TNF alpha, interleukin-2, fibroblast growth factor, and platelet derived growth factor, which promote hypervascularisation, osteoclast activation and bone resorption causing ossicular damage. TNF-alpha also produces neovascularisation and hence granulation tissue formation. CSOM is thus an inflammatory process with a defective wound healing mechanism (4). This inflammatory process in the middle ear is more harmful the longer it stays and the nearer it is to the ossicular chain (5). The ossicular chain—comprising the malleus, incus, and stapes—plays a crucial role

in sound transmission. Damage to these structures due to chronic inflammation or cholesteatoma can lead to conductive hearing loss. Knowing the pattern of ossicular erosion is essential for surgical planning, ossicular reconstruction, and prognostication.

Pathologies that interrupt the ossicular chain result in large hearing losses. Complete disruption of the ossicular chain can result in a 60 dB hearing loss (6,7). We present here the intra-operative ossicular chain status of 150 cases of CSOM who underwent surgery, at our institution over a 12 month period including both safe and unsafe type pathology. This study aims to compare the intraoperative status of ossicles in safe and unsafe CSOM in patients from a rural region of Bihar, where delayed presentation is common, and ear care services are limited.

II. Material And Methods

This prospective comparative study was carried out on patients of Department of ENT at Katihar Medical College and Hospital, Katihar, Bihar from November 2023 to November 2024. A total 150 adult subjects (both male and females) of aged ≥ 18 , years were enrolled for in this study.

Study Design: Prospective open label observational study

Study Location: Department of ENT at Katihar Medical College and Hospital, Katihar, Bihar

Study Duration: November 2023 to November 2024

Sample size: 150 patients.

Subjects & selection method: Patients presenting with CSOM of either sex and age >16 years posted for middle ear surgery were included in the study using convenient sampling methodology.

Inclusion criteria:

1. Both gender
2. Patients with CSOM
3. Aged > 16 years

Exclusion Criteria

1. Congenital ear abnormalities
2. Recent ear surgery
3. Deaf
4. Pregnant women
5. On aminoglycoside, diuretic medication
6. Age <16 years

Procedure methodology

After written informed consent was obtained, all patients underwent detailed history and routine clinical examination of the ear using Bull's eye lamp, oto-endoscopy, Tuning fork tests, and PTA. Average air conduction hearing loss was obtained. Initially, routine tests such as blood tests, X-ray mastoid (bilateral Schueller's view) to assess the pathology and surgical anatomy of the mastoid. ECG were examined for all participants. Intra-operative middle ear findings including ossicular chain status, erosion of the individual ossicles, and continuity of the malleo-incudal and incudo-stapedial joint were noted. The ossicular chain status in safe and unsafe ear was compared statistically.

Preoperative Evaluation

- Otoscopic and otoendoscopic examination
- Audiological evaluation (Pure Tone Audiometry)
- HRCT temporal bone (in suspected cholesteatoma cases)
- Routine preoperative investigations

Surgical Approach

- Safe CSOM: Tympanoplasty with or without cortical mastoidectomy
- Unsafe CSOM: Modified radical mastoidectomy (MRM) or canal wall down procedures

Intraoperative Ossicular Assessment

The ossicular chain was examined for:

- Intactness or erosion of the **malleus, incus, and stapes**
- Degree of erosion: partial vs. complete
- Presence of ossicular discontinuity

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

A total of 150 cases were selected for this study and divided into 'safe' and 'unsafe' CSOM based on the history and clinical findings. The number of cases with safe CSOM was 96 (64.00%) and that with unsafe CSOM was 54 (36.00%). The patients were aged between 16 and 70 years. The mean age was 29.78 years with SD 13.09. The number of cases in the 16–25 years age group was 77 (51.33%), and this formed the largest group in the study. The number of male and female patients was 72 (48.00%) and 78 (52.00%). The right ear was operated in 78 (52.00%) cases and left ear in 72 (48.00%) cases.

