

Research Article

Association of Middle Ear Risk Index with Anatomical and Audiological Outcomes Following Tympanoplasty: A Prospective Observational Study

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Received: 10.06.26, Revised: 12.07.26, Accepted: 14.08.26

ABSTRACT

Background: Chronic middle-ear disease may cause tympanic membrane perforation, chronic inflammation, ossicular damage, and conductive hearing loss, thereby affecting the outcome of tympanoplasty. The Middle Ear Risk Index (MERI) combines adverse middle-ear factors into a composite score and may assist in assessing disease severity and postoperative risk.

Objective: To evaluate the association between MERI severity and anatomical and audiological outcomes following tympanoplasty and tympanomastoid surgery and to assess its relationship with the extent of surgical intervention.

Methods: This prospective observational cohort study was conducted in the Department of Otorhinolaryngology, Hind Institute of Medical Sciences, Sitapur, Uttar Pradesh, from July 2023 to August 2024. A total of 111 patients were enrolled, of whom 88 had postoperative outcome data and were included in the final analysis. MERI was categorized as mild (1-3), moderate (4-6), or severe (7-12). The principal anatomical outcome was graft uptake at 6 months. Functional outcome was assessed using postoperative air-bone gap (ABG) and ABG gain. Categorical variables were analyzed using chi-square tests, within-group audiological changes using paired t-tests, and differences in ABG gain across MERI categories using one-way analysis of variance.

Results: Among 88 analyzed patients, 19 (21.6%) had mild, 37 (42.0%) moderate, and 32 (36.4%) severe MERI. Six-month graft uptake was 94.7%, 81.0%, and 68.7% in the mild, moderate, and severe groups, respectively; the categorical association was not statistically significant ($\chi^2=5.04$, $p=0.080$). Mean 6-month ABG gain was 17.7, 16.1, and 13.9 dB in the mild, moderate, and severe groups, respectively, with a significant between-group difference ($F=32.24$, $p=3.8 \times 10^{-11}$). MERI category was also significantly associated with the extent of surgical intervention ($\chi^2=21.44$, $p=0.002$).

Conclusion: Increasing MERI severity was associated with greater surgical complexity and a progressive reduction in postoperative hearing improvement. Graft uptake also showed a clinically relevant decline with increasing MERI, although the categorical association did not reach statistical significance. MERI may therefore be useful as a structured component of preoperative assessment and patient counselling, while larger multicentre studies with longer follow-up and multivariable analysis are needed to establish its independent prognostic value.

Keywords: Middle Ear Risk Index, Meri, Tympanoplasty, Tympanomastoidectomy, Chronic Otitis Media, Graft Uptake, Air-Bone Gap, Hearing Outcome.

INTRODUCTION

Chronic suppurative otitis media and other chronic middle-ear disorders can result in persistent inflammation, tympanic membrane perforation, otorrhoea, ossicular damage, retraction, granulation tissue, cholesteatoma,

and conductive hearing loss. These pathological changes may increase the technical difficulty of tympanoplasty and influence postoperative anatomical and functional outcomes [1,2].

Tympanoplasty aims to eradicate or control middle-ear disease, establish a safe and dry ear, reconstruct the tympanic membrane, and restore sound conduction. Depending on the extent of disease and ossicular status, tympanoplasty may be combined with cortical mastoidectomy, modified radical mastoidectomy, and ossiculoplasty. Surgical outcome may be influenced by middle-ear mucosal status, Eustachian tube function, ossicular integrity, cholesteatoma, previous surgery, and patient-related factors [3].

The Middle Ear Risk Index (MERI) was developed from earlier ossicular reconstruction risk concepts and subsequently modified by Becvarovski and Kartush. It combines adverse factors including otorrhea, tympanic membrane perforation, cholesteatoma, ossicular status, middle-ear granulation, previous surgery, and smoking into a composite score [4]. Subsequent studies have evaluated the usefulness of MERI for predicting anatomical and functional outcomes following middle-ear surgery [3,5–7].

The present study was undertaken to prospectively evaluate the relationship between MERI severity and graft uptake and hearing outcomes following tympanoplasty and tympanomastoid surgery. A secondary objective was to determine whether increasing MERI severity was associated with more extensive surgical intervention.

Objectives

- To categorize patients undergoing tympanoplasty according to MERI severity.
- To assess the association between MERI category and postoperative graft uptake.
- To evaluate postoperative hearing improvement across MERI categories using ABG measurements.
- To assess the relationship between MERI category and the extent of surgical intervention.

Study stage	Number
Enrolled	111
Without postoperative outcome data/lost to follow-up	23
Included in final analysis	88

The distinction between recruited and analyzed participants was maintained throughout the analysis. A participant flow diagram should accompany the manuscript submission. STROBE recommends reporting participant numbers at each study stage and

METHODS

Study Design and Setting

This prospective observational cohort study was conducted in the Department of Otorhinolaryngology, Hind Institute of Medical Sciences, Mau, Ataria, Sitapur, Uttar Pradesh, India. Recruitment and data collection were performed from July 2023 through August 2024.

Ethical Approval and Consent

The study received approval from the Institutional Ethics Committee/Institutional Review Board (Ref. No. IHEC-HIMSA/MD/MS-23/RD-48/07-24). Participants were counselled regarding the study, potential benefits and risks, confidentiality, and their right to withdraw. Written informed consent was obtained.

Participants

Patients aged ≥ 10 years with chronic middle-ear disease, chronic otitis media, tympanic membrane perforation, or relevant middle-ear pathology who were planned for tympanoplasty were eligible. Patients unwilling to participate or unable to provide written consent were excluded. Other exclusion criteria included sensorineural hearing loss, congenital ear/nose/throat deformity, acute otitis media, otosclerosis, inner-ear pathology, Ménière disease, labyrinthitis, active middle-ear tuberculosis, malignant middle-ear tumours, severe Eustachian tube dysfunction despite medical management, and uncontrolled systemic disease affecting wound healing.

Study Size and Participant Flow

A total of 111 patients were enrolled. During follow-up, 23 patients were lost to follow-up, migrated, or had no postoperative outcome data. The final analyzable cohort consisted of 88 patients.

describing missing data and loss to follow-up [8].

Preoperative Assessment

All participants underwent detailed history taking and otological examination. Otoscopy,

otoendoscopy, and otomicroscopy were used to assess tympanic membrane status, perforation, middle-ear mucosa, and other pathology. Pure-tone audiometry was performed. Complete blood count, aural culture where clinically indicated, and computed tomography of the temporal bone were obtained according to clinical requirements.

Meri Assessment

MERI was calculated using documented middle-ear risk factors. When preoperative and intraoperative findings differed, the final intraoperatively confirmed score was used. The assessment incorporated otorrhea, tympanic membrane perforation, cholesteatoma, ossicular-chain status, middle-ear granulation, previous surgery, and smoking [4].

MERI score	Category
0	Normal
1–3	Mild
4–6	Moderate
7–12	Severe

For analysis, patients were categorized as mild, moderate, and severe MERI.

Surgical Management

Surgery was performed under local anaesthesia with intravenous sedation. Depending on intraoperative disease extent and ossicular status, patients underwent tympanoplasty or tympanomastoidectomy, including canal-wall-up or canal-wall-down procedures, with or without ossiculoplasty.

Follow-up and Outcome Measures

Patients underwent postoperative follow-up with assessment of graft status and pure-tone audiometry, including evaluations at 3 and 6 months. The principal anatomical outcome was graft uptake at 6 months. Functional outcome was evaluated using postoperative ABG and ABG gain.

ABG gain = Preoperative ABG – 6-month postoperative ABG

The study protocol defined surgical success at 6 months as an intact graft with an improvement in mean air-conduction threshold of >10 dB.

Categorical variables were compared using chi-square tests. Preoperative and postoperative ABG values within MERI groups were compared using paired t-tests. One-way analysis of variance was used to compare mean 6-month ABG gain among MERI categories, with Tukey's HSD post-hoc analysis where applicable. Statistical significance was defined as $p < 0.05$. Missing postoperative outcomes were handled by restricting the final outcome analysis to participants with available postoperative data. No multivariable adjustment or sensitivity analysis was reported.

RESULTS

Participant Characteristics

Of the 111 enrolled patients, 88 had postoperative outcome data and were included in the final analysis. Age ranged from 11 to 55 years, with a mean age of 29.8 ± 10.2 years. There were 42 males (47.7%) and 46 females (52.3%).

Statistical Analysis

Data were entered into an Excel master chart and analyzed using SPSS version 26.

Table 1. Age Distribution of the Study Population

Age group (years)	n	%
11–20	14	15.9
21–30	38	43.2
31–40	22	25.0
41–50	10	11.4
>50	4	4.5
Total	88	100

MERI Distribution

Table 2. Distribution of Patients According To MERI Category

MERI category	Score	n	%
Mild	1–3	19	21.6
Moderate	4–6	37	42.0
Severe	7–12	32	36.4
Total	—	88	100

Moderate MERI was the most frequent category. Overall, 69/88 (78.4%) patients had moderate or severe MERI.

Surgical Procedures

Table 3. Distribution of Surgical Procedures

Procedure	n	%	Usual MERI association in cohort
Type I tympanoplasty	19	21.6	Mild
Cortical mastoidectomy + tympanoplasty	25	28.4	Moderate
Modified radical mastoidectomy – CWU	22	25.0	Moderate/severe
Modified radical mastoidectomy – CWD	22	25.0	Severe
Total	88	100	—

MERI category was significantly associated with the surgical procedure performed ($\chi^2=21.44$, $p=0.002$). More extensive

procedures were increasingly represented among patients with higher MERI categories.

Tympanic Membrane Pathology

Table 4. Tympanic Membrane Pathology According To MERI Category

MERI category	Perforation, n (%)	Retraction pocket, n (%)	Total
Mild (n=19)	19 (100)	0 (0)	19
Moderate (n=37)	31 (83.8)	6 (16.2)	37
Severe (n=32)	6 (18.7)	26 (81.3)	32
Total	56	32	88

Tympanic membrane pathology differed significantly across MERI categories ($\chi^2=58.77$, $p<0.001$). Perforation

predominated in the mild and moderate groups, whereas retraction pockets were concentrated in the severe MERI group.

Graft Uptake

Table 5. Graft Uptake at 3 And 6 Months

MERI category	n	3-month success	6-month success
Mild	19	94.7%	94.7%
Moderate	37	83.8%	81.0%
Severe	32	75.0%	68.7%
Overall	88	83.0%	79.5%

Six-month graft uptake decreased progressively with increasing MERI severity. However, the categorical association was not statistically significant ($\chi^2=5.04$, $p=0.080$).

The source dataset reported an odds ratio of 8.18 for graft failure in severe versus mild MERI. Because the confidence interval and full model specification were not available, this estimate should be interpreted cautiously.

Audiological Outcomes

Table 6. Preoperative Audiological Findings According To MERI Category

MERI category	Mean preoperative AC (dB)	Mean preoperative BC (dB)	Mean preoperative ABG (dB)
Mild	46.2	17.5	28.7
Moderate	50.4	18.2	32.2
Severe	54.8	19.1	35.7

Preoperative ABG increased progressively with increasing MERI severity, indicating greater

conductive hearing impairment in the higher-risk groups.

Table 7. Postoperative Audiological Outcomes

MERI category	3-month ABG (dB)	6-month ABG (dB)	ABG gain (dB)
Mild	14.2	11.0	17.7
Moderate	18.5	16.1	16.1
Severe	23.9	21.8	13.9

All three MERI groups demonstrated significant preoperative-to-postoperative ABG improvement. Reported paired t-test statistics were 38.54 for mild MERI ($p < 0.001$), 44.96 for moderate MERI ($p < 0.001$), and 36.11 for severe MERI ($p < 0.01$).

