

Association of Preoperative Audiological and Radiological Ossicular Findings with Peroperative Findings in Patients with Chronic Otitis Media- A Prospective Clinical Study

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ABSTRACT

Introduction: Chronic Otitis Media (COM) refers to a chronic infection of mucosa lining the middle ear cleft and is the leading cause of conductive hearing loss in adults. The erosion or disruption of ossicular chain is determined while during the surgery. Complete disruption of ossicular chain can lead up to 60 decibels (dB) hearing loss. Preoperative High-Resolution Computed Tomography (HRCT) scan of temporal bone can give a clue of ossicular integrity.

Aim: To determine the association of preoperative audiological and radiological findings with the peroperative findings in cases of chronic otitis media.

Materials and Methods: This prospective clinical study was conducted in the Department of Otorhinolaryngology at Subharti Medical College and associated Chhatrapati Shivaji Subharti Hospital, Meerut, Uttar Pradesh, India, from October 2019 to August 2021. Seventy five patients of unilateral uncomplicated chronic otitis media (mucosal or squamosal), with conductive hearing loss, aged between 10 to 50 years were included in the study. Audiological assessment was done in form of pure tone

audiometry using Alps 2100 instrument to measure hearing loss in decibels (dB). Radiological assessment was done using bilateral X-ray mastoid Schuller's view, and HRCT temporal bone. Association of audiological and radiological findings was determined with intraoperative findings using Statistical Package for Social Sciences (SPSS) version 24.0.

Results: The mean age of the study population was found to be 26.34±9.14 years. Females 42 (56%) were found to be affected more than males 33 (44%). Significant association was found between severity of hearing loss and necrosed ossicles seen peroperatively as p-value <0.05 in mucosal type of CSOM. Chances of peroperative ossicular necrosis (mucosal) were more in sclerosed (76.47%) and diploic (84.61%) mastoid as compared to pneumatized mastoid (7.69%) with statistically significant difference as p-value <0.01. Maximum accuracy of reporting for HRCT was found for the involvement of part of Incus.

Conclusion: There was a significant association of audiological findings and number of ossicles necrosed peroperatively. Hence, it can be concluded that greater the degree of hearing loss, more the chances of ossicular necrosis peroperatively.

Keywords: Conductive hearing loss, Ossicles, Pure tone audiometry, Temporal bone

INTRODUCTION

Chronic Otitis Media (COM) refers to a chronic infection of mucosa lining the middle ear cleft, which includes the middle ear, attic, aditus, antrum, mastoid air cells and eustachian tube [1]. The Browning pathological classification of COM broadly divides COM into mucosal and squamous subtypes [2]. It has been further subdivided into active and inactive forms. This classification is now more accepted than the former one comprising tubotympanic or safe Chronic Suppurative Otitis Media (CSOM) and atticointral or unsafe CSOM, which were defined as "intermittent or persistent, chronic purulent drainage through a perforated tympanic membrane, which can be associated with cholesteatoma." in developing countries like India incidence of CSOM varies from 3-57% while in developing countries it varies from 0.5-2% [3]. In India, incidence of CSOM is up to 30% with prevalence rate of 15 and 46 per 1,000 population, respectively in urban and rural areas [3].

Chronic suppurative otitis media is the leading cause of conductive hearing loss in adults, which is secondary to damage of the eardrum and middle ear ossicles induced by chronic inflammation, occurring in approximately one third of CSOM cases. It may lead to total failure of middle ear mechanics, resulting in substantial hearing loss [4]. Malleus, incus and stapes along with tympanic membrane are vital for impedance matching mechanism of the middle ear. Necrosis of long process of the incus, suprastructure of stapes, body of incus and manubrium occur in decreasing order of frequency, respectively [5].

Erosion is a result of non specific hyperaemia associated with mucosal inflammation, with ossicular chain being the predominant site for bone resorption and damage [6]. Various factors that are known to contribute in bone erosion in cholesteatoma are osteoclasts, pressure necrosis, collagenolytic enzyme, Tumour Necrosis Factor (TNF)- α , lysosomal enzymes, and non lysosomal enzymes calpain I and II, leading to hypervascularisation, osteoclast activation and bone resorption and ossicular damage [7-9].

Erosion or discontinuity of the ossicular chain is confirmed only during surgery. Preoperative High-Resolution Computed Tomography (HRCT) scan of temporal bone can give a clue of ossicular integrity. However, it's high-cost and degree of radiation exposure limits its use in developing countries like India, especially in cases of mucosal type of CSOM. Preoperative knowledge of ossicular discontinuity is important because it enables the surgeon to discuss with the patient the possible outcome of surgery and take the consent accordingly [5].

Complete disruption of the ossicular chain can result in a 60 dB hearing loss [10,11]. Hence, knowledge of the risk factors causing ossicular necrosis and the different pattern of ossicular involvement would be helpful to plan the ossicular surgery. Previous studies [5,9] do not focus on association of preoperative audiological and radiological findings with preoperative ossicular necrosis. Association between these findings is a direct indicator, of how much useful these investigations are in current times, to plan the surgeries before hand

by giving a clear idea of the types and number of ossicles involved to the treating surgeon. Hence, present study was conducted to determine the association between preoperative audiological and radiological findings with peroperative ossicular chain involvement, in both mucosal and squamous type of chronic otitis media.

MATERIALS AND METHODS

The present prospective clinical study was conducted in the Department of Otorhinolaryngology at Subharti Medical College and associated Chhatrapati Shivaji Subharti Hospital, Meerut, Uttar Pradesh, India, from October 2019 to August 2021. Written informed consent was obtained from all the study participants for inclusion in the study.

Inclusion criteria: Patients with pure conductive hearing loss, aged between 10 to 50 years, having unilateral, mucosal or squamous type of chronic otitis media and who were scheduled to undergo ear surgery were included in the study.

Exclusion criteria: Patients with Sensorineural Hearing Loss (SNHL), age less than 10 years and more than 50 years, with complications of COM, B/L chronic otitis media and patients with previously operated ear/trauma were excluded.

Sample size calculation: With confidence interval of 95% ($z=1.96$), considering incidence of CSOM as 15% ($p=0.15$) in urban city of Meerut [3], and precision of 8% ($e=0.08$), sample size was found to be 75, the calculation for which is as follows:

Prevalence(p)=0.15, hence $q=1-0.15=0.85$; level of precision ($e=0.08$); critical value of confidence level (z)=1.96+ $n = \frac{z^2 pq}{e^2}$
So, $n = \frac{(1.96)^2(0.15)(0.85)}{(0.08)^2} \sim 75$

Thus, a total of 75 patients were taken in the study, who were clinically diagnosed as cases of chronic otitis media (mucosal or squamous type) and later operated.

Study Procedure

Patients clinically diagnosed as cases of unilateral chronic otitis media were included in the study. A detailed evaluation of the middle ear by otoscopy was done and classification of type of COM was performed according to the Browning classification [2], according to the classification patients were divided in mucosal and submucosal type COM. Demographic data such as age, gender, socio-economic status were collected from all the participants. Modified kuppuswamy Scale [12] was used to determine the socio-economic status of the study participants.

All the patients underwent audiological assessment in the form of pure tone audiometry to measure the associated hearing loss in dB. Radiological assessment was done using bilateral X-ray mastoid Schuller's view [Table/Fig-1], and HRCT temporal bone.

Pure Tone Audiometry (PTA): The PTA was done using Alps 2100. Test was done in acoustically treated room. Both air and

bone conduction were tested. For assessing the hearing loss, pure tone average was calculated by taking the average of the hearing threshold level at 500 Hz, 1000 Hz and 2000 Hz only. PTA was done so as to find the type and degree of hearing loss and to exclude the patient having Sensorineural Hearing Loss (SNHL). Degree of deafness was graded according to World Health Organisation (WHO) classification, 1980 [2]:

- Normal hearing: 0 to 25 dB
- Mild deafness: 26 to 40 dB
- Moderate deafness: 41 to 55 dB
- Moderately severe deafness: 56 to 70 dB
- Severe deafness: 71 to 90 dB
- Profound deafness: Above 90 dB

HRCT temporal bone: It was done in all 19 patients having squamous type of chronic otitis media and in 32 patients, out of 56 having mucosal type of disease, based on PTA findings, who were having moderate and moderately severe conductive hearing loss to see the ossicular status of affected ear [Table/Fig-2].

Surgical procedure such as cortical mastoidectomy, modified radical mastoidectomy were performed in all the patients [Table/Fig-3]. Association of preoperative audiological and radiological findings was determined with intraoperative findings in terms of ossicular chain continuity and ossicular necrosis.

STATISTICAL ANALYSIS

Data was collected and entered in excel sheet. Statistical Package for Social Sciences (SPSS) version 24.0 was used to do the statistical analysis. The test used to determine the significance of association was Chi-square with 95% confidence interval, considered significant with p -value <0.05 .

RESULTS

In the present study, the mean age of the study population was found to be 26.34 ± 9.14 years. Maximum number of patients were found in the age group of 21-30 years i.e. 38 (50.6%) followed by 10-20 years i.e. 18 (24%), out of 75 patients, 33 (44%) were males and 42 (56%) were females. Majority of the patients i.e. 36 (48%) were belonged to upper lower class, followed by 18 (24%) in lower class [Table/Fig-4].

In the present study, out of total 75 patients, 56 (74.67%) were diagnosed as cases of mucosal type of CSOM, and 19 (25.33%) as squamous type of CSOM. Mild conductive hearing loss was seen in 24 patients, out of which 3 patients (12.5%) had ossicular necrosis peroperatively, moderate conductive hearing loss was seen in 25 patients, out of which, 16 patients (64%) had ossicular necrosis, moderately severe deafness was seen in 7 patients and all seven patients (100%) had ossicular necrosis peroperatively. Significant association was found between severity of hearing loss and necrosed ossicles seen peroperatively (p -value <0.01) [Table/Fig-5].



[Table/Fig-1]: X-ray mastoid Schuller's view depicting pneumatization of mastoid air cells on left side and unilateral sclerosis of mastoid air cells on right side.

[Table/Fig-2]: High-Resolution Computed Tomography (HRCT) showing erosion of the lenticular process of the incus of right side (red arrow). The head of stapes and the rest of the supra structure are intact. The tympanic membrane of left side is in contact with handle of malleus in position.

[Table/Fig-3]: Specimen showing the incus with erosion of the lenticular process, with intact long process, body and short process. (Images from left to right)

Demographic category		No. of patients
Age (years)	10-20	18 (24%)
	21-30	38 (50.6%)
	31-40	10 (13.3%)
	41-50	9 (12%)
Gender	Male	33 (44%)
	Female	42 (56%)
Socio-economic group (modified kuppuswamy) [12]	Upper	2 (2.6%)
	Upper middle	4 (5.3%)
	Lower middle	15 (20%)
	Upper lower	36 (48%)
	Lower	18 (24%)

[Table/Fig-4]: Socio-demographic factors of the study participants (N=75).

Hearing loss (in dB)	Total	Peroperative ossicular necrosis	p-value
Mild (26-40)	24	3 (12.5%)	<0.01
Moderate (41-55)	25	16 (64%)	
Moderately severe (56-70)	7	7 (100%)	
Severe (71-90)	0	0	
Profound (91+)	0	0	

[Table/Fig-5]: Association of hearing loss (Pure Tone Audiometry (PTA) findings) with the peroperative findings of ossicular necrosis in mucosal CSOM (n=56). Chi-square test, level of significant p-value <0.05

In present study, moderately severe conductive hearing loss was seen in 10 patients, out of which, all 10 patients (100%) had ossicles necrosed peroperatively, moderate conductive deafness was seen in nine patients, out of which, all nine patients had ossicles necrosed peroperatively [Table/Fig-6].

PTA findings (in dB)	Total	Peroperative ossicular necrosis
Mild (26-40)	0	0
Moderate (41-55)	9	9 (100%)
Moderately Severe (56-70)	10	10 (100%)
Severe (71-90)	0	0
cxProfound (91+)	0	0
Total	19	19

[Table/Fig-6]: Findings of hearing loss (Pure Tone Audiometry (PTA)) and peroperative findings of ossicular necrosis in squamosal CSOM (n=19).

Pneumatisation of mastoid was seen in 26, out of 56 patients, out of which 2 patients (7.69%) had necrosed ossicles peroperatively. A total of 17, out of 56 patients, had sclerosed mastoid, out of which, 13 patients (76.47%) had peroperative ossicular necrosis. 13 out of 56 patients had diploic mastoid, out of which, 11 (84.61%) patients had peroperative ossicular necrosis. Chances of peroperative ossicular necrosis (mucosal) was more in sclerosed and diploic mastoid as compared to pneumatisation of mastoid with statistically significant difference as p-value <0.01 [Table/Fig-7].