The primary complaints of the patients were ear discharge, seen in 100% of the cases and hearing loss, seen in 88.67% of the cases. The duration of ear discharge ranged from 6 months to 50 years, with 39 cases (26.00%) having duration between 10 and 15 years. In safe CSOM, 26 (32.29%) cases had duration of ear discharge ranging from 1 to 5 years. In unsafe CSOM, 17 (35.19%) had discharge duration from 10 to 15 years.

Duration of hearing loss varied from patients who did not complain of any hearing loss to those who had the complaint for about 40 years. Maximum number, 50 (33.33%) cases complained of hearing loss from 1 to 5 years while 17 (11.33%) cases had no hearing loss. In safe CSOM 31 (32.39%) cases and in unsafe CSOM 17 (35.19%) cases were in this category.

Based on the intra-operative findings, the patients were reclassified into those with safe CSOM, 90 (60.00%) cases, and those with unsafe CSOM, 60 (40.00%) cases. Six (4.00%) cases which were clinically diagnosed as safe were found to be unsafe, intra-operatively.

Table no 1: Status of malleus in both safe and unsafe CSOM in our study

| Malleus | CSOM (%) <i>n</i> = 150 | Safe (%) <i>n</i> = 90 | Unsafe (%) <i>n</i> = 60 | <i>P</i> value |
|------------------------|-------------------------|------------------------|--------------------------|----------------|
| Intact | 121 (80.67) | 88 (97.78) | 33 (55.00) | 0.028* |
| HOM necrosed | 18 (12.00) | 2 (2.22) | 16 (26.67) | 0.000* |
| Head necrosed | 4 (2.67) | – | 4 (6.67) | 0.016* |
| Handle + head necrosed | 1 (0.66) | – | 1 (1.66) | 0.223 |
| Absent | 6 (4.00) | – | 6 (10.00) | 0.004* |
| Total | 150 (0.00) | 90 (100.00) | 60 (100.00) | |

The malleus was found to be the most resistant ossicle to erosion in CSOM. It was found intact in 121 (80.67%), eroded in 23 (15.33%) and absent in 6 (4.00%) of the cases. In safe CSOM, 88 (97.78%) of the cases had an intact malleus while in 2 (2.22%) cases the tip of handle of malleus was found necrosed. In unsafe CSOM, the malleus was found intact in 33 (55.00%), necrosed in 21 (35.00%) and absent in 6 (10.00%) cases (Table 1).

Table no 2: Status of incus in both safe and unsafe CSOM in our study

| Incus | CSOM (%) <i>n</i> = 150 | Safe (%) <i>n</i> = 90 | Unsafe (%) <i>n</i> = 60 | <i>P</i> value |
|-------------------------------------|-------------------------|------------------------|--------------------------|----------------|
| Intact | 92 (61.33) | 83 (92.23) | 9 (15.00) | 0.000* |
| Absent | 26 (17.33) | 2 (2.22) | 24 (40.00) | 0.000* |
| Long + lenticular process necrosed | 23 (15.33) | 2 (2.22) | 21 (35.00) | 0.000* |
| Lenticular process necrosed | 4 (2.66) | 3 (3.33) | 1 (0.67) | 0.545 |
| Short process necrosed | 1 (0.67) | – | 1 (0.67) | 0.223 |
| Body + long process necrosed | 1 (0.67) | – | 1 (0.67) | 0.223 |
| Body + lenticular process necrosed | 1 (0.67) | – | 1 (0.67) | 0.223 |
| Long + short process necrosed | 1 (0.67) | – | 1 (0.67) | 0.223 |
| Lenticular + short process necrosed | 1 (0.67) | – | 1 (0.67) | 0.223 |
| Total | 150 (100.00) | 90 (100.00) | 60 (100.00) | |

Incus was the ossicle most commonly found eroded in our study. We found the incus intact in 92 (61.33%), eroded in 32 (21.34%) and absent in 26 (17.33%) cases. The most commonly necrosed parts of the incus were the lenticular process in 29 (19.33%) and the long process in 25 (16.67%) of the cases. In safe CSOM, the incus was found intact in 83 (92.23%), eroded in 5 (5.55%), and absent in 2 (2.22%) cases. Lenticular process was the most commonly necrosed part of the incus and was found eroded in 5 (5.55%) cases.