Mean 6-month ABG gain was greatest in the mild group (17.7 dB), followed by the moderate group (16.1 dB) and severe group (13.9 dB). The difference in ABG gain between MERI categories was statistically significant (one-way ANOVA $F = 32.24$, $p \approx 3.8 \times 10^{-11}$).

Postoperative Complications

Table 8. Postoperative Complications

Complication	n	MERI distribution
Otorrhoea	5	1 mild, 2 moderate, 2 severe
Graft retraction	3	0 mild, 1 moderate, 2 severe
Wound infection	1	0 mild, 1 moderate, 0 severe
Total	9	—

Nine postoperative complications were documented, corresponding to approximately 10.2% of the analyzed cohort.

DISCUSSION

This prospective study evaluated the relationship between MERI severity and outcomes following tympanoplasty and tympanomastoid surgery. The main findings were that higher MERI was associated with greater surgical complexity and lower postoperative hearing improvement. Graft uptake also showed a progressive decline from mild to severe MERI, although this difference did not reach statistical significance.

The association between MERI and surgical complexity is clinically expected because higher scores reflect a greater burden of adverse middle-ear pathology. MERI was originally developed as a composite measure incorporating factors such as otorrhoea, tympanic membrane disease, cholesteatoma, ossicular status, middle-ear inflammation,

previous surgery, and smoking [4]. Previous studies have also demonstrated the prognostic relevance of MERI in tympanoplasty [3,5,6]. A prospective study reported poorer outcomes with increasing MERI severity, while other work has supported its potential role in preoperative counselling [5,6]. More recent evidence has also found that MERI > 3 may be associated with poorer postoperative hearing outcomes [7].

In the present study, six-month graft uptake decreased from 94.7% in mild MERI to 68.7% in severe MERI. Although the numerical difference was clinically relevant, the association was not statistically significant ($p = 0.080$). Therefore, the present findings support a trend rather than a definitive statistical relationship between MERI category and graft uptake.

The clearest association was observed for hearing outcome. Preoperative ABG increased with MERI severity, while mean ABG gain decreased from 17.7 dB in mild MERI to 13.9

dB in severe MERI. The significant between-group difference suggests that patients with greater middle-ear disease burden may have less hearing improvement after reconstruction. This is consistent with the concept that ossicular damage, chronic inflammation, cholesteatoma, and previous surgery may limit restoration of the conductive mechanism [4–7].

The study has several limitations. The final sample comprised only 88 patients, 23 participants were unavailable for postoperative analysis, and the study was conducted at a single centre. Different surgical procedures were included, which may introduce clinical heterogeneity. The analysis did not use multivariable adjustment; therefore, the independent prognostic value of MERI cannot be established. Follow-up was limited to six months, and confidence intervals for the main effect estimates were not available.

Overall, the findings suggest that MERI may be useful for structured preoperative assessment and counselling, particularly in relation to expected hearing improvement. However, MERI should be considered alongside the underlying disease characteristics, ossicular status, surgical procedure, and other clinical factors rather than used as a stand-alone predictive tool.

CONCLUSION

In this prospective cohort, increasing MERI severity was associated with greater surgical complexity and reduced postoperative hearing improvement. Six-month graft uptake showed a progressive numerical decline with increasing MERI severity, although the association was not statistically significant. MERI may therefore provide useful structured information for preoperative assessment and patient counselling in tympanoplasty and tympanomastoid surgery. Larger multicentre studies with longer follow-up and multivariable analysis are required to determine its independent predictive value.

Declarations

Ethics Approval

Institutional ethical approval was obtained from the Institutional Ethics Committee/Institutional Review Board (Ref. No. IHEC-HIMSA/MD/MS-23/RD-48/07-24).

Consent

Written informed consent was obtained from all participants.

Funding

No external funding was reported in the source dissertation.

Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Dr. Arji Nagendra Kumar: Conceptualization, methodology, investigation, data collection, data curation, analysis, and manuscript preparation.

Dr. Syed Mohd. Ahmad: Study supervision, conceptualization, methodology, interpretation, and critical review of the manuscript.

Dr. Nitya Singh: Study supervision, interpretation, and critical review of the manuscript.

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