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A retrospective study on middle ear risk indices in analyzing postoperative outcomes following tympanoplasty

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Introduction: Middle Ear Risk Index (MERI) of a patient suffering from Chronic otitis media (COM) is a numerical grading to stratify the severity of the disease. The study aimed to evaluate MERI in the postoperative outcome following tympanoplasty in terms of hearing improvement and graft uptake. **Materials and Methods:** A retrospective study on patients with COM undergoing tympanoplasty within the age group 15-50 from February 2017 - February 2018 was done. Data was collected from the medical records department through case sheets. Graft uptake status at the end of one month was obtained from the minor procedure register. Postoperative Audiograms done at the end of 3 months were obtained from the Audiology Database. **Results:** 25 patients with unilateral perforation were operated on and followed up in this period. There were 11 male and 14 female patients. 88% of patients had mild MERI scores, 8% had moderate and 4% had severe MERI scores. About 84% had mild conductive hearing loss while the rest had moderate hearing loss. Graft acceptance was 88%, it was 95% in mild MERI and 50% in moderate MERI groups respectively. In occasionally wet ears graft rejection was 11% and 40% in persistently wet ears. The mean preoperative Air-Bone gap in the Mild MERI and Moderate MERI groups was 21.45 decibels (dB) and 22.3 dB. The mean post-operative Air-Bone gap in the Mild MERI risk group was 10.35 dB and 14.5 dB in the moderate MERI risk group which was significant($p<0.05$). **Conclusion:** Hence MERI index is a very useful predictor of graft uptake and audiological gain in patients undergoing tympanoplasty surgeries.

Keywords: MERI, Tympanoplasty, postoperative outcome, Audiology

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Introduction

Chronic otitis media (COM) has been defined as infection or inflammation of the middle ear and mastoid cavity with or without ear discharge through a tympanic membrane perforation. The main aim of surgery for chronic otitis media is to remove the disease, make the ear dry and restore hearing. The incidence of the ears becoming dry after surgery and the ears not having recurrent or residual cholesteatoma ranges between 70 to 90 % in various large clinical trials [1]. There has been a difference in opinion about the staging of the surgical procedure for COM. Some studies supported single-stage surgery for both eliminations of disease and tympanoplasty [2,3]. Whereas others advocate a two-stage procedure for achieving the same objectives [4,5].

Tympanomastoidectomy is the procedure for removal of disease from the middle ear cleft done either as an open or closed cavity procedure – the closed cavity procedure is tympanoplasty. This procedure, tympanoplasty, is the mainstay for the reconstruction of the middle ear. The success of surgery is dependent not only upon the surgical principle but also on the pathophysiological factors associated with the disease. Although there is huge literature present about the techniques of tympanomastoidectomy with tympanoplasty - the data about factors affecting the outcome is limited. The pathologic condition of the middle ear as a predictor of outcome has been a confusing issue in literature [6-8]. The decision for single or multiple-stage procedures for COM can be made based on the pathological factors associated with the disease. For this purpose, a grading system has been devised, known as the Middle ear risk index (MERI).

The Middle Ear Risk Index (MERI) of a patient suffering from Chronic otitis media is a numerical grading to stratify the severity of the disease. MERI is determined by assigning a specific value for each risk factor, and these values are added to get the MERI score. The risk factors include Belluci criteria to assess the degree of otorrhoea, Austin/Kartush criteria for ossicular status, presence of perforation, cholesteatoma middle ear granulation/effusions and history of previous surgery. The suggested risk categories can be derived from MERI as follows: MERI 0 = Normal; MERI 1-3 = Mild disease; MERI 4-6 = Moderate disease; MERI 7-12 = Severe disease [9]. There are very few studies to correlate the surgical outcome of the disease based on all pathological factors of the disease as most of the studies concentrate on one factor exclusively [10-12]. But there is only one study combining these factors - surgical, prosthetic, infection, tissue and Eustachian tube (SPITE), which is an exception [6].

There are two schools of thought regarding the outcome of ear surgery – one group believes that various pathological factors are important in determining the success of the surgery [13]. whereas the other claims that the outcome is independent of these factors [14,15]. Hence it is imperative to study the various factors influencing the disease of the ear. If the surgical outcome of the disease can be predicted based on the presentation it will help in the cost-effectiveness of the patient and will also boost patient compliance.

The main aim of the study is to evaluate the middle ear risk indices in the postoperative outcome following tympanoplasty. This will be done by the following criteria

1. To evaluate MERI score concerning the Degree of Air -Bone gap (A-B gap) closure and uptake of graft following tympanoplasty procedures in the study group

2. To assess the degree of AB gap closure (post-op AB gap >20 dB – failure, 11 – 20 dB as markedly improved, 0 – 10 as successful) following tympanoplasty procedures

3. To assess the closure of perforations based on Belluci criteria.

Materials and Methods

A retrospective study for one year from February 2017 - 2018 was conducted in the ENT department of a tertiary care hospital. Patients who came and got operated on for tympanoplasty, within the age group 15-50 years, irrespective of sex were included in the study (inclusive of the follow-up of the patients). People with a previous history of middle ear surgeries, co-morbid conditions and the use of ototoxic drugs were excluded. Patients who had cholesteatoma, tinnitus and vertigo were not included as well.

