



# A Prospective Study to Evaluate Role of Middle Ear Risk Index in Tympanoplasty with Mastoidectomy as a Prognostic Parameter

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Ann Otol Neurotol ISO 2022;5:31–35.

## Abstract

**Introduction** Chronic otitis media (COM) is an otological challenge in the developing countries as it is a persistent disease causing severe destruction of middle ear with irreversible sequelae. To assess Middle Ear Risk Index (MERI) score and study its prognostic effect in postoperative outcome following mastoidectomy with tympanoplasty. To evaluate MERI score with respect to graft uptake and A-B gap closure.

**Materials and Methods** This prospective study comprised 25 patients suffering from COM who presented to the Department of ENT, HSK Hospital, Bagalkot, over a period of 1 year from November 2020 to November 2021. The patients underwent tympanoplasty with mastoidectomy. MERI 2001 was used in the current study, and risk factors were assessed based on pre- and intra-operative findings to obtain the MERI score. Patients were segregated into those with mild (1–3), moderate (4–7), and severe (8–15) MERI. They were evaluated at 1 month follow-up visit.

**Results and Conclusion** The study reveals the degree to which MERI score can predict the extent of disease and indicate outcome of surgery. In the present study, patients with lower MERI score benefitted more favorably in terms of graft uptake and hearing improvement as compared with success rate of severe MERI score. MERI index is in fact a very reliable predictor of graft uptake and audiological alteration in patients undergoing tympanoplasty with mastoidectomy surgeries for COM.

## Keywords

- chronic otitis media
- middle ear risk index
- mastoidectomy

## Introduction

COM is an otological challenge in the developing countries as it is a persistent disease causing severe destruction of the middle ear with irreversible sequelae.<sup>1</sup> It is important to assess the severity of the disease and predict the outcome of the surgical management whenever done.<sup>2</sup> The main aim of surgery for COM is to remove the disease, make the ear dry and to restore hearing.<sup>3</sup> Tympanomastoidectomy is the procedure for removal of the disease from the middle ear cleft done

either as open or closed cavity procedure, and tympanoplasty is the procedure for reconstruction of the middle ear.<sup>3</sup>

The success of tympanomastoidectomy with tympanoplasty is dependent not only upon the surgical principle but also on the pathological factors associated with the disease.<sup>4</sup> Kartush introduced the Middle Ear Risk Index [MERI] (► **Table 1**).<sup>5</sup>

In the present study, we aimed to assess MERI predictive factors in patients undergoing tympanoplasty with mastoidectomy and determine its role as a prognostic parameter.

**DOI** <https://doi.org/10.1055/s-0043-1761402>  
**ISSN** 2581-9607

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**Table 1** Middle ear risk index 2001

S. no.	Risk factor	Risk value
1. Otorrhea		
	I Dry	0
	II Occasionally wet	1
	III Persistently wet	2
	IV Wet, cleft palate	3
2. Perforation		
	Absent	0
	Present	1
3. Cholesteatoma		
	Absent	0
	Present	1
4. Ossicular status		
	O: M + I + S+	0
	A: M + S +	1
	B: M + S-	2
	C: M – S+	3
	D: M – S-	4
	E: Ossicle head fixation	2
	F: Stapes fixation	3
5. Middle ear granulation or effusion		
	No	0
	Yes	2
6. Previous surgery		
	None	0
	Staged	1
	Revision	2
7. Smoker		
	No	0
	Yes	2

Abbreviations: I, incus; M, malleus; S, stapes.

## Aims and Objectives

- To assess MERI score and study its prognostic effect in the postoperative outcome following mastoidectomy with tympanoplasty.
- To evaluate MERI score with respect to graft uptake and A-B gap closure.

## Methodology

The present paper is a prospective study. Sample size estimation was done using OPENEPi software version 2. With 95% confidence level and 80% power of the study, for error of 15%, sample size was estimated to be 25. According to the study conducted by Kumar et al<sup>2</sup>, value used is number of ears that

achieved air bone gap of 0–10 dB = 82.5% = p. It was calculated using formula:  $n = [DEFF * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p)]$ .

