

Pre-operative Indicators of Ossicular Necrosis in Tubotympanic CSOM

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Abstract Ossicular necrosis and erosion is commonly seen in CSOM with cholesteatoma but can also occur in tubotympanic CSOM. This usually comes as a surprise during surgery. Preoperative knowledge of ossicular necrosis helps the surgeon to be better prepared for the surgery and ossicular reconstruction if required. Hence, this study is intended to identify the pre-operative indicators of ossicular necrosis. This cross sectional study was conducted in Father Muller Medical College in Mangalore. Sixty nine consecutive patients with tubotympanic CSOM underwent a detailed clinical examination with pure tone audiometry and subsequently tympanoplasty with or without cortical mastoidectomy. All clinical findings, pure-tone audiometry, and intraoperative otomicroscopic observations were recorded. Incidence of ossicular necrosis was 23 %. The incus was most frequently eroded followed by malleus and then stapes. On bivariate analysis patients age above 30 years ($p = 0.05$), duration of CSOM more than 10 years ($p = 0.02$), presence of granulation ($p < 0.05$), absence of tympanosclerosis ($p = 0.01$), moderately severe (45–60 dB) hearing loss ($p = 0.01$) and an air bone gap of more than 55.7 dB in the right ear and 63.95 dB in the left ear was found to be statistically significant ($p < 0.05$). On multivariate analysis only presence of middle ear granulation tissue was found to be the significant predictor

[($p = 0.005$), OR 14.37, 95 % CI 2.26–90.0]. The presence of granulation tissue and a wide air bone gap on pure tone audiometry were the best indicators of ossicular necrosis. Preoperative identification of these indicators can help the surgeon to be better prepared for the surgery.

Keywords Ossicular necrosis · Ossicular erosion · Pre-operative indicators · Tubotympanic CSOM

Introduction

Chronic suppurative otitis media (CSOM) refers to a chronic infection of the mucosa lining the middle ear cleft. CSOM is characterized by chronic inflammation of the middle ear and mastoid mucosa. Active mucosal CSOM is often associated with resorption of parts or all of the ossicular chain (resorptive osteitis) [1]. Resorption of bone is a feature of active mucosal and active squamous epithelial CSOM. The ossicles thus affected typically show hyperaemia with proliferation of capillaries and prominent histiocytes [2]. The long process of the incus, stapes crurae, body of incus and manubrium are involved in that order of frequency [1]. Although ossicular erosion can occur in both types of CSOM, the incidence of ossicular erosion in tubotympanic CSOM is low. High resolution three dimensional computed tomography can help define the middle ear and identify ossicular erosion and discontinuity, however this is not a routine investigation for patients with CSOM without cholesteatoma. Hence ossicular chain erosion is confirmed only during surgery and usually comes as a surprise. Pre-operative knowledge of ossicular necrosis enables the surgeon to plan operative scheduling, allowing a longer duration for surgery and arrange for specific equipment and materials required for ossiculoplasty.

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Anaesthetists would also use a longer acting anaesthetic according to the surgeon's estimate of the duration of surgery. The surgeon can discuss the probability of performing an ossiculoplasty, the surgical complications and the expected outcome with the patient prior to surgery and obtain consent. There are no well defined factors to indicate the presence of ossicular erosion preoperatively in cases with tubotympanic CSOM. Hence this study is intended to identify few of pre-operative clinical findings which may predict ossicular necrosis and to correlate audiological evaluation with ossicular necrosis.

