

# Evaluating the Role of Middle Ear Risk Indices in Assessing Postoperative Outcome following Tympanoplasty Procedure

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## ABSTRACT

### Introduction

Tympanoplasty is the treatment of choice for patients suffering with Chronic Otitis Media (COM). Outcome of tympanoplasty depends on various factors like size and location of tympanic membrane perforation, ear ossicles, degree of otorrhea, cholesteatoma, smoking history, granulation tissue etc. Prediction of outcome of tympanoplasty procedure prior to surgery with respect to graft uptake and hearing improvement can serve as a crucial factor in decision making in resource limited nations. Hence, a study was conducted to evaluate the role of Middle Ear Risk Indices (MERI) in predicting the outcome among patients undergoing tympanoplasty procedure.

### Materials And Methods

A prospective study at a tertiary care centre was conducted for a duration of 2 years among 60 patients with COM who underwent tympanoplasty.

### Result

The mean age of patients was  $25.32 \pm 8.43$  years with a male to female ratio of 3:2. Majority (78.46%) of the patients had Mild MERI score; 18.46% patients had moderate MERI score and 3.08% patients had severe MERI risk score. The difference in mean Air - Bone (AB) gap in the mild and moderate MERI groups' pre and post operatively was found to be statistically highly significant ( $p < 0.001$ ).

### Conclusion

Lower MERI scores prior to surgery showed significantly better outcomes with respect to graft uptake, degree of AB gap closure and hearing improvement.

### Keywords

Tympanoplasty; Otitis Media; Middle Ear Risk Index

Chronic Otitis Media (COM) is a permanent disease resulting from chronic inflammation of middle ear cleft causing persistent ear discharge through a perforated tympanic membrane. COM is defined as persistent disease of middle ear involving tympanic membrane perforation and ear discharge of longer duration i.e., more than 3 months of active disease.<sup>1</sup> COM is highly prevalent in a developing country like India owing to factors like lower socio-economic status, overcrowding, poor hygiene & housing conditions, poor nutrition and frequent upper respiratory tract infections.<sup>2</sup>

COM causes conductive hearing loss - typically a

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mild conductive loss of 10 to 20 dB; while in some cases, ossicular chain erosion can occur, causing a more profound audiologic variation of 50 to 70 dB, which is usually considered as a serious disability.<sup>3</sup> Tympanoplasty is an operative procedure which helps in reconstruction of the sound conducting mechanism of the middle ear. It is a procedure aimed to prevent reinfection and restore hearing ability. In this surgical technique, repair of perforated tympanic membrane is done with/without reconstruction of ossicles.<sup>4</sup>

Some studies concluded that outcome of tympanoplasty depends on various factors like size and location of perforation, ossicular status, type of surgical technique, degree of otorrhoea, etc.<sup>5,6</sup> The ability to predict the outcome of surgical procedure prior to surgery will play a crucial role in explaining and convincing patient for a surgery especially in developing nations where cost of surgery is a major limitation.

Middle Ear Risk Index (MERI) is a numerical grading to stratify the patient based on severity of COM. MERI is determined by assigning a specific value for each risk factor, and these values are added to get the cumulative MERI score. The risk factors include smoking; degree of otorrhoea; ossicular status; presence of perforation; cholesteatoma; middle ear granulations/effusion and history of previous surgery.<sup>7</sup>

The present study was taken with an aim to evaluate the role of Middle Ear Risk Indices (MERI) in predicting the outcome among patients undergoing tympanoplasty procedure for COM in terms of degree of Air -Bone gap closure and uptake of graft.