In unsafe CSOM, the incus was found intact in 9 (15.00%), necrosed in 27 (45.00%) and absent in 24 (40.00%) cases. Lenticular process was, once again, the most commonly necrosed part of the incus and was found eroded in 24 (40.00%) cases, followed closely by the long process, which was eroded in 23 (38.33%) cases (Table 2).

Table no 3: Status of stapes in both safe and unsafe CSOM in our study

| Stapes | CSOM (%) <i>n</i> = 150 | Safe (%) <i>n</i> = 90 | Unsafe (%) <i>n</i> = 60 | <i>P</i> value |
|-------------------------|-------------------------|------------------------|--------------------------|----------------|
| Intact | 118 (78.67) | 89 (98.89) | 29 (48.33) | 0.008* |
| Superstructure necrosed | 32 (21.33) | 1 (1.11) | 31 (51.67) | 0.000* |
| Total | 150 (100.00) | 90 (100.00) | 60 (100.00) | |

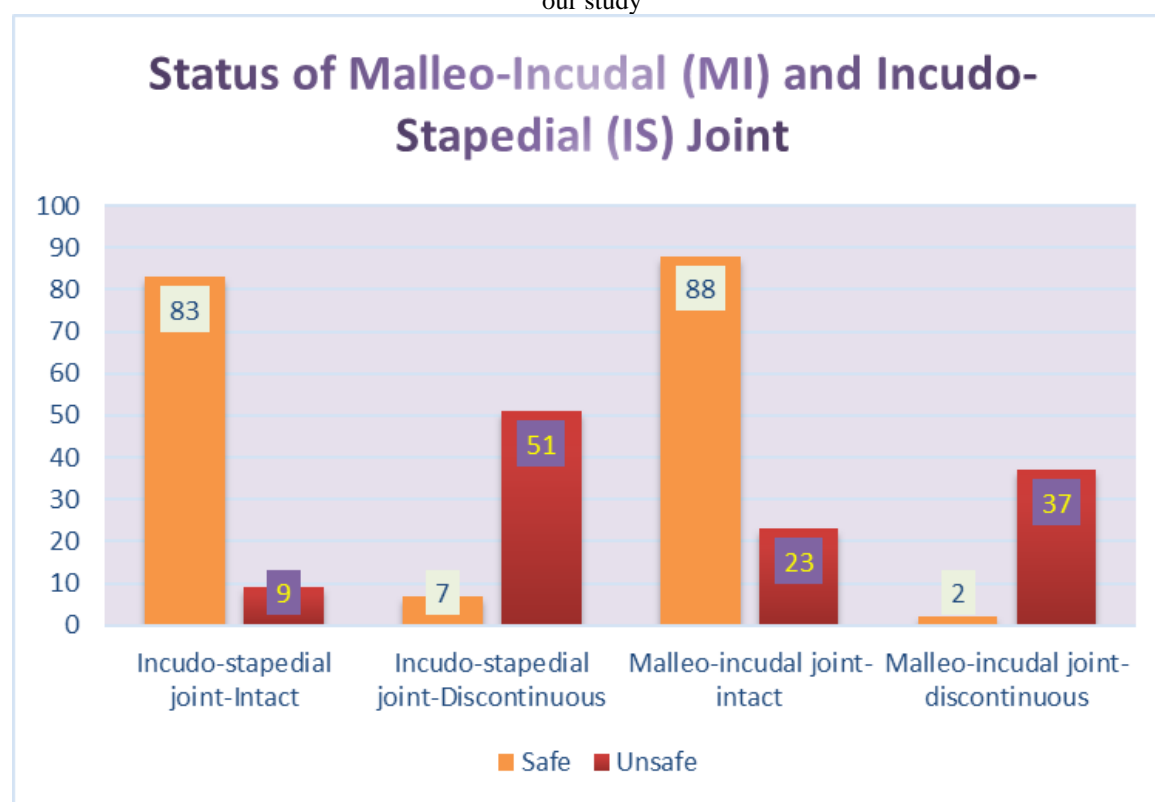
Stapes was found intact in 118 (78.67%) cases while in 32 (21.33%), the superstructure of stapes was found eroded by the disease. In safe CSOM, 89 (98.89%) of the cases had an intact stapes and only 1 (1.11%) case had erosion of the superstructure. In unsafe CSOM, 29 (48.33%) cases had an intact stapes and 31 (51.67%) showed erosion of the superstructure of stapes (Table 3).