Materials and Methods

This cross sectional study was conducted in the Department of Otorhinolaryngology, Father Muller Medical College, Mangalore. Sixty-nine patients were included by consecutive sampling technique after an informed consent from August 2010 to March 2012. Existing evidence suggests that presence of granulation tissue is one of the best predictors of ossicular necrosis and its prevalence in tubotympanic disease was 9.5 %. Sample size was calculated as 69 using the formulae $4PQ/d^2$ with absolute precision of 7 [3]. Those with more than 15 years of age with tubotympanic chronic suppurative otitis media and scheduled to undergo tympanoplasty with or without cortical mastoidectomy were included whereas patients who were with attic antral CSOM, marginal perforation and previous history of ear surgery in the same ear were excluded from the study. The recruited patients underwent a detailed clinical examination which included otoscopic and microscopic examination and all findings were recorded. Pure tone audiogram was also done. Perforation involving a single, two, three or more quadrants were classified into small, medium and large perforation respectively and if the entire pars tensa involved with intact annulus was considered as subtotal perforation. All patients underwent tympanoplasty with or without cortical mastoidectomy under general anesthesia and findings like tympanosclerosis, status of middle ear mucosa, presence of any polyps, ossicular necrosis and granulation tissue were noted. Patients with history of ear discharge within 3 months with no active ear discharge or moist middle ear mucosa during pre-operative evaluation or evidence of polypoidal mucosa during the surgery underwent cortical mastoidectomy. In patients who underwent cortical mastoidectomy additional findings like pneumatization of mastoid air cells, status of antrum and patency of aditus were also documented. Patients who had ossicular erosion underwent ossiculoplasty if feasible. An informed written consent was taken before the conduct of the study. Data was entered in Microsoft office Excel 2007 was analyzed using the

Statistical Package of Social Sciences (SPSS Version 16.0). Descriptive data were given as mean with standard deviation (SD), or as median (range). The association between ossicular necrosis and factors such as age, duration of illness, gender, size of perforation, presence of granulation and sclerosis was analyzed by Chi-square test. Association between audiogram and ossicular necrosis was analyzed using independent 't' test. A multivariate logistic regression model was derived to predict the best predictors. For all tests, a two-sided *p* value of 0.05 or less was considered statistically significant. This study was approved by the Ethics Committee of Father Muller Medical College, Mangalore and the confidentiality of the participants during the study and the analytical phase was maintained using unique identifiers.

Results

The study group consisted of 69 patients with chronic suppurative otitis media—tubotympanic type. The age of patients ranged from 15 to 56 years and the mean age was 29 years. Majority of the patients were in the age group of 21–30 years (40.6 %) as shown in Table 1. More than two-third (68.1 %) of the patients were women. More than half (58 %) of the patients had unilateral CSOM. Nearly two-third (62.3 %) of them had a large central perforation. Majority (53.6 %) of the patients were operated on the right side.

Out of 69 patients, 16 (23.1 %) had ossicular erosion which was observed during surgery. Among those who had ossicular necrosis half of them [50 % (8/16)] belonged to the age group of 31–40 years and nearly two-third [62.5 % (10/16)] of them were men. Nearly one-third [31.2 % (5/16)] of the patients had CSOM for 11–20 years and one-third of them for 21–30 years. Two-third of the patients with ossicular erosion [62.5 % (10/16)] had a large perforation as shown in Table 1.

Patients who were above than 30 years of age [(37.9 vs 12.5 % (*p* < 0.05)] and had CSOM for more than 10 years [(33.3 vs 13.9 % (*p* = 0.05)] had a higher incidence of ossicular necrosis as compared to younger patients (<30 years) with CSOM for <10 years and these differences were statistically significant as shown in Table 2. Those more than 30 years of age had 4.27 times higher odds having ossicular necrosis than those less than 30 years of age (95 % CI 1.28–14.2). Similarly, patients who were found to have granulation tissue [80 vs 13.6 % (*p* < 0.05)] during clinical examination had higher incidence of ossicular necrosis when compared with those who did not have granulation tissue and this difference was statistically significant. Patients with granulation tissue in the middle ear had 25.5 times higher odds of having ossicular necrosis