After obtaining the institutional ethics committee clearance the following data was

Collected from the medical records department - a) Detailed history followed by the clinical examination of Ear, Nose and Throat including general physical and systemic examination. b) Documentation of the investigations done like Diagnostic Nasal Endoscopy, X-ray Para-nasal Sinus, and pre-operative audiogram. c) Intro operative findings obtained from the operative notes and were incorporated. The main factors that were noticed – Status of the ossicular chain, Presence of granulation/cholesteatoma

Based on these data the MERI index was generated and patient data was divided into respective groups based on the score. Tympanic membrane status of the operated ear at the end of one month was derived from the minor procedure book maintained in the outpatient department (OPD) which contains the data of the post-op patients' oto-endoscopies done and its corresponding findings. Postoperative Audiograms done at the end of 3 months were obtained from the Audiology Database maintained by the department audiologist

SPSS software was used for the statistical analysis. Results were analyzed with paired student t-test (significance of differences in continuous variables before and after the procedure) and chi-square test (level of significance and analyze categorical variables).

Results

A total of 34 patients underwent tympanoplasty in our institute in the above-mentioned time frame. 8 patients were eliminated from the study due to co-morbid conditions and improper follow-up. Finally, 25 patients were included in the study and followed up. All the patients had unilateral perforation. The total number of ears was (n = 25). The mean age of the patients in the study was around 31.84 years. Out of the 25 patients, there were 11 male and 14 female patients in a ratio of 1:1.27.

Based on the indices of ossicular status, discharge, perforation, cholesteatoma and history of previous surgery, obtained from the case sheets, the study population were assessed and assigned their respective MERI index. According to our data majority of the patients fell into the mild category - 22 patients. Two patients had moderate MERI scores while only one patient was in the severe category (persistently wet ear, stapes fixity with previous smoking history)

The patients were also categorized based on their pre-operative hearing status. About 84% (21 patients) had mild hearing loss while four patients had moderate hearing loss.

Table I: Association between MERI and pre-operative hearing loss

	Mild MERI	Moderate MERI	Severe MERI	Total
Mild hearing loss	20	1	-	21
Moderate hearing loss	2	1	1	4
Severe hearing loss	-	-	-	-
Total	22	2	1	25

In this study, the graft was accepted in 22 patients (88%) and rejected in 3(12%) patients. In patients in the mild MERI risk group n=22, the graft was accepted in 21 (95%) patients and rejected in 1 patient (5%). Patient had a residual perforation. In patients in the moderate MERI risk group n=2, the graft was accepted in 1 (50%) patient and rejected in 1 patient(50%).In the severe risk group, none of the grafts was accepted(100%). The graft acceptance in the mild MERI risk group was significantly higher and statistically significant ($p < 0.05$).

Table II: Association of Belluci's Criteria with graft uptake/rejection in each risk group

Belluci's criteria	Graft accepted	Graft rejected	Total
Dry	11(100%)	-	11(100%)
Occasionally wet	8(88%)	1(12%)	9(100%)
Persistently wet	3(60%)	2(40%)	5(100%)

The presence of discharge – occasional or persistent was significantly associated with graft rejection ($p<0.05$).

The mean preoperative Air Bone gap in the Mild MERI risk group (n=22) was 21.45 dB and in the moderate MERI risk group (n= 2) was 22.3 dB. The only ear in the severe MERI risk group had an AB gap of 32 dB. The mean postoperative Air Bone gap in the Mild MERI risk group (n=22) was 10.35 dB and in the moderate MERI risk group (n= 2) was 14.5 dB.

The difference in the preoperative AB gap among the different risk groups and also the post-operative AB gap difference among the groups were not significant. But the difference between the pre-operative and post-operative AB gap among the mild and Moderate MERI risk groups was statistically significant ($p < 0.05$).

Table III: Post-operative AB Gap and outcome in MERI groups

MERI RISK GROUP	Post-op AB gap			Total
	0 – 10 dB(success)	11 – 20 dB(improvement)	>20 dB (Failure)	
Mild	13	7	2	22
Moderate	-	1	1	2
Severe	-	-	1	1

As mentioned earlier AB gap >20 dB was considered unsuccessful, 11-20 dB as marked improvement and the AB gap less than 10 dB as successful. Accordingly, in the Mild MERI risk group n=22, 13 patients were successful, 7 patients had improvement And 2 patients failed. In the moderate MERI risk group n=2, 1 had moderate improvement while 1 patient failed

Among the 25 patients taken in this study, 4 patients had ossicular fixity and one patient had incus necrosis. All underwent type 1 tympanoplasty except patients with ossicular fixity and incus necrosis who underwent ossiculoplasty (Type III tympanoplasty – Nodol and Schuknecht modification). Only one patient among the 4 with ossicular fixity failed (25%). The one with incus necrosis was successful. None of the patients had granulations/ cholesteatoma. Just one patient had a history of smoking.