Status of Malleo-Incudal (MI) and Incudo-Stapedial (IS) Joint

The malleo-incudal joint was found intact in 111 (74.00%) and discontinuous in 39 (26.00%) cases. In safe CSOM, malleo incudal joint was intact in 88 (97.78%) cases. In unsafe CSOM, malleo incudal joint was and discontinuous in 37 (61.67%) cases.

The incudo-stapedial joint was found intact in 92 cases (61.33%) and discontinuous in 58 (38.67%) cases of CSOM. In safe CSOM, it was intact in 83 (92.22%) cases of the cases and discontinuous in 7 (7.78%). In unsafe CSOM, it was intact only in 9 (15.00%) cases and discontinuous in 51 (85.00%) (Fig. 1).

Figure no 1: Status of Malleo-Incudal (MI) and Incudo-Stapedial (IS) Joint in both safe and unsafe CSOM in our study



Status of Ossicular Chain

The ossicular chain was found intact (M+I+S+) in 92 (61.34%) cases. In safe CSOM, 83 cases (92.22%) had an intact chain, 7 cases (7.77%) had ossicular damage. In unsafe CSOM, intact malleus with eroded incus and stapes (M+S-) was seen in 16 (26.67%) cases, followed by M-S- in 15 cases (25.00%) (Figs. 2,3).

Figure no 2: Ossicular Status of Malleus-Incus and Stapedius in safe CSOM in our study

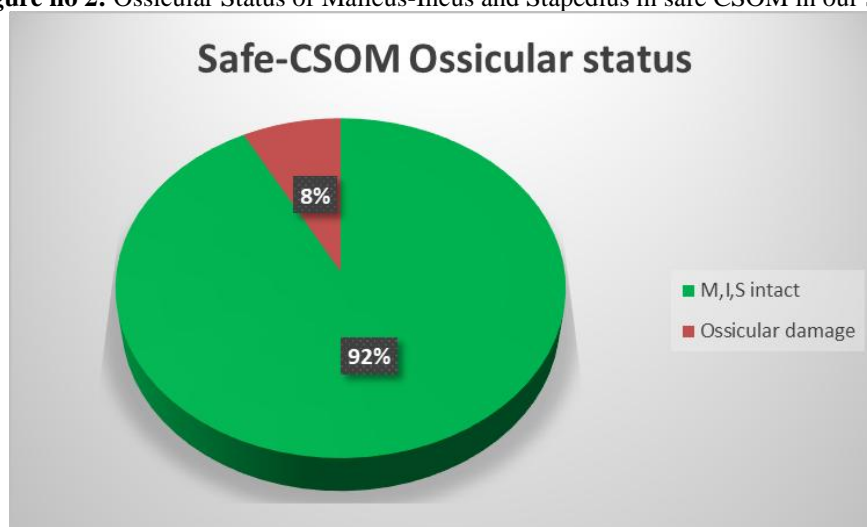
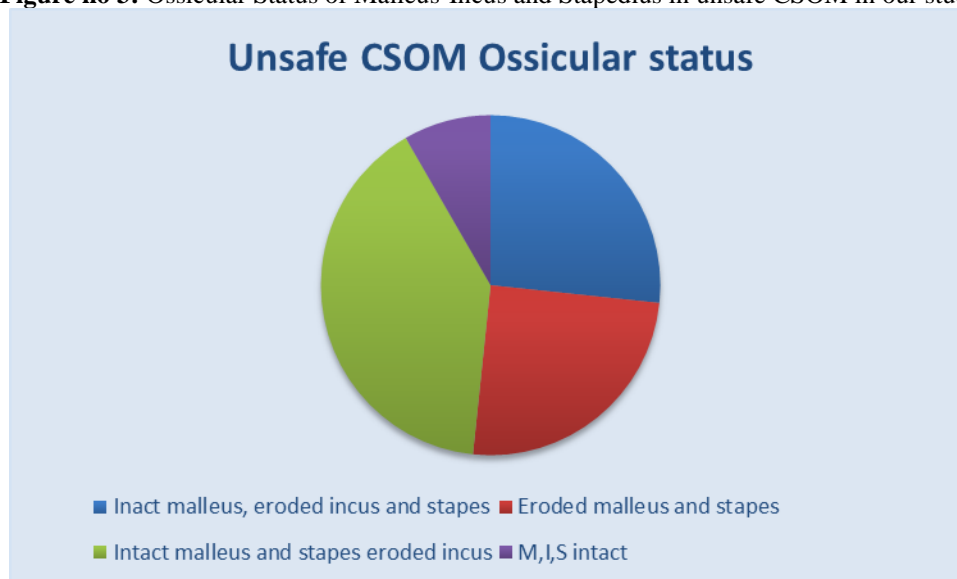


