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Retraction

The article "A retrospective study on middle ear risk indices in analysing the postoperative outcome following tympanoplasty" is retracted by the Editor-in-Chief, on the request of corresponding author and co-author, due to violation of the policies and practices of International Journal of Otorhinolaryngology and Head and Neck Surgery.[1] The authors communicated the above article without knowledge of the principal investigator, Dr. Roopak and co researchers involved in the study. The principal investigator informed to the Editor-in-Chief regarding plagiarism of the data from his unpublished research paper.

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1. Vignadutt P, Shaik A. A retrospective study on middle ear risk indices in analysing the postoperative outcome following tympanoplasty. Int J Otorhinolaryngol Head Neck Surg 2019;5:1234-9. DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20193861.

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A retrospective study on middle ear risk indices in analysing the postoperative outcome following tympanoplasty

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ABSTRACT

Background: Otitis media is an important and a highly prevalent disease of the middle ear and poses serious health problem worldwide especially in developing countries where large percentage of the population lack specialized medical care. A normally functioning eustachian tube is an equally essential physiologic requirement for a healthy middle ear and normal hearing. In this study we have used the middle ear risk index (MERI) developed by Kartush which generates a numeric indicator of the severity of the middle ear disease to stratify patient groups according to the severity of the disease and to evaluate the efficiency of MERI score in predicting the outcome of tympanoplasty.
Methods: Patients who came and got operated for tympanoplasty to the ENT Department in Konaseema Institute of Medical Sciences and RF, Amalapuram during the study period of February 2017 to February 2018.
Results: In this study graft was accepted in 22 patients (88%) and rejected in 3 (12%) patients. In patients in the mild MERI risk group n=22, 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, graft was accepted in 1 (50%) patients and rejected in 1 patient (50%).In severe risk group none of the grafts were accepted (100%).
Conclusions: MERI index is in fact a very useful and honest predictor of the 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 the graft uptake.

Keywords: Middle ear risk index, Postoperative outcome, Tympanoplasty

INTRODUCTION

Chronic suppurative otitis media 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 (COM) is to remove the disease, make the ear dry and to 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 percent in various large clinical trials.[1] There has been difference in opinion about the staging of the surgical procedure for COM. Some studies supported the single stage surgery for both elimination of disease and tympanoplasty.[2,3] Whereas others advocate two stage procedure for achieving the different objectives.[4,5] Tympanomastoidectomy is the procedure for removal of disease from middle ear cleft done either as open or closed cavity procedure, and tympanoplasty is the procedure for 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 disease. Although there is huge literature present about the techniques of tympano-mastoidectomy with tympanoplasty but the data about factors affecting the outcome is limited.

The pathologic condition of the middle ear as a predictor of outcome has been confusing issue in the literature.[6-8] The decision for single or multiple stage procedure for COM can be made depending upon the pathological factors associated with disease. For this purpose a grading system has been devised, known as middle ear risk index (MERI).

MERI of a patient suffering from chronic suppurative 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: (0=normal; 1-3=mild disease; 4-6=moderate disease; 7-12=severe disease).[9] There are very less 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, the surgical, prosthetic, infection, tissue and eustachian tube (SPITE) method which is an exception.[6]

There are two schools of thought according to various authors regarding the outcome of surgery of ear – one group believes that various pathological factors are important in determining the success of the surgery whereas the other claims that the outcome is independent of these factors. 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 the patient compliance.

Aim and objective

To evaluate the middle ear risk indices (MERI) in the postoperative outcome following tympanoplasty. To evaluate MERI score with respect to Degree of AB gap closure and uptake of graft following tympanoplasty procedures in the study group. To assess the degree of AB gap closure (post op AB gap >20 dB– failure, 11–20 dB- markedly improved, 0–10- as successful) following tympanoplasty procedures. To assess the closure of perforations based on Belluci criteria.

METHODS

Method of study: Retrospective study.

Duration of study: February 2017 to February 2018 (inclusive of the follow up of the patients).

Informed consent: Participants should be informed about the project in detail and their consent will be obtained.

Place of study: Patients who came and got operated for tympanoplasty to the ENT Department in Konaseema Institute of Medical Sciences and RF, Amalapuram.

Approval from ethical committee

The project has been carried out after approval from the institutional ethics committee

Data collection

After obtaining the institutional ethics committee clearance the following data was collected from the medical records department.

- Detailed history followed by the clinical examination of ear, nose and throat including general physical examination and systemic examination
- Documentation of the investigations done like
  - Diagnostic nasal endoscopy
  - X-ray paranasal sinus
  - Audiogram preoperatively
- Intro operative findings obtained from the operative notes and was incorporated. The main factors that were noticed was
  - Status of ossicular chain
  - Presence of granulation/cholesteatoma
- Based on these data the MERI index was generated and patient data was divided into the respective groups based on the score.
  - Tympanic membrane status of the operated ear at the end of one month which was derived from the minor procedure book maintained in the OPD which contains the data of the post op patients' oto-endoscopies done and its corresponding findings.
  - Post op audiograms done at the end of 3 months which was obtained from the audiology database maintained by the department Audiologist.