X-ray mastoid Schuller's	No. of patients	Peroperative ossicular status (necrosed)	p-value
Pneumatised Mastoid	26	2 (7.69%)	<0.01
Sclerosed Mastoid	17	13 (76.47%)	
Diploic Mastoid	13	11 (84.61%)	
Total	56	26 (46.43%)	

[Table/Fig-7]: Pneumatisation of mastoid (as seen in X-ray mastoid Schuller's view) and the peroperative ossicular necrosis in mucosal COM (n=56). Chi-square test, level of significant p-value <0.05

In present study, it was found that, out of 19 patients; all the 19 patients had ossicular necrosis peroperatively. Fourteen, out of 19 patients had sclerosed mastoid, out of which, all 14 patients had peroperative ossicular necrosis. Five out of 19 patients had diploic mastoid, out of which, all five patients had peroperative ossicular necrosis [Table/Fig-8].

X-ray mastoid Schuller's view	No. of patients	Peroperative ossicular status (necrosed)
Pneumatised Mastoid	0	0
Sclerosed Mastoid	14	14 (100%)
Diploic Mastoid	5	5 (100%)
Total	19	19

[Table/Fig-8]: Pneumatisation of mastoid (as seen in X-ray mastoid Schuller's view) and the peroperative ossicular necrosis in squamosal COM (n=19).

The HRCT was done in 32 out of 56 patients with mucosal type of disease (excluding the cases associated with mild hearing loss), in which, 17 patients showed normal ossicular status, and 15 cases showed ossicular necrosis on HRCT [Table/Fig-2]. On observing the peroperative findings with HRCT, total false positives were found to be two, and false negatives to be 13. Sensitivity was found to be 100% in involvement of Incus, both malleus and incus, and in involvement of both incus and stapes suprastructure. Maximum accuracy of reporting for HRCT was found for the involvement of part of incus [Table/Fig-9].

Extent of ossicular erosion		HRCT findings	Intraop findings	False positives	False negatives
Malleus	Malleus handle (Tip) only	0	2	0	2
	Malleus head	0	0	0	0
Incus	Incus lenticular process	7	11	0	4
	Incus long process	3	5	0	2
	Incus body	0	0	0	0
	Incus short process	0	0	0	0
Involvement of part of malleus and incus		1	6	0	5
Involvement of part of incus and stapes suprastructure		4	2	2	0
Total		15	26	2	13

[Table/Fig-9]: Association of hrct temporal bone findings and peroperative ossicular necrosis in mucosal COM (n=32).

The HRCT was done in all the 19 patients with squamosal type of disease, out of which 17 cases showed ossicular necrosis on HRCT. On observing the peroperative findings with HRCT, total false negatives were found to be two. No false positives were found. A total of 100% sensitivity was reported when either, both malleus and incus were involved or, both incus and stapes suprastructure were involved. A total of 100% specificity was reported in the involvement of any part of incus. Maximum accuracy was reported for involvement of long process of incus, and when both incus and stapes suprastructure were involved [Table/Fig-10].

Extent of ossicular erosion		CT findings	Intraop findings	False positives	False negatives
Malleus	Malleus handle (Tip) only	0	0	0	0
	Malleus head	0	0	0	0
Incus	Incus lenticular process	1	2	0	1
	Incus long process	1	1	0	0
	Incus body	0	0	0	0
	Incus short process	0	0	0	0
Involvement of part of malleus and incus		4	5	0	1
Involvement of part of incus and stapes suprastructure		11	11	0	0
Total		17	19	0	2

[Table/Fig-10]: Association of HRCT temporal bone findings with peroperative ossicular necrosis in squamosal COM (n=19).

DISCUSSION

Ossicular necrosis more commonly occurs in finely constructed parts of the chain, mainly at long process of incus and stapes superstructure where osteoclastic activity is abundant as compared to weak osteoblastic activity. The ability to predict the presence of ossicular discontinuity in such patient using certain preoperative factors, would be of benefit in allowing the surgeon, to plan ahead with regard to the need for an ossiculoplasty and also to give the patient a realistic explanation of the expected outcome [13].