Figure no 3: Ossicular Status of Malleus-Incus and Stapedius in unsafe CSOM in our study



- **Incus** was the most frequently eroded ossicle in both types, but especially in unsafe CSOM.
- **Stapes erosion** was significant in unsafe CSOM, often involving the suprastructure.
- **Malleus** was relatively preserved, especially in safe CSOM.

IV. Discussion

In this study we studied a total of 150 patients of CSOM to assess the intra-operative ossicular status.

The cases were divided clinically into safe CSOM, 96 (64.00%) cases, and unsafe CSOM, 54 (36.00%) cases. Intra-operatively, 90 (60.00%) cases were found to be safe and 60 (40.00%) cases to be unsafe. Six (4.00%) cases which were clinically diagnosed as safe were found to be unsafe intra-operatively.

The most commonly affected age group was between 16 and 25 years, as observed by various other studies also (8-10). The early presentation may be due to increased awareness to health issues and difficulty in hearing affecting the work efficiency, leading patients and parents to seek early medical intervention. The ratio of male to female patients was 1.00:1.08. Similar findings have been reported by several other authors (11-13).

The findings demonstrate that **unsafe CSOM** is significantly more destructive to the ossicular chain than safe CSOM. The **incus** is particularly vulnerable, likely due to its poor vascularity and tenuous anchorage. **Stapes erosion**—particularly of the suprastructure—is frequently associated with cholesteatoma-mediated enzymatic activity and pressure necrosis.

Our study supports the observations made by:

- **Mokhtar et al. (2020)**, who reported incus erosion in 72% and stapes in 58% of unsafe CSOM cases (14).
- **Sinha et al. (2019)**, who documented similar patterns in the rural population of Bihar (15).

The duration of hearing loss was in all cases found to be lesser than the duration of discharge. This may be attributed to difficulty in appreciating minor degrees of hearing loss by the patient. The hearing loss would be noticed only when the disease has progressed sufficiently to cause a significant impairment of hearing by perforation or ossicular destruction.

Malleus was found to be the most resistant ossicle, found intact in 121 (80.67%) cases in our study. It was eroded in 23 (15.33%) and absent in 6 (4.00%) cases. The handle of malleus in 19 (12.66%) cases, was the most commonly necrosed part of malleus. In safe CSOM, malleus was intact in 88 (97.78%) and eroded in 2 (2.22%) cases. In unsafe CSOM, malleus was intact in 33 (55.00%), eroded in 21 (35.00%) and absent in 6 (10.00%). These findings were consistent with those of Udaipurwala et al. (17). Sade et al. found a higher incidence, around 06.00%, of erosion of malleus in cases of safe CSOM. In unsafe disease they found malleus necrosis in 26.00% cases which correlates well with our finding (5).