## Inclusion Criteria

- Patients with chronic otitis media presenting to the outpatient department of otorhinolaryngology at HSK Hospital, Bagalkot, willing for surgery.
- Patients between the age group of 13 and 75 years of both the genders.

## Exclusion Criteria

- Patients below the age of 13 and above 75 years.
- Patients with previous history of use of ototoxic drugs.
- Patients with otomycosis, septic foci.
- Patients found to have intracranial complications of chronic otitis media.

## Collection of Data

- Patients attending outpatient department of ENT, HSK Hospital, Bagalkot, with chronic otitis media.
- Risk categories as per the MERI were analyzed and severity of disease condition was determined.

## Materials and Methods

This was a prospective study conducted in Department of ENT, HSK Hospital, Bagalkot, from November 2020 to November 2021. The study protocol was cleared by institutional ethics committee. This study was performed in 25 patients suffering from chronic otitis media, both mucosal and squamous types. They belonged to the age group of 13 to 75 years.

Detailed history was taken from all cases followed by general and systemic examinations. Patients were also subjected to ear, nose, and throat examination. They underwent routine blood investigations, otological evaluation namely pure tone audiometry (PTA), otomicroscopy and radiological work-up. The nature and extent of the disease, presence or absence of perforation, granulation tissue, cholesteatoma, ossicular chain status, type, and degree of hearing loss was established.

Factors such as age, sex, presence of systemic diseases, smoking history, duration of dry period of ear, and prior ear surgery were recorded. Patients with discharging ear were treated conservatively with antibiotics, antihistaminic, and topical ear drops. Once septic foci were ruled out, surgical procedure was planned according to disease condition. Tympanoplasty with mastoidectomy, either canal wall up (CWU) or canal wall down (CWD), with post-aural surgical approach was performed. Tympanoplasty by underlay technique was done in all patients by harvesting temporalis fascia as graft material.

MERI 2001 was used in the current study and risk factors were assessed based on pre- and intraoperative findings to obtain the MERI score. Patients were segregated into those with mild (1–3), moderate (4–7), and severe (8–15) MERI. They were evaluated at 1 month follow-up visit and data were collected through clinical examination and audiometry.

Graft status was analyzed as healed graft/ atelectatic graft or perforation of graft. Hearing benefit of surgery was found using PTA.

Surgical outcome in terms of graft uptake and audiological gain were compared in group of patients with mild, moderate, and severe MERI. Their statistical significance along with that of other risk factors were studied to determine the role of MERI as a prognostic indicator in predicting success of surgery.

### Statistical Analysis

Data were entered in the Microsoft excel and analyzed using the SPSS software version 19. Percentages and proportions were used for qualitative data and mean and standard deviation for quantitative data. Appropriate statistical tests such as Fisher's exact test and paired *t*-test were applied. A *p*-value of less than 0.05 was considered as statistically significant.

### Observation and Results

The present study was performed in 25 patients with COM of both mucosal and squamous types. The mean age of the patients in the study was 28.60 (SD 12.626) years with the minimum and maximum age of 13 and 60 years, respectively. Out of the 25 patients, there were 10 (40%) males and 15 (60%) female patients.

Based on the risk parameters such as discharge, perforation, cholesteatoma, ossicular status, middle ear effusion/granulations, history of previous surgery and smoking habits, the study population were assessed and assigned their respective MERI index (►Table 2, 3).

In our study, out of 25 patients, 21 patients had tympanic membrane perforation and 4 had retraction pocket. Out of these 21 patients, 1 had small size, 7 had medium size, 10 had large size, and 3 patients had attic perforations.

Middle ear pathological conditions such as cholesteatoma sac were present in 6 patients and granulation tissue was seen in 6 out of total 25 patients.