Table 1 Baseline characters of study population

Characters	Category	Study population (n = 69)		Patients with necrosis (n = 16)	
		Number	Percentage	Number	Percentage
Age in years	11–20	12	17.3	0	0
	21–30	28	40.5	5	31.2
	31–40	18	26.0	8	50
	41–50	7	10.1	1	6.2
	>50	4	5.7	2	12.5
Sex	Male	47	68.1	10	62.5
	Female	22	31.8	6	37.5
Duration of CSOM	<1	18	26.0	2	12.5
	1–10	19	27.5	3	18.7
	11–20	17	24.6	5	31.2
	21–30	13	18.8	5	31.2
	31–40	2	2.8	1	6.2
Operated side	Right	37	53.6	8	50
	Left	32	46.3	8	50
Type of perforation	Large	43	62.3	10	62.5
	Medium	20	28.9	3	18.7
	Subtotal	6	8.6	3	18.7

Table 2 Predictors of ossicular necrosis

Predictors	Category	Necrosis present (%)	Necrosis absent (%)	Total (100 %)	Odd's ratio (95 % CI)	<i>p</i> value
Gender	Male	10 (21.3)	37 (78.7)	47	1.38 (0.43–4.46)	0.58
	Female	6 (27.3)	16 (72.7)	22		
Duration of CSOM	<10 years	5 (13.9)	31 (86.1)	36	3.1 (0.94–10.1)	0.05 [†]
	>10 years	11 (33.3)	22 (66.7)	33		
Age	<30 years	5 (12.5)	35 (87.5)	40	4.27* (1.28–14.2)	0.02 [†]
	>30 years	11 (37.9)	18 (62.1)	29		
Site of operation	Left	8 (25)	24 (75)	32	0.82 (0.27–2.5)	0.74
	Right	8 (21.6)	29 (78.4)	37		
Perforation	Large	13 (26.5)	36 (73.5)	49	0.48 (0.12–0.194)	0.36
	Medium	3 (15)	17 (85)	20		
Sclerosis	Present	0	16 (100)	16	0.69 (0.5–0.8)	0.01 [†]
	Absent	16 (30.2)	37 (69.8)	53		
Granulation	Absent	8 (13.6)	51 (86.4)	59	25.5* (4.5–142.3)	0.01
	Present	8 (80)	2 (20)	10		
Hearing loss	Mild/Moderate	4 (11.4)	31 (88.6)	35	4.22* (1.2–14.85)	0.01 [†]
	Mod. Severe	12 (35.3)	22 (64.7)	34		

CI Confidence interval

* Significant odd's ratio, [†] significant *p* value

than those who had no granulation (95 % CI 4.5–142.3). Those who had moderately severe hearing loss [35.3 vs 11.4 %; $p < 0.05$; OR 4.22 (95 % CI (1.2–14.85))] were found to have higher incidence of hearing loss than those

with mild and moderate hearing loss. A statistically significant difference in incidence of ossicular necrosis was found between patients who did not have sclerosis [0 vs 30.2 % ($p < 0.05$)] and who had sclerosis as shown in

Table 3. Among 44 patients who underwent cortical mastoidectomy in 65.9 % of patients the mastoid antrum was normal. The aditus was patent in 68.1 % of the patients and the remaining had either granulation tissue (13.6 %), polypoidal mucosa (9.1 %) or a blocked aditus (9.1 %). The mastoid was well pneumatised in 61.4 %, sclerotic in 29.5 % and diploic in 9.1 % of patients.

Among the patients who were operated on the right ear, those with ossicular necrosis had a higher mean air bone gap (ABG) on pure tone audiometry (mean = 55.72 dB HL, SE = 2.0) when compared to patients who had no ossicular necrosis (mean = 39.37 dB HL, SE = 1.99) and this mean difference was statistically significant [t statistics = (-5.77), $p < 0.05$]. Similarly, on the left ear those with ossicular necrosis had a higher mean ABG (mean = 63.95 SE = 6.78 vs mean = 41.64, SE = 2.18) and this difference was also significant [t statistics = (-3.13), $p < 0.05$] as shown in Table 4.

A logistic regression was performed to ascertain the effects of age, duration of illness, absence of sclerosis and presence of granulation tissue on the likelihood that participants developing ossicular necrosis. Ossicular necrosis was entered as dependent variable and predictors such as age above 30 years, duration of CSOM more than 10 years, presence of granulation tissue and absence of tympanosclerosis and type of hearing loss were entered as independent variables. The model explained 51.4 % (Nagelkerke R^2) of the variance in ossicular necrosis and correctly classified 85.5 % of cases. Presence of granulation tissue is 14.2 times more likely to result in ossicular necrosis than absence of granulation tissue. However, the absence of sclerosis was not associated with an increased

likelihood of resulting ossicular necrosis. The incus was most frequently eroded (62.5 %), followed by malleus (31.2 %) and stapes (6.25 %).

Discussion

Ossicular erosion is most commonly seen in atticotympanic type of CSOM with cholesteatoma. However it has been well established that ossicular erosion or discontinuity can be seen even in tubotympanic type of CSOM [4, 5]. The proposed mechanism for erosion is chronic middle ear inflammation as a result of overproduction of cytokines—Tumour Necrosis Factor (TNF)- α , interleukin 2, fibroblast growth factor and platelet derived growth factor, which promote hypervascularisation, osteoclast activation and bone resorption causing ossicular damage. TNF- α also produces neovascularisation and hence granulation tissue formation [6]. CSOM is thus an inflammatory process with a defective wound healing mechanism [7]. This inflammatory process in the middle ear is more harmful the longer it stays and the nearer it is to the ossicular chain [8].

In cases in which the tympanic membrane, malleus, and incus are lost, the conductive hearing loss is in the order of 40–60 dB. This condition results in hearing sensitivities that are 10–20 dB superior to cases with an intact tympanic membrane and complete ossicular interruption. The 40–50 dB loss can be explained by a loss of ossicular coupling together with an enhancement of acoustic coupling of 10–20 dB, as compared to the normal ear [8]. The enhancement of acoustic coupling results from loss of the shielding effect of tympanic membrane, which in the

Table 3 Comparison of mean Airbone gap

Side of illness	Ossicular necrosis	Number	Mean (dB)	SD	Standard error	t statistics	p value
Right	Present	8	55.7	5.66	2.004	-5.77	<0.05*
	Absent	29	39.37	10.76	1.99		
Left	Present	8	63.95	19.19	6.78	-3.13	<0.05*
	Absent	24	41.64	10.69	2.18		

* Significant p value

Table 4 Logistic regression model for predictors of ossicular necrosis

Predictors	B	Sig.	Exp (B)	95 % CI
Age more than 30 years	0.91	0.228	2.49	0.56–11.03
CSOM for more than 10 years	1.047	0.183	2.84	0.61–13.28
Presence of granulation	2.65	0.005*	14.37 [†]	2.26–90.0
Moderately severe hearing loss	0.68	0.378	1.98	0.43–9.11

CI Confidence interval

* Significant p value, [†] significant odd's ratio

normal ear attenuates middle ear sound pressure by 10–20 dB relative to ear canal sound pressure. Continuing activity in COM is likely to result in ossicular necrosis. Necrosis commonly occurs in the finely constructed parts of the chain, mainly long process of incus and stapes superstructure where there is abundant osteoclastic activity but weak osteoblastic activity [9].

Majority of the population in our study belonged to younger age group (21–30 years) and predominantly men. Anglitoiu et al. [6] also reported that the most commonly affected age group was between 18 and 30 years. This early presentation may be due to increased awareness to health issues and difficulty in hearing affecting the efficiency of work, leading patients to seek early medical intervention. Male predominance is also in correspondence with evidence from Raichur and could be because of gender discrimination in availing healthcare [10].