Incus was observed to be the most common ossicle to get necrosed in cases of CSOM. In our study, incus was found intact in 92 (61.33%) cases, eroded in 32 (21.34%) cases and absent in 26 (17.33%) cases. The commonest defect was erosion of the lenticular process in 29 (19.33%) cases followed by long process in 25 (16.67%) cases. In safe CSOM, incus was intact in 83 (92.23%) cases, eroded in 5 (5.55%) cases and absent in 2 (2.22%) cases while in unsafe CSOM it was intact in 9 (15.00%) cases, eroded in 27 (45.00%) cases and absent in 24 (40.00%) cases. The most frequently involved parts were again the lenticular process (40.00%) and the long process (38.33%) of incus. Udaipurwala et al. had a very similar incidence of necrosis of the incus at 41.00%. The long process of incus was found to be the most commonly necrosed part as compared to our study where lenticular process was more commonly necrosed. This can be explained, as Udaipurwala et al. have probably considered the lenticular process to be a part of the long process of incus, since they have not mentioned it separately (17). Austin reported the most common ossicular defect to be the erosion of incus, with intact malleus and stapes, in 29.50% cases (18). Kartush found erosion of long process of incus with an intact malleus handle and stapes superstructure (type A) as the most common ossicular defect (19). Shreshtha et al. and Mathur et al. also reported similar findings in unsafe CSOM (20,21).

Stapes was found intact in 118 (78.67%) cases and involvement of stapes superstructure was noted in 32 (21.33%) cases of CSOM. The footplate was found intact in all cases. In safe CSOM, stapes was found intact in 89 (98.89%) cases and eroded in 1 (1.11%) case. In unsafe CSOM, stapes was intact in 29 (48.33%) cases and eroded in 31 (51.67%) cases.

The incidence of stapedia necrosis in our study was found to be very similar to the study by Udaipurwala et al. They found the superstructure to be necrosed in 21.00% cases, which matches with our findings (17). Austin reported erosion of stapes at around 15.50% (18). Sade et al. reported stapes involvement in unsafe CSOM to be 36.00% (5). Shreshtha et al. found involvement of stapes superstructure in 15.00% cases of unsafe CSOM (20). Motwani et al. reported stapes arch necrosis in 30.00% cases of CSOM (22).

We found an intact and mobile ossicular chain (M+I+S+) in 92 (61.34%) of our cases. In safe CSOM the ossicles were mostly intact. M+S+ configuration was found in 5.55%. M-S+ and M-S- both were 1.11% each. In unsafe CSOM, we found only 9 (15.00%) cases with intact ossicular chain. M+S+ was seen in 8 (13.33%) cases, M-S+ in 12 (20.00%) cases, M+S- in 16 (26.67%) cases and M-S- in 15 (25.00%) cases. These findings were in tandem with those of Dasgupta et al. in two studies on unsafe CSOM. Toran et al. reported similar findings of ossicular chain in M-S- category (23-25).

Late presentation, untreated infections, and lack of awareness contribute to widespread ossicular damage in rural patients. Most patients sought care only after substantial hearing loss had occurred, and some had associated complications like facial nerve dehiscence or labyrinthine fistula.

Understanding ossicular status is not just academically important but essential for:

- Surgical planning (ossiculoplasty vs. second-stage surgery)
- Counseling patients about realistic postoperative hearing expectations

V. Conclusion

This study confirms that ossicular erosion is significantly more prevalent and severe in unsafe CSOM, with the incus being the most frequently eroded, followed by the stapes and malleus. In contrast, safe CSOM tends to preserve the ossicular chain better.

Early identification and timely surgical intervention can reduce the burden of hearing loss and associated complications in rural populations. Integration of ENT services into rural primary care and awareness campaigns can make a significant difference in long-term outcomes.

Limitations

- The study was limited to a single center
- No postoperative audiological outcomes were evaluated
- Cholesteatoma extent was not graded

Recommendations

- Routine ENT screening in schools and community health centers
- Training primary care physicians to detect early signs of unsafe CSOM
- Promoting early referral and subsidized surgical services.

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