Discussion

The main course of management of chronic otitis media is the removal of diseased mucosa from the middle ear cleft and restoration of hearing as much as possible. The current study was conducted to assess the prognostic value of the various pathological and technical factors associated with the COM on the outcome of the surgery. The factors analyzed in the present study include the presence of perforation, cholesteatoma, granulation tissue, ossicular status & necrosis and technique of surgery. These factors were studied in COM patients undergoing tympanoplasty for their effect on anatomical and functional outcome of the surgery, evaluated in terms of tympanic membrane graft uptake and audiological gain.

In our study, the average age of the patient in the study was 31.84 years. The total number of males in the study was 11(44%) and females were 14 (56%) which were almost comparable. The male-to-female ratio was 1:1.2.These results

Were in accordance with Lima JCBD et al [16]. Sharma A et al [17] claimed that the mean age group was 22.66 years which is very low compared to our study but the same study had similar gender distribution. Another study by Ahmed K et al [18] shows the male-to-female ratio was 1.3:1 which is also almost similar to our study.

These variations show that the disease was common in the second and third decades of life and that there was no significant gender distribution.

Our data shows that 22 (88%) patients fell into the mild MERI category.2 (8%) patients were categorized as moderate MERI group and one (4%) patient was categorized as severe MERI. Similar findings were observed in the studies conducted by Kumar N et al [19] which was a prospective study and also in Pinar E et al [20]. which retrospectively examined the role of MERI in the success of tympanoplasty.

All patients 25 (100%) suffered from conductive hearing loss which is following all the studies compared so far. About 21 patients (84%) had mild conductive hearing loss and 4 patients (16%) had moderate conductive hearing loss. In the study done by Lima JCBD et al [16] majority had moderate conductive hearing loss (46%) which may be due to the late presentation of the patients due to low awareness compared to our state.

About 90% in the mild MERI Group and 50% in the moderate MERI group had improvement. Overall among 25 patients 21(84%) had improvements. Lima JCBD et al [16]. had overall hearing improvements that are AB gap <20 dB at 86% post-operatively and Kumar N et al19 also had hearing improvements in 92.5% similar to our study.

The mean pre-op and post-op AB gaps in both studies were also comparable to the current study.

The mean audiological gain in the current study which was about 10 dB is very much in alignment with results seen in Sharma A et al [17]. which was 12 dB. Serviceable hearing (AB Gap < 20 dB – 18.8dB) was seen in 93.3 % in the study by Naderpour et al21 which is also comparable to our study which was 84%.

Based on these findings it was concluded that the MERI index was a good predictor of hearing status.

Graft acceptance was seen in 22 patients (88%) and rejected in 3(12%) patients. The maximum uptake of 95% was in the mild MERI group. Comparable results were observed in Kumar N et al [19]. where overall acceptance was 80% and acceptance in the mild MERI group was 86% and 75% in the moderate group. Becvarovski Z et al [22]. showed that all patients had graft uptake but delayed failure was observed in smokers at about 20%. Current study has no patients who were smokers.

Based on Belluci criteria, there was no graft rejection in dry perforations. In occasionally wet ears, graft rejection was 11% and in persistently wet ears graft rejection was 40%. This signifies that occasionally or persistently wet ears were more associated with graft rejection which concurred with the other studies compared so far

Totally 4 patients had ossicular fixity. Two patients had malleus fixity to the promontory, one patient had included stapedial joint fixity and another had stapes head fixity. These patients underwent type III tympanoplasty of Nodol and Schuknecht modification**.** All these patients had successful outcomes (75%), except for the patient who had stapes head fixity. The failure of that ear may have been due to a combination of other existing factors like persistently wet ears, and smoking (MERI – Severe group). One patient had necrosis of the incus and the outcome of this patient was also successful. In studies like Ahmed et al [18] the graft acceptance was comparatively low in patients with ossicular necrosis or fixity but since the patients with ossicular abnormality were very less in the current study further evaluation and data are necessary.

Conclusion

Hence from the above results and observations, it can be concluded that the MERI index is a very useful and honest predictor of graft uptake and audiological gain in patients undergoing tympanoplasty surgeries for CSOM. Lower the MERI index better the outcome. Positive Belluci Criteria were also found to be inversely associated with graft uptake. This can significantly reduce the economic burden and man hours lost from the patients' side and also give a rough idea as to what to tackle from the surgeons' side. So MERI index can be routinely used as a predicting tool

For the outcome of tympanoplasty surgery in modern ENT practice.

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