## Materials and Methods

A Prospective study was carried out at a tertiary care Centre in Telangana state, India. The study was conducted from October 2015 to September 2017 with a total of 60 patients who underwent tympanoplasty. All patients of COM undergoing Tympanoplasty procedure aged between 15 - 60 years, who were willing to take part in the study were included. Patients who have undergone previous middle ear surgeries or had cholesteatoma and other co-morbidities like hypertension and diabetes mellitus were excluded from the study. Patients on

ototoxic drugs and patients with complaints of tinnitus and vertigo were also excluded. Detailed history was taken and thorough clinical examination which included general physical examination, Ear Nose and Throat examination and systemic examination was done for all the 60 study participants. Oto endoscopy, CT scan of both temporal bones and pure tone audiometry were the investigations done for all the study subjects. Ossicular defects, Presence of granulations / middle ear effusions were evaluated intra-operatively. The middle ear risk indices thus generated were used as indicators of severity of the middle ear disease and patients were stratified according to severity of disease.<sup>7</sup> A MERI score of 0 was normal. MERI score ranging from 1 – 3 was considered as mild disease state, MERI Score of 4 – 6 was considered as Moderate disease state and a score of 7 – 12 was taken as severe disease state.

The aggregate of MERI score of each patient was assessed using the risk factors like degree of otorrhoea, which was assessed by Bellucci criteria; Ossicular status which was assessed by Austin/Kartush criteria; presence of perforation, cholesteatoma; middle ear granulations/effusion and history of previous surgery and smoking history.<sup>7</sup>

Assessment criteria of MERI risk score for each patient was based on individual risk factors like otorrhoea assessed by Bellucci criteria (I – Dry ear had a risk value of 0, II – Occasionally wet ear had a risk value of 1, III – persistently wet ear had a risk value of 2, IV- Wet, cleft palate was given a risk value of 3); Perforation (No perforation of tympanic membrane had a risk value of 0, perforated tympanic membrane had a risk value of 1); Cholesteatoma (None – 0, Present – 2); Ossicular status as assessed by Austin/Kartush criteria ( Malleus, incus, stapes intact – 0, Malleus and stapes intact – 1, Malleus intact with erosion of stapes – 2, Stapes intact with erosion of malleus – 3, Erosion of malleus and stapes – 4, Malleus head fixed – 2, stapes fixed – 3); Middle ear granulations (None – 0, Present – 2); History of previous surgery (None – 0, Staged – 1, Revision – 2); Smoker (No – 0, Yes – 2).

All the patients were categorized based on hearing impairment using World Health Organization (WHO) classification of Hearing Impairment. Based on pure tone audiometry findings, grades of hearing impairment

**Table I: Distribution of patients as per MERI Score and pre-operative hearing loss**

	MILD MERI (%)	MODERATE MERI (%)	SEVERE MERI (%)	TOTAL (%)
Mild Hearing Impairment	26 (40)	7 (10.8)	0 (0)	33 (50.8)
Moderate Hearing Impairment	25 (38.4)	5 (7.7)	0 (0)	30 (46.1)
Severe Hearing Impairment	0 (0)	0 (0)	2 (3.1)	2 (3.1)
Total	51 (78.4)	12 (18.5)	2 (3.1)	65 (100)

were ascertained as  $\leq 25$  dB – No impairment; 26 – 40 dB – Mild impairment; 41 – 60 dB – Moderate impairment; 61 – 80 dB – Severe impairment and  $\geq 81$  dB – Profound impairment.<sup>8</sup> Depending on the pathology, the following surgical procedures were done: Type I Tympanoplasty ( Myringoplasty ) , Myringoplasty with Cortical Mastoidectomy, Type III Tympanoplasties (with Ossiculoplasty ) with Cortical Mastoidectomy . Efficiency of MERI in predicting the outcome of tympanoplasty were evaluated during the follow up of the patients. The graft status was examined on 21st post-operative day by otoendoscopy. On postoperative follow up, assessment of hearing was done by pure tone audiometry in 3rd month of postoperative period. Degree of AB gap closure was assessed post operatively. Following tympanoplasty procedure, an AB gap of  $>20$  dB post operatively was considered as failure of procedure, 11-20 dB as Markedly improved, 0-10 dB as Successful. Data was analyzed using SPSS v 23.0. Descriptive statistics were expressed in percentages and appropriate test of significance were used to determine p value. A p value of  $<0.05$  was taken as statistically significant value.