Audiological assessment was done of all the patients, and it was found that 24 patients (32%) had mild hearing loss, 34 patients (45.33%) had moderate degree of hearing loss and rest 17 patients (22.67%) had moderately severe hearing loss. In case of mucosal disease; mild conductive hearing loss was seen in 24 patients, out of which 3 patients (12.5%) had ossicular necrosis peroperatively, moderate conductive hearing loss was seen in 25 patients, out of which 16 patients (64%) had ossicular necrosis, moderately severe deafness was seen in 7 patients and all seven patients (100%) had ossicular necrosis peroperatively. In case of squamosal disease; moderately severe conductive hearing loss was seen in 10 patients, out of which all 10 patients (100%) had ossicles necrosed peroperatively, moderate conductive deafness was seen in nine patients, out of which all nine patients had ossicles necrosed peroperatively. Shinta N et al., in their study found that hearing loss moderate to severe degree was found in this study of 29.3%, followed by moderate degree, as much as, 24.6%, severe degree, as much as, 20.0%, profound degree, as much as, 13.8% and mild degree, as much as, 12.3% [14]. Sharma M and Shetty DP [15] in their study showed that the most common type of hearing loss encountered was mild followed by moderate. When incus was necrosed, hearing loss was mainly moderate type and with stapes necrosis, profound or moderately severe type [15].

The possible reason for majority of patients presenting with moderate and moderately severe hearing loss in the present study is that, most of the patients in our country come relatively late in hospital for treatment, when the disease has already advanced.

On investigating the 56 patients of mucosal type with X-ray mastoid, it was reported that 26 patients (46.24%) of them had pneumatic changes in the mastoid and mastoid antrum. Sclerotic changes were seen in 17 patients (30.35%) and diploic changes in 13 patients (23.21%). X-ray mastoid Schuller's view of 14 squamosal patients (73.68%) showed sclerotic changes and five patients (26.31%) showed diploic changes. These are comparable with findings of Mahesh HC et al., [16] and Henry KG and Wlodyka J [17]. They stated that, sclerotisation of mastoid process is neither hereditary nor congenital, nor sequelae of otitis media in infancy, but is a result of the suppurative process, representing a defense mechanism consisting in growth of bone, which displaces the pathologic process towards the antrum.

Out of 32 patients (mucosal), 17 patients had normal HRCT findings. In 15 patients, HRCT showed ossicular destruction, out of which in 10 patients (31.25%) incus was involved. In 1 patient (3.12%) both malleus and incus were involved and in 4 patients (12.55%) incus and stapes suprastructure were involved. HRCT was done in all 19 cases of squamosal disease. In majority i.e. in 11 patients (57.89%) both incus and stapes suprastructure were involved, followed by involvement of only incus in 2 patients (10.52%), and both malleus and incus were involved in 4 patients (21.09%). The long process incus was an ossicle that has a long and hanging structure, a location in mesotympanum, as well as, rare vascularisation, so susceptible to destruction. Shinta N et al., [14] in their study reported that incus was found to be in most destructed condition which is similar to our study. Stapes was obtained most intact condition as much as 50.8%. This is in accordance to the study done by Sunita M and Sambandan AP [18], where, in a total of 31 cases of tubotympanic type of CSOM, the ossicular destruction was detected by the HRCT

temporal bone was more common in incus (3 cases, 9.7%), followed by stapes (2 cases, 6.5%) in actively discharging tubotympanic type of CSOM. No case showed erosion of the malleus bone. Rawat V et al., [19] also did a similar study, where HRCT correlation of ossicular necrosis was done in 41 patients of COM (TTD/mucosal type) and 59 patients of COM (AAD/squamosal type). Out of the 41 patients, on HRCT temporal bone, majority had erosion of handle of malleus (44%), followed by erosion of incus seen in 41%, as they were the most commonly eroded bone in COM. There was no erosion of head of the malleus and stapes suprastructure.

Limitation(s)

The present study was conducted on a limited sample size, taken from one hospital. Audiological assessment to measure hearing loss in the present study was done using Pure Tone Audiometer (ALPS - AD2100). Advance methods (impedance audiometry, auto acoustic impedance) of audiological assessment using newer models of audiometers have emerged in market today.

CONCLUSION(S)

The present study concludes that in both mucosal and squamosal type of CSOM, there was significant association, between audiological findings and number of ossicles necrosed seen peroperatively hence, greater the degree of hearing loss, more the chances of ossicular necrosis peroperatively. Chances of peroperative ossicular necrosis (mucosal) is more in sclerosed and diploic mastoid, as compared to pneumatization of mastoid. The HRCT is a reliable and specific investigation with a good accuracy rate to detect ossicular necrosis. Future studies should be conducted with larger sample size, taken from different geographical locations.

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