Jareen and Vedantam [11] conducted a prospective study on 150 patients with tubotympanic CSOM and found that the incidence of incus necrosis was 16 %. This was attributed to the long standing nature of the disease leading to progressive bone erosion with repeated episodes of infection. This is almost in concordance with our finding in which the incidence of necrosis was 23.1 %.

A bivariate analysis from our study showed that patients above 30 years of age and duration of CSOM for more than 10 years were significant indicators of ossicular necrosis. A review of literature revealed that there are no research supporting the association of ossicular erosion with increasing age of the patient. We are of the opinion that this could be due to negligence of patients to seek early treatment for childhood ear infections or due to inadequate treatment. Chronic long standing CSOM of more than 10 years duration can be supported by work from Chole and Choo who found that long standing CSOM can lead to the growth of granulation tissue and inflammatory products in small, dead spaces of the middle ear cleft which could lead to significant bone erosion over a period of time [12].

In our study, presence of granulation tissue was associated with ossicular necrosis in 80 % of the cases. This was found to be statistically significant in bivariate as well as multivariate analysis. This corresponds with literature which states that middle ear granulations are known to cause ossicular resorption. Existing evidences have also proved that granulation tissue is significantly associated with ossicular discontinuity and this possibility increased by 7.95 times when the edges of the perforation were adherent to the promontory [13, 14]. Our findings also in correspondence with findings from Jareen [11].

Moderately severe hearing loss was also found to be a significant indicator in bivariate analysis which corroborates with findings from Vellore [11]. In a similar study, Feng reports that air conduction threshold and air bone gap

are the most reliable indicators to identify ossicular conditions in patients with CSOM [15]. The air conduction threshold and air bone gap in patients with ossicular discontinuity are higher than that in patients with ossicular continuity.

The presence ossicular necrosis and pure tone audiometric findings of an air bone gap (ABG) of more than 55.7 dB in the right ear and 63.95 dB in the left ear was found to be statistically significant in our study. According to literature an ABG of greater than 30 dB at 2 kHz and greater than 40 dB at 4 kHz increased the probability of ossicular discontinuity to 89 % [16]. Narrow ABG at low frequencies suggested absence of ossicular discontinuity and wide ABG at higher frequencies suggested presence of ossicular discontinuity. A raised pure tone audiometric average threshold of 41–70 dB is also significantly associated with necrosis of incus [13].

Austin who classified ossicular chain defects in 1151 ears affected by CSOM, found incus erosion to be the most common type of ossicular defect [17]. However Sade et al. and Jareen [8, 11] found that both the malleus and incus could be equally affected. In contrast, Schuknecht noted that the frequency of involvement of ossicles was long process of incus, crura of stapes, body of incus and manubrium of malleus [1]. Thomsen et al. and Tos observed that the long process of the incus and stapes suprastructure are the most frequently affected ossicle [18, 19]. In this study, the incus was the most commonly eroded ossicle followed by malleus and then stapes.

In our study other factors like gender, unilateral or bilateral CSOM, side of CSOM, size of perforation were also analyzed and was not found to be statistically significant and this is in concordance with literature where these factors were not found to be significant [13]. An interesting observation made in this study is that ossicular erosion was associated with the absence of tympanosclerosis. Although this cannot explained by the known pathogenesis of ossicular necrosis and progression of the disease process, our findings can not be ignored. This also contradicts existing evidences which proves that the presence of tympanosclerosis is associated with ossicular erosion [20]. A multicentric research with larger sample size in the future may throw light on this observation.

Conclusion

Ossicular necrosis is best predicted by the presence of middle ear granulations and an elevated pure tone audiometric average threshold of more than 55 dB. All patients with tubotympanic chronic suppurative otitis media can be assessed preoperatively for the indicators of ossicular erosion. This preoperative knowledge can influence the

surgical decision and also help the surgeon be prepared for reconstruction of the hearing mechanism or ossiculoplasty.

Compliance with Ethical Standards

Conflict of interest None.

Ethical approval All procedures in this study were performed in accordance with the ethical standards of the institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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