**Table 2** Otorrhea in cases

	Frequency	Percentage
Dry	1	4.0
Occasionally wet	17	68.0
Persistently wet	7	28.0
Total	25	100.0

**Table 4** Graft uptake versus MERI

			Category of MERI			Total
			Mild	Moderate	Severe	
Graft	Success	Count	14	5	3	22
		%	63.6%	22.7%	13.6%	100.0%
	Failure	Count	0	1	2	3
		%	0.0%	33.3%	66.7%	100.0%

Twenty-three patients underwent tympanomastoid surgery for the first time, whereas 2 patients had prior history of surgery. Of all, three patients (12%) had a habit of smoking.

Some additional factors which were not constituents of the MERI were analyzed such as the presence of tympanosclerosis and mastoidectomy technique. In our study, tympanosclerosis was present in nine patients. None had any systemic disease.

MERI score was calculated for each patient. It was observed that the maximum number of ears 14 (56%) fell under MERI 1 to 3, i.e., mild disease, followed by 6 (24%) ears with a MERI score of 4 to 7, i.e., moderate disease, and then by 5 (20%) ears with an MERI score of 8 to 15, i.e., severe disease.

The patients were also categorized based on their pre-operative hearing status. About 36% (9 patients) had mild, 9 had moderate, 5 had moderately severe hearing loss, while 2 patients had severe hearing loss.

Six among 14 patients with MERI scores in the mild category had mild hearing loss with 6 patients having moderate loss. Patients with moderate MERI scores had 3 patients with mild hearing loss and 2 patients with moderate hearing loss. Among the five patients in the severe category, one had moderate hearing loss and three had moderately severe hearing loss.

The tympanic membrane graft uptakes were evaluated at 1 month postoperatively. In this study, graft was accepted in 22 patients (88%) and rejected in 3 (12%) patients (►Table 4). In patients in the mild MERI risk group *n* = 14, graft was accepted in all these patients. In patients in the moderate MERI risk group *n* = 6, graft was accepted in five patients (22.7%) and rejected in one patient (33.3%). The patient had a residual perforation. In all, 66.7% of the grafts were rejected in the severe risk group. The graft acceptance in the mild MERI risk group was significantly higher and statistically significant (*p* = 0.039).

Patients were also assessed for the average hearing threshold and A-B gap (ABG). In this study, the mean preoperative PTA average was 48.88 dB (SD 14.76 dB). First month

**Table 3** Ossicular status

	Frequency	Percentage
M + I + S+	18	72.0
M + S+	1	4.0
M – S+	5	20.0
M – S-	1	4.0
Total	25	100.0

**Table 5** A-B closure of 0–10 in various categories of MERI

			Category MERI			Total
			Mild	Moderate	Severe	
A-B gap < 10	Present	Count	11	5	0	16
		%	68.8%	31.2%	0.0%	100.0%
	Absent	Count	3	1	5	9
		%	33.3%	11.1%	55.6%	100.0%

post-operative PTA average was 30.84 dB (SD 18.20 dB), which was statistically significant compared with prior PTA value ( $p = 0.001$ ). Preoperative mean A-B gap was 27.80 and the mean A-B gap at follow-up was 11.80. The difference between the preoperative and postoperative AB gap was statistically significant ( $p = 0.001$ ).

The amount of air bone gap closure achieved was noted. It was observed that the maximum number of ears (16) achieved air bone gap closure of 0 to 10 dB. AB gap less than 10 dB was considered as successful.<sup>3</sup> Accordingly, in the mild MERI risk group  $n = 14$ , 11 patients were successful, 3 patients had improvement, and none of these patients failed. In the moderate MERI risk group  $n = 6$ , five patients were successful. In the severe MERI risk group  $n = 5$ , all patients failed (→ **Table 5**). There was a statistically significant hearing improvement in the A-B gap for patients with mild MERI ( $p < 0.05$ ).

On the basis of this study, tympanosclerotic plaque was not predictive or determinant of successful tympanomastoidectomy with tympanoplasty. We evaluated the mean audiological gain at 1 month after surgery. Postoperative average hearing gain was 16.00 (SD 11.99). Mastoidectomy performed was canal wall up type in 18 (72%) patients and canal wall down type in 7 (28%) patients. The difference in mean audiological gain between CWU and CWD mastoidectomy group of patients was not statistically significant.

## Discussion

Although there is huge literature present about the techniques of tympanomastoidectomy with tympanoplasty but the data about factors affecting the outcome are limited.<sup>5</sup> The literature contains many reports discussing various prognostic factors in tympanomastoid surgery and their impact on hearing results.<sup>5</sup>

The MERI combines the known preoperative and intraoperative risk factors for tympanoplasty prognosis into a numeric value.<sup>5</sup> It also allows meaningful study comparisons by delineating essential data and stratifying cases within various prognostic categories.<sup>5</sup> The risk parameters are assigned a numerical value corresponding to the MERI index, which helps us to identify the extent of disease and thereby predict the outcome of surgery.<sup>6</sup>

Pinar et al<sup>7</sup> evaluated the prognostic factors such as age, sex, systemic disease, type of surgery, and MERI indices in tympanoplasty on 231 patients. Finally, the success rate was approximately 74.4% and after analyzing the different factors, they concluded that size of tympanic membrane perforation

(TMP) ( $> 50\%$ ), health status of the opposite ear, lack of myringosclerosis, more than 3 months of the dryness of the ear, and low MERI were among the prognostic factors that should be improved to affect the result of tympanoplasty. The MERI score varies from zero to 15 and is categorized as follows: MERI 0 is normal; MERI 1 to 3 is mild diseases; MERI 4 to 7 is moderate disease; MERI 8 to 15 is severe disease.<sup>8</sup>

Becvarovski et al<sup>5</sup> stated that delayed failure of the graft was more commonly seen in smokers (60%) than non-smokers (20%). The patients without tympanic membrane perforation had better graft uptake in the absence of other significant middle ear pathology.

Kumar et al<sup>2</sup> evaluated the use of MERI and eustachian tube function as predictive factors for the evaluation of the result of tympanoplasty. In that study, 50 patients with unilateral and bilateral TMP were evaluated for 2 years. Graft was successful in 80% of patients and failed in 20% of them because six patients showed inappropriate eustachian tube function, two patients had a MERI score from 7 to 12, and two patients had an upper respiratory tract infection after surgery.

In the study done by Shishegar et al,<sup>8</sup> 200 patients were classified in the medium- and low-risk groups ( $n = 100$ , MERI: 1–7) and high-risk group ( $n = 100$ , MERI: 8–15). The comparison of the mean MERI scores between intact canal wall (ICW) and canal wall down (CWD) procedures showed that there was no significant difference between the mean MERI scores between these two types of surgery. There was a significant difference between MERI scores of the two types of surgery with and without mastoidectomy. This study showed that patients with a MERI lower than 3 or mild group had higher success rates. The mean MERI score was significantly higher in patients underwent CWD than ICW.

Similar study was done by Chrobok et al<sup>9</sup> shows patients with lower MERI had significantly better pre-op and post-op air and bone conduction than patients with a higher MERI. In patients with a mild MERI hearing improved by 4 to 6 dB. In patients with moderate and severe MERI hearing improvement was not seen.

## Conclusion

Various factors were analyzed in the present study, which were constituents of the MERI. These factors were studied in COM patients undergoing tympanomastoidectomy with tympanoplasty for their effect on the outcome of the surgery, evaluated in terms of tympanic membrane graft uptake and A-B gap closure. Statistically significant prognostic difference was

found among the patients with mild, moderate, and severe MERI at 1 month after surgery. This study clearly shows that ears that are staged into mild MERI disease have a higher graft acceptance rate in comparison to ears termed to have a severe disease, which have an increased chance of graft rejection. The mild MERI group had the maximum overall hearing improvements that is assessed as AB gap of less than 10. MERI is a thus a good prognostic factor for predicting outcomes after surgery.

#### Conflict of Interest

None declared.

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