### Results

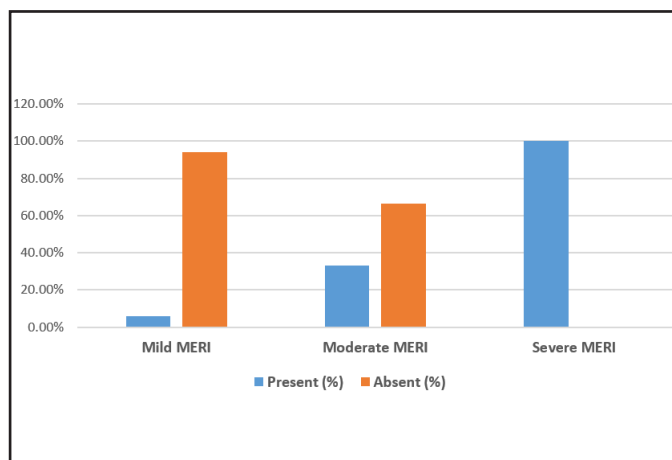
In this study, a total of 60 patients of COM who underwent tympanoplasty were evaluated and the middle ear risk indices (MERI) were assessed to predict the outcome following tympanoplasty procedure. A total of 55 (91.67%) patients had a unilateral perforation and 5 (8.67%) patients had bilateral perforations. Patients with bilateral perforation, were operated for both ears with minimum interval of 6 months. Therefore, a total of 65 ears were operated and all these operated cases were further evaluated for graft uptake, average hearing threshold and Air - Bone (AB) gap postoperatively.

The mean age of patients in this study was observed to be  $25.32 \pm 8.43$  years. The study included a total of 36 (60%) males and 24 (40%) females. Around 41.66% patients were smokers and 58.33% were non-smokers. In the present study, MERI risk criteria assessment score was determined for each diseased ear and it was found that majority (78.46%) of the patients were categorized as Mild MERI (Score of 1 – 3); 18.46% patients were categorized as moderate MERI (Score of 4 – 6) and only 2 subjects (3.08%) were categorized as severe risk category (Score of 7 – 12). As per the findings of pure tone audiogram it was found that in this study 50.77% of subjects suffered with Mild hearing impairment. Almost 46.15% with moderate hearing impairment and 3.08% with severe hearing impairment.

Table I shows that there was almost equal distribution of mild (40%) and moderate (38.4%) hearing impairment among all patients who had mild MERI disease state. Among patients who had moderate MERI disease state, 10.8% had mild hearing impairment and 7.7% had moderate hearing impairment. All the patients with severe MERI disease state had severe hearing impairment.

Around 13.15% of patients had middle ear granulations. Middle ear Granulation was observed in all (100%) patients of severe MERI group; In mild MERI risk group, 3 (5.88%) patients had middle ear Granulation and in moderate MERI risk group, middle ear Granulation was observed in 4 (33.33%) of patients. (Fig. 1)

Graft was accepted in 80% patients and rejected in 20% patients. In patients in mild MERI risk group, graft acceptance rate was 86.27% and rejection rate was 13.73%. In moderate MERI risk group, graft was

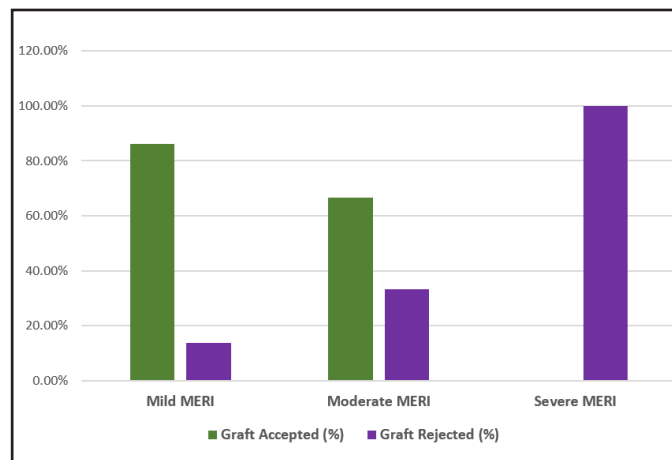


**Fig. 1. Distribution of study population according to middle ear granulation and MERI scores**

accepted in 66.67% patients and rejected in 33.33% patients. In severe MERI risk group, graft was rejected in all (100%) patients. (Fig. 2) Among patients in low MERI risk group, graft acceptance was observed to be statistically higher as compared to patients in moderate and severe MERI risk group ( $p < 0.05$ ).

Among patients in mild MERI risk group with middle ear granulations, only 1 patient (33.3%) showed acceptance of graft and among patients in moderate MERI risk group and severe MERI risk group with granulations all the patients (100%) showed graft rejection. The difference in graft acceptance among patients with middle ear granulations was found to be statistically not significant ( $p > 0.05$ ).

The graft acceptance rate was 97.9% in patients with dry ear. Around 71.5% of patients who had occasionally wet ear and 100% of patients who had persistently wet ear showed graft rejection. Patients with dry ear had significantly better graft acceptance as compared to patients with occasionally wet and persistently wet ears



**Fig. 2. Status of graft uptake according to MERI risk scores**

( $p < 0.05$ ). (Table II)

Assessment of hearing was done for only mild and moderate MERI groups post operatively at end of 3 months. The mean preoperative AB gap in mild MERI group was  $26.34 \pm 4.14$  dB; in the moderate MERI group it was  $37.04 \pm 3.72$  dB. The mean postoperative AB gap in mild MERI group was  $14.26 \pm 4.35$  dB; in the moderate MERI group it was  $24.78 \pm 4.06$  dB. The difference in mean AB gap in the mild and moderate MERI group's pre and post operatively was found to be statistically highly significant ( $p < 0.001$ ). There was marked improvement in terms of AB gap closure following tympanoplasty procedure among the study subjects. (Table III)

In present study, among 65 operated ears, 12 ears (18.46%) had ossicular necrosis i.e, erosion of long process of incus. Patients with ossicular necrosis underwent type III tympanoplasty (i.e. repair of the Tympanic membrane onto the stapes head) and remaining patients underwent type I tympanoplasty

**Table II: Relationship between degree of otorrhoea and graft acceptance/rejection**

DEGREE OF OTORRHOEA AS PER BELLUCCI CRITERIA	GRAFT	GRAFT REJECTED (%)	TOTAL (%)	P VALUE
Dry	48 (97.9)	1 (2.1)	49 (100)	<0.05
Occasionally wet	4 (28.5)	10 (71.5)	14 (100)	
Persistently wet	0 (0)	2 (100)	2 (100)	

**Table III: Comparison of pre and postoperative Air–Bone (AB) gap in MERI groups**

MERI RISK SCORE	PRE-OP. AB GAP (DB)	POST- OP. AB GAP (DB)	P VALUE
Mild	26.34 ± 4.14	14.26 ± 4.35	<0.001
Moderate	37.04 ± 3.72	24.78 ± 4.06	<0.001

(repair of the TM alone; no abnormality of the middle ear). In type I tympanoplasty, graft acceptance was observed in 96.22% of study subjects and graft acceptance was observed in only 1 patient (8.33%) who underwent type III tympanoplasty. The graft acceptance was significantly poor in presence of ossicular necrosis ( $p < 0.05$ ).

Among patients who underwent Type I tympanoplasty, 27.4% were successful (Postoperative AB gap 0 – 10 dB), 64.7% were markedly improved (Postoperative AB gap 11 – 20 dB) and 7.8% failed (Postoperative AB gap >20dB) in terms of hearing assessment and AB gap closure. Among Patients who underwent Type III tympanoplasty, only one patient (8.3%) showed graft acceptance in which hearing assessment was done and it was found to be failure (Postoperative AB gap >20dB).

In mild MERI group, 18.1% were successful (AB gap 0 -10 dB), 75% had moderately improved (AB gap 11-20 dB) and 6.9% had AB gap >20 dB (failed). In moderate MERI group 50% had moderately improved and 50% failed. (Fig. 3)

## Discussion

The present study affirms the findings that COM has no sex predilection and can occur in early adulthood of life. The present study findings were similar to a study by Naderpour et al and Sharma et al in which mean age of study subjects was  $33.6 \pm 7.3$  years and  $22.6 \pm 9.1$  years respectively.<sup>9,10</sup>

Patients with COM usually have mild MERI risk scores as seen in present study. This study findings concurred with a study by Kumar et al in which 72% had mild MERI; 24% - moderate MERI and 4% had severe MERI risk scores.<sup>11</sup> These findings were different as compared to a study by Sharma et al in which 64% had mild MERI score, 20% had severe MERI scores and 16% had moderate MERI scores.<sup>10</sup>

In this study, pure tone audiogram showed that 50.77% of subjects suffered with Mild hearing impairment; 46.15% with moderate hearing impairment and 3.08% with severe hearing impairment. The present study findings were similar to a study by Muftah et al in which 37.3% of study subjects with COM had mild hearing impairment, 25.5% had moderate hearing impairment and 3.9% had severe hearing impairment.<sup>12</sup>

Patients with low MERI risk scores in this study, showed statistically higher graft acceptance rate as compared to patients in moderate and severe MERI risk group ( $p < 0.05$ ). This can be attributed to the fact that low MERI risk scores lead to lesser complications and better acceptance of graft. The present study findings were comparable with previous literature done by Kumar et al and Ahmed et al in which graft acceptance rate in mild MERI patients was 86% and 80% respectively and in moderate MERI risk groups it was 75% and 72% respectively.<sup>11,13</sup>

Patients with dry ear had significantly better graft acceptance as compared to patients with occasionally wet and persistently wet ears ( $p < 0.05$ ). Discharge from ear corresponds to infection and infections can lead to graft rejection. The present study findings were different as compared to a study conducted by Naderpour et al in which 96.7% of patients with dry ear and 93.3% of patients with wet ear showed graft acceptance.<sup>9</sup>

The difference in mean AB gap in the mild and moderate MERI group's pre and post operatively was found to be statistically highly significant ( $P < 0.001$ ). This signifies that lower MERI risk scores pre operatively can lead to better closure of AB gap and marked improvement in hearing ability. The present study findings can be compared with a study by Shetty et al and Shreshta et al in which the difference in AB gap pre and postoperatively was found to be statistically significant.<sup>5,14</sup>

In this study, around 86% of patients have achieved



an AB gap closure postoperatively of <20 dB. Majority of successful surgical procedure in terms of AB gap closure was observed in patients with mild MERI risk scores. The present study findings concurred with a study by Lima et al in which 82% of study subjects achieved an AB gap postoperatively of <20 dB.<sup>4</sup> Kumar et al reported that among their study subjects an air bone gap closure of 0 – 10 dB was achieved in almost 92.5% of patients.<sup>11</sup>

The graft acceptance was significantly poor in presence of ossicular necrosis ( $p < 0.05$ ). The present study findings concluded with a study by Ahmed et al in which graft rejection was found to be associated with ossicular necrosis.<sup>13</sup>

Among patients who underwent Type I tympanoplasty, only 27.4% achieved AB gap closure of 0 – 10 dB. The present study findings were different with a study done by Lima et al and Kumar et al in which 56% and 82.5% of patients had AB gap closure of 0 – 10 dB post-operatively.<sup>4,11</sup>

## Conclusion

From this study, it can be concluded that MERI risk score can be used to predict the outcome of tympanoplasty. Patients with lower MERI risk score had better prognosis in terms of graft acceptance, improvement in hearing and also in achieving good AB gap closure. Patients with higher MERI risk scores had higher rates of graft rejection and no significant improvement in hearing was noted. Presence of middle ear granulations and ossicular necrosis predict a poor outcome following tympanoplasty in COM patients. Patients with dry ears as per Bellucci criteria had better graft acceptance and successful outcome in terms of hearing improvement when compared to patients with occasionally wet and persistently wet ears.

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