Inclusion criteria

Inclusion criteria were all Patients of CSOM who underwent tympanoplasty procedure; age between 15–50 years.

Exclusion criteria

Exclusion criteria were patients who had undergone previous middle ear surgeries; patients who had cholesteatoma; age groups below 15 years and above 45 years, patients who had co morbid conditions like diabetes and hypertension, previous history of use of ototoxic drugs, patients who had complaints of tinnitus and vertigo.

Statistical analysis

Results obtained will be 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). SPSS software will be used for the statistical analysis.

RESULTS

With the help of the medical records department the details of patients with CSOM operated for tympanoplasty and their follow up details from the OPD were collected. According to the data collected a total of 25 patients were operated and followed up in this time period. All the patients had a unilateral perforation. The total number of ears was 25.

The mean age of the patients in the study was around 31.84. Out of the 25 patients there were 11 males and 14 females patients in the ratio of 1:1.27.

Table 1: Demographic characteristics of study group.

Demographic characteristics	Mean	P value
Age	31.84	
Sex	11 male / 14 female	>0.05

Based on the following 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.

Table 2: Classification of patients according to MERI scores.

MERI index	N	%
Mild	22	88
Moderate	2	8
Severe	1	4
Total	25	100

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

20 among 22 patients with MERI scores in the mild category had mild hearing loss with 2 patients having moderate loss. Whereas the patients with moderate MERI scores had 1 patient with mild hearing loss and one patient with moderate hearing loss. The single patient in the severe category also had moderate hearing loss.

In this study graft was accepted in 22 patients (88%) and rejected in 3 (12%) patients. In patients in the mild MERI risk group n=22, 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, graft was accepted in 1 (50%) patients and rejected in 1 patient (50%). In severe risk group none of the grafts were accepted (100%).

Table 3: Classification of study group based on WHO classification of hearing impairment.

Hearing impairment grading	Hearing loss (dB)	N	%
Mild conductive	26–40	21	84
Moderate conductive	41-60	4	16
Severe conductive	61-80	-	-
Total		25	100

Table 4: 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

Table 5: Graft status among the MERI risk groups.

MERI category	No of ears (N)	Graft accepted	%	Graft rejected	%
Mild	22	21	95.45	1	4.55
Moderate	2	1	50	1	50
Severe	1	-	0	1	100
Total	25	22		3	

The graft acceptance in the mild MERI risk group was significantly higher and statistically significant (p>0.05).

According to Belluci criteria, in dry ears n=11, there was no graft rejection. In occasionally wet ears n=9, graft rejection was observed in one patient (11%) and in persistently wet ears graft rejection was 2 in number (40%).

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 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.

Table 6: Association of Belluci's criteria with graft uptake/rejection in each risk group.

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

Table 7: Comparison of pre and postoperative AB gap in MERI groups.

MERI score	Preoperative AB gap (mean)	Postoperative AB gap (mean)
Mild (n=22)	21.45 dB	10.36 dB
Moderate (n=2)	22.4 dB	14.5 dB

The difference in the preoperative AB gap among the different risk groups and also the postoperative AB gap difference among the groups were not significant. But the difference between the preoperative and postoperative AB gap among the mild and moderate MERI risk groups were statistically significant (Table 7).

As mentioned in objectives AB gap >20 dB was considered unsuccessful, 11-20 dB as marked improvement and 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.

Table 8: Postoperative 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

Among the 25 patients taken in this study 4 patients had ossicular fixity and one patient had incus necrosis. All the patients underwent type 1 tympanolpasty with only one patient with incus necrosis underwent ossiculoplasty which was successful. Only one patient among the 4 with ossicular fixity failed (25%). None of the patients had granulations and none were chronic smokers.

DISCUSSION

The main course of management of chronic otitis media is 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 the technical factors associated with the COM on the outcome of the surgery. The staging was done according to the MERI scores. MERI score was calculated for each patient as mild, moderate and severe (groups) and were compared for outcome of surgery. MERI was found to be a predictor of outcome in the ear surgeries. The factors analyzed in the present study include presence of perforation, cholesteatoma, granulation tissue, ossicular status and 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 as per the inclusion criteria only patients between 15 and 45 years and people belonging to both sexes were included. The average age of the patient in the study done 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 et al.[13] Sharma et al 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.[14] Another contrasting result was noted in Ahmed et al where the male to female ratio was 1.3:1 which is also almost similar to our study.[15] These variations show that the disease was common in the second and third decade 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 only one (4%) patient was categorized as the severe MERI. Similar findings were observed in the studies conducted by Kumar et al which was a prospective study and also in Pinar et al who retrospectively examined the role of MