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Original Research Article

Correlation of Chole Classification with Hearing Outcomes

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Abstract:

Introduction: Cholesteatoma is a progressive disease that may impair the patient's quality of life and bears the risk of very serious intracranial complications such as meningitis, brain abscess and sigmoid sinus thrombosis

Materials and Methodology: It is a prospective study conducted at pramukh swami medical collage Shree Krishna Hospital, Karamsad, 83 patients with chronic otitis media with cholesteatoma underwent surgery between January 2020 and January 2024. Data was collected using a prestandard proforma, including demographic information, medical history, clinical examination findings, preoperative HRCT, and pure tone audiometry (PTA).Intraoperative notes provided details on ossicular chain status, cholesteatoma extension, and surgical complications. The "Chole Online App" was used to calculate the chole score for staging the cases. Follow-up assessments were conducted for three months postoperatively, comparing postoperative PTA with the chole stage and preoperative PTA.

Results: The study included 42 males (50.60%) and 41 females (49.40%), with a mean age of 28.58 years. Class II ChOLE was the most common stage, accounting for 83.13% of cases. Postoperative results showed a significant reduction in mean AC Threshold (preop 54.51 dB vs. Post op 33.67 dB, p=0.0038). The CHOLE classification correlated well with preoperative and postoperative AC thresholds, and its subdivisions (ossicular chain status, cholesteatoma extension, and complications) also showed strong correlations.

Conclusion: ChOLE classification has predictive value in both pre and postoperative hearing outcomes following middle ear surgeries Specifically, patients with cholesteatoma with varying extensions, ossicular erosion and complications as classified by ChOLE. Clinicians can leverage this information to tailor treatment strategies and manage patient expectations effectively, ultimately optimizing postoperative hearing outcomes.

Keywords: ChOLE, Cholesteatoma.

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Introduction

Cholesteatoma is a progressive disease that may impair the patient's quality of life and bears the risk of very serious intracranial complications such as meningitis, brain abscess and sigmoid sinus thrombosis. [12] Its diagnosis always leads to an indication for surgery with the principle of complete removal of the keratinizing epithelium from the mastoid and middle ear including hearing restoration. [12] We here aimed to systematically investigate the association between the ChOLE classification and hearing. These data may increase the utility of the ChOLE classification in clinical practice and research by stratifying patients according to expected outcomes or risks for complications. [13]

The ChOLE classification consists of four subdivisions: [14]

- Ch: The extent of the cholesteatoma inside the middle ear and temporal bone
- O: The status of the ossicular chain
- L: Life threatening complications
- E: Eustachian tube function as defined by the aeriation of the temporal bone

The results of this study shows that larger cholesteatomas tend to have poorer hearing thresholds preoperatively. This effect can no longer be observed with the postoperative values after hearing restoration and regarding the shifts. It is hypothesized that the results of hearing restoration are comparable independently from the size of the cholesteatoma. This finding is well in accordance to existing studies demonstrating that even after largely extended cholesteatoma, a satisfying hearing restoration can be achieved. [12]

The study by David Bächinger Adrian Rrahman Nora M. Weiss Evaluating hearing outcome and complications in cholesteatoma surgery using the ChOLE classification system ·The ChOLE classification is a new system to classify cholesteatomas. This study provides evidence that hearing outcomes vary among different ChOLE stages. There was no association between the ChOLE stage and the difference of pre- and postoperative hearing. In particular, hearing outcomes are associated with the ChOLE subdivision "O" and "L". Thus, the ChOLE classification system has a predictive value regarding hearing outcomes.[13]

The study by Priti Hajare used ChOLE Classification to evaluate treatment outcomes found that according to ChOLE classification stage II cholesteatoma was the most prevalent and statistically significant improvement in postoperative ABG. they concluded that Staging of cholesteatoma by ChOLE classification allows standardization in assessment of gravity of disease and in reporting surgical outcomes.[25]

Despite being a common otologic diagnosis, there are still large differences in the definition, classifications and management of cholesteatomas [13]. Yet, standardized reporting of cholesteatoma characteristics and surgical outcomes is a prerequisite for comparison of surgical techniques and outcomes among a different center. So our study will help in adding database of this new classification as there is not much literature is available in India. It will help in standardized reporting of cholesteatoma.

Materials and Methodology

Source of Data: All Patients, regardless of age and sex, presenting to the ENT department Shree Krishna Hospital, Karamsad during the study period with chronic otitis media with cholesteatoma underwent surgery were included in the study.

Methodology: It is a record-based study. Study period-January 2020 till IEC approval Retrolective data and from IEC approval till January 2024 protective data During the study period, 89 cases of chronic otitis media with cholesteatoma underwent surgery out of which 6 patient was loss to follow up leaving 83 patients with data for analyses are included in study. A prestandard Proforma were used to collect Patients' demographic data, medical history, clinical examination findings, preoperative HRCT scans of the temporal bone, and preoperative pure tone audiometry (PTA) results were taken from the patient's records. Information regarding ossicular chain status, cholesteatoma extension, and the presence of any complications during surgery was recorded from intraoperative notes. The data from all 83 cases were entered into the "Chole Online App," a freely accessible tool that calculates a chole score. This score was then used to classify the staging of the cases. Surgically treated cases were followed up to the third postoperative month for postoperative PTA, which was then compared with the chole stage and preoperative PTA results.

Details about ChOLE Classification

Score Description for cholesteatoma extension (intra operative) findings

Chx: not identifiable (not specified)

Ch1: Middle ear space

A: Middle ear cavity and/ or limited extension toward epitympanum

B: Middle ear cavity and/ or limited extension toward epitympanum + sinus tympanum

Ch2: Middle Ear and Attic and Antrum (up to lateral canal)

A: Middle ear with extension into the attic and mastoid

B: Middle ear with extension into the attic and mastoid +supratubal space

/Eustachian tube and /or sinus tympani

Ch3: Extensive Destruction

Stage 2a or 2b + wide exposure into mastoid and /or extensive canal wall destruction

Ch4:

A: Supra labyrinthine or Infra labyrinthine Extensions

B: Petrous Apex Cholesteatoma medial to otic capsule

Intra operative ossicular chain status

Ox: not identifiable (not specified)

O0: ossicular chain intact

O1: Malleus and Stapes present

O2: Malleus and stapes Footplate only

O3: Stapes only / Mobile Footplate only

O4: Fixed Stapes only / Fixed Footplate only

L- life threatening complications:

Lx: not identifiable (not specified**)**

L2**:** Mastoiditis, mastoid fistula, Facial palsy, Labyrinthine fistula, labyrinthitis or Tegmen defect requiring surgical repair

L4: Meningitis, Brain abscess (temporal and cerebellar lobe abscess),

Subdural abscess, Sigmoid sinus thrombosis

Eustachian tube function: pneumatization and ventilation of mastoid air cells on CT scan

Ex: not identifiable (not specified)

E0 - >50 % cells aerated

E1 - <50 % cells aerated

E2 - poor pneumatization and ventilation

CHOLE score:

Classification: CHOLE class

Class I: 1-3

Class II: 4-8

Class III: >8

Inclusion Criteria: All Patients with chronic otitis media with cholesteatoma underwent surgery were included in the study.

Exclusion Criteria: Child bellow 10 year of age and mentally retarded patient and revision cases were excluded from the study.

Results

A total of 83 patients were included in the study out of which 42 [50.60%] were males and 41 [49.40%] were females with a mean age of 28.58 years (SD 14.80 years). The affected side was left in 44 (53.01%) cases and right in 39 (46.99%) cases. This suggests a nearly equal distribution of genders within this study.

- Out of 83 cases 33(39.75%) cases had attic cholesteatoma and 50 (60.24%) cases had posterosuperior quadrant cholesteatoma. Thus, majority of the cases had posterosuperior quadrant cholesteatoma.
- The mean pre-operative AC threshold was found to be 54.51 dB while the mean post-operative AC threshold was 50.42 dB. The calculated pvalue for this correlation was 0.0029, indicating that there is a significant decrease in AC threshold following surgery.
- Majority of cases exhibit extensive ossicular chain destruction in with stapes only / mobile footplate only (O3) at 61.45%, followed by O2 in which malleus and stapes footplate present at 18.07% and O1 in which malleus and stapes present 15.66%. Notably, complete preservation of the ossicular chain (O0) is rare, constituting only 4.82% of cases. The p-value for pre-operative mean AC threshold is 0.0462, and for post-operative mean AC threshold is 0.0147, which indicate increased AC threshold with increasing Ossicular chain erosion.

The majority of cases exhibit stage Ch2 of chole classification in which disease limited to middle ear and attic and antrum (74.69%), followed by Ch1 in which disease limited to middel ear space (12.04%) and a extensive extensive destruction (Ch3)(13.25%), with no cases of supra labyrinthine or infra labyrinthine extension or petrous apex cholesteatoma (Ch4).The mean pre-operative and post operative AC threshold increases with extend of disease indicating that extensive cholesteatoma has the highest mean AC threshold before surgery

- The majority of cases had no complications (Lx) at 85.54%, followed by cases with extracranial complications (L2) at 12.04%, with a minority experiencing intracranial complications (L4) at 2.41%. There is a progressive worsening in both pre- and post-operative AC thresholds with increasing severity of complications (no complications < extra-cranial < intracranial).
- In the present study, cases exhibiting <50 % cells aereated(E1) at 48.19%, were marginally outnumbered by sclerosed mastoid (E2) at 43.37%, with well pneumatization (E0) being less prevalent at 8.43%.The mean preoperative AC threshold varied across the different mastoid pneumatization groups, with well pneumatization (E0) having the lowest mean of 40.71 dB, followed by sclerosed mastoid (E2) with 52.63 dB, and E1(<50 % cells aereated) with the highest mean of 58.62 dB. Similarly, the mean post-operative AC threshold showed variations among the groups, with E0 having a mean of 40.71 dB, E2 with 48.75 dB, and E1 with 53.62 dB. They suggest that the mastoid pneumatization has no significance role on hearing outcomes both before and after surgical intervention.

Table 1: Correlation of Chole class with Mean pre op AC threshold and post op AC threshold

Chole Class (chole score)	Number of case (%)	Mean pre op AC threshold in dB	Mean post op AC threshold in dB
Class I (1-3)	5(6.02%)	37 dB	27 dB
Class II (4-8)	69(83.13%)	55.14 dB	50.50 dB
Class III (>8)	9(10.84%)	59.44 dB	62.77 dB

As shown in table I The mean pre-operative AC threshold varied across the different cholesteatoma classes, with Class I having the lowest mean of 37 dB, followed by Class II with 55.14 dB, and Class III with 59.44 dB.

Similarly, the mean post-operative AC threshold levels showed variations among the classes, with Class I having the lowest mean of 27 dB, followed by Class II with 50.50 dB, and Class III with 62.77 dB which indicate increase in AC threshold from class I-III.

The p-value for mean pre-operative and post-operative AC threshold within Class II is 0.0030, indicating a significant decrease in AC threshold following surgery in class II. Additionally, the p-values for comparisons between Class II and Class I are 0.0575 for pre-operative AC threshold and 0.0033 for post-operative AC threshold, suggesting class II has higher AC threshold than the class I.Furthermore, comparisons between Class III and Class I showed significant differences in both pre-operative and post-operative AC threshold (p=0.019 for pre-operative AC threshold, p=0.002 for post-operative AC threshold), indicating that Class III has significantly higher AC threshold compared to Class I.These findings highlight the association between cholesteatoma class and both pre-operative and post-operative AC threshold . They suggest that the severity or extent of cholesteatoma may influence hearing outcomes both before and after surgery.

As shown in table I The mean pre-operative AC threshold varied across different cholesteatoma classes, with Class I having the lowest mean of 37 dB, followed by Class II at 55.14 dB, and Class III at 59.44 dB, indicating an increase in AC threshold from Class I to Class III. The p-value for the comparison between Class II and Class I is 0.0575, suggesting Class II has a higher AC threshold than Class I. Moreover, the p value for the comparison between Class III and Class I is 0.019, indicating that Class III has a significantly higher AC threshold than Class I before surgery.

The mean post-operative AC threshold levels showed variations among the classes, with Class I having the lowest mean of 27 dB, followed by Class II with 50.50 dB, and Class III with 62.77 dB, which indicate an increase in AC threshold from Class I to Class III. The p-values for comparisons between Class II and Class I are 0.0033 for post-operative AC threshold, suggesting Class II has a higher AC threshold than the Class I. The p-values for comparisons between Class III and Class I are 0.002 for post-operative AC threshold, Class III has a higher AC threshold than the Class I after surgery.

The p-value for mean pre-operative and post-operative AC threshold within Class II is 0.0030, indicating a significant decrease in AC threshold following surgery in Class II. These findings highlight the association between cholesteatoma class and both pre-operative and post-operative AC threshold. They suggest that the severity or extent of cholesteatoma may influence hearing outcomes both before and after surgery

Images

Figure 1: Intra OP picture of Cholesteatoma at Mastoid Tip

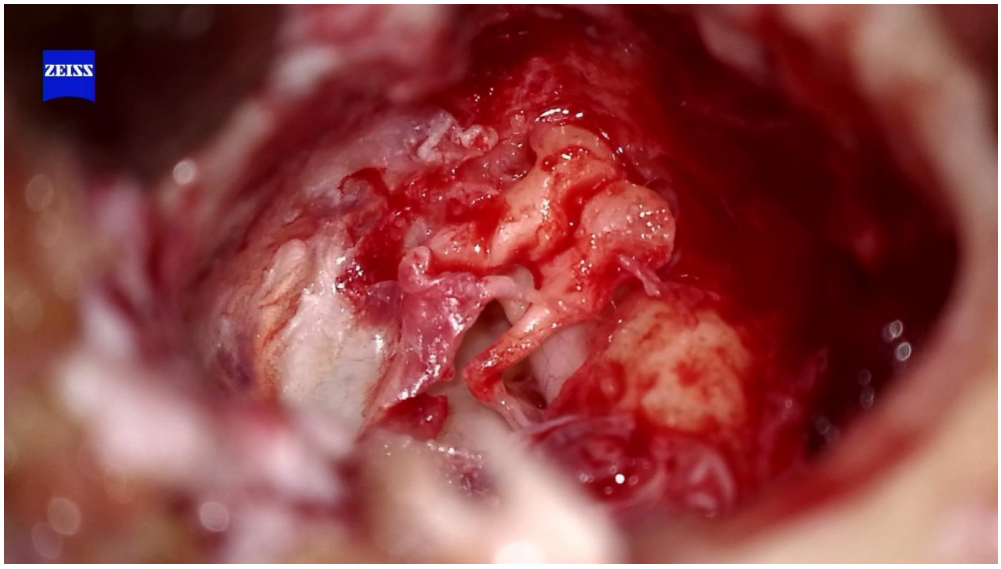

Figure 2: Intact Ossicles After Removal of Cholesteatoma

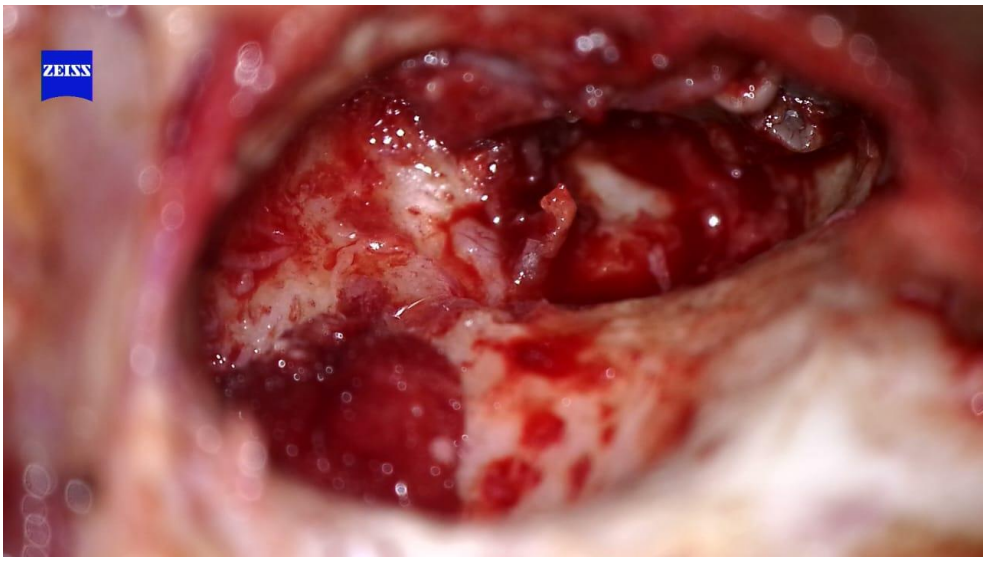

Figure 3: Image of intra op MRM with Dehiscent Facial and stapes Head

Discussion

Chronic otitis media accompanied by cholesteatoma formation is a prevalent condition within otology, often necessitating surgical intervention in the majority of instances and posing risks of serious intracranial complications if not managed effectively. The primary objective of cholesteatoma surgery is the complete elimination of the disease and the prevention of its recurrence. Secondary goals include achieving a dry ear and preserving or enhancing auditory function. [28] Frequent reliance on subjective descriptions by surgeons, particularly regarding cholesteatoma extent, poses challenges in objectively comparing surgical techniques and outcomes. Classification systems have been proposed to address this issue, aiming to standardize reporting and enable better comparison. These systems often focus on factors like the localization of adhesions or retraction pockets, which are deemed crucial. Notably, cholesteatomas impacting the pars tensa tend to result in poorer post-surgical hearing outcomes. Despite cholesteatoma's common occurrence, significant disparities persist in its definition, classifications, and management. Standardized reporting of cholesteatoma characteristics and surgical results is essential for facilitating meaningful comparisons across international centers.[13] During conferences and panel discussions, otologic surgeons frequently discuss cholesteatomas described as "huge," with "massive" extensions, and displaying "severe" bony erosion. However, the absence of a uniform classification system poses challenges in objectively comparing outcomes and learning from colleagues' surgical approaches. Previous efforts to classify cholesteatoma disease have been made, including modifications of the TNM system utilized for tumors and reliance on anatomical barriers or

prognostic factors. Despite these attempts, none have gained widespread adoption. [14]

The latest classifications of cholesteatoma have evolved to better guide surgeons in selecting the most suitable surgical approach, considering factors such as the extent of the condition and associated complications like abscesses or facial palsy. Unlike previous classifications that primarily focused on growth patterns and extension, newer systems like the ChOLE classification offer a more comprehensive assessment. This includes considerations such as mastoid pneumatization, ossicular chain status, and clinical symptoms, providing a more nuanced understanding of the condition. The ChOLE classification system divides cholesteatoma cases into four subdivisions: Ch for extent within the middle ear and temporal bone, O for ossicular chain status, L for life-threatening complications, and E for Eustachian tube function based on temporal bone aeration. By incorporating these additional factors, the ChOLE classification enhances surgical decision-making and facilitates better comparisons of outcomes across different surgeons and medical centers. [12] A numerical staging system is employed to categorize cholesteatoma severity, with stages spanning from stage I to stage III. [13] To effectively compare surgical outcomes across different techniques, it's essential to categorize the baseline severity of the disease as well. Implementing the ChOLE classification system for reporting cholesteatoma cases will streamline these crucial discussions and facilitate meaningful comparisons. [14]

These findings could enhance the practicality of the ChOLE classification in both clinical settings and research endeavors by stratifying patients based on anticipated outcomes or risks for complications. Thus, our study aimed to explore the correlation between the ChOLE classification system and hearing outcomes. Numerous studies conducted over recent decades have identified factors influencing hearing outcomes following tympanomastoid surgery for cholesteatoma. Notably, the preservation of the stapes suprastructure consistently predicts favorable hearing outcomes, whereas factors such as large perforations, otorrhea, and the absence of the malleus handle are associated with less favorable hearing outcomes. These results underscore the significance of the ossicular chain in determining postoperative hearing outcomes.[13]

While the ChOLE classification provides valuable information for surgical planning and prognostication, it is important to note that hearing outcomes can vary widely among individuals based on a combination of factors beyond the extent of cholesteatoma involvement. These factors include pre-existing hearing status, surgical expertise, patient factors, and post-operative care. Therefore, while the ChOLE classification may offer insights into potential challenges and outcomes, individualized assessment and management are essential for optimizing hearing outcomes in patients undergoing cholesteatoma surgery.

The present study was carried out in 83 cases with chronic otitis media with cholesteatoma, who presented to the Department of Otorhinolaryngology and Head and Neck Surgery at Shree Krishna Hospital, Karamsad and underwent surgery during the study period. It was carried out during the time period between January 2020 till IEC approval retrolective data and from IEC approval till January 2024 prospective data. A prestandard Performa were used to collect relevant data from patients' records. Patients' demographic data, medical history, clinical examination findings, preoperative HRCT scans of the temporal bone, and preoperative pure tone audiometry (PTA) results were collected from the records. Information regarding ossicular chain status, cholesteatoma extension, and the presence of any complications during surgery was recorded from intraoperative notes. The data from all 83 cases were entered into the "ChOLE Online App," a freely accessible tool that calculates a ChOLE score. This score was then used to classify the staging of the cases. Surgically treated cases were followed up to the third postoperative month for postoperative pure tone average.

Correlation of ChoLE class with hearing outcomes: In our study mean pre-operative air conduction threshold increase with increase in class. The p-value for the comparison between disease confined to middle ear attic and antrum with ossicular erosion (Class II) and disease confined to middle ear without any complications (Class I) is 0.0575, suggesting that middle ear attic and antrum with ossicular erosion (Class II) has a higher air conduction threshold than disease confined to middle ear without any complications (Class I). Moreover, the p-value for the comparison between extensive disease (Class III) and disease confined to middle ear without any complications (Class I) is 0.019, indicating that extensive disease (Class III) has a significantly higher air conduction threshold than disease confined to middle ear without any complications (Class I) before surgery.In

Nora M. Weiss et al.'s study, a significant relationship was identified between cholesteatoma stages and preoperative air conduction pure-tone average. They observed a trend towards higher hearing thresholds with larger cholesteatomas, particularly between stage I and stage III cholesteatomas (p=0.006), as well as between stage II and stage III cholesteatomas (p=0.02). Both our study and n Nora M. Weiss et al.'s study found that more extensive cholesteatoma is associated with worse pre-operative hearing (higher air conduction thresholds). This is consistent, as more extensive

disease is likely to cause more significant mechanical disruption and ossicular erosion, leading to worse hearing before surgery.

In our study post-operative air conduction threshold increase with increase in class. The p-values for comparisons between middle ear attic and antrum with ossicular erosion (Class II) and disease confined to middle ear without any complications (Class I) are 0.0033 for post-operative air conduction threshold, suggesting middle ear attic and antrum with ossicular erosion (Class II) has a higher air conduction threshold than the disease confined to middle ear without any complications (Class I). The p-values for comparisons between extensive disease (Class III) and disease confined to middle ear without any complications (Class I) are 0.002 for post-operative air conduction threshold, suggesting extensive disease (Class III) has a higher air conduction threshold than the disease confined to middle ear without any complications (Class I) after surgery. While In Nora M. Weiss et al.'s study there was no association found between the Chole stage and either the air-bone gap or air-bone gap shift, or post op air conduction threshold indicating that the stage of cholesteatoma did not significantly impact hearing outcomes. In David Bächinger et al.'s study, they observed a trend towards increasing postoperative air conduction thresholds with higher Chole stages ($p = 0.05$). In our study found a significant relationship between cholesteatoma class and post-operative air conduction thresholds, with higher thresholds in more severe classes. In David Bächinger et al..'s study found a trend towards higher post-operative air conduction thresholds with higher stages aligning somewhat with our findings. Weiss et al.'s study did not find a significant post-operative trend which contrasts with our findings and Bächinger et al.'s study. Differences in clinical management, surgeon expertise, and the extent of surgical intervention (e.g., ossicular reconstruction) could impact outcomes

Conclusion

The CHOLE classification correlate well with pre and post-operative AC threshold. The subdivision of Chole classification the ossicular chain status (0), Cholesteatoma extension (Ch) and complications (L) correlate well with pre and post-operative AC threshold. Although the study suggests mastoid pneumatization did not significantly impact overall hearing outcome. ChOLE classification has predictive value in both pre and postoperative hearing outcomes following middle ear surgeries Specifically, patients with cholesteatoma with varying extensions, ossicular erosion and complications as classified by ChOLE. Clinicians can leverage this information to tailor treatment strategies and manage patient expectations effectively, ultimately optimizing postoperative hearing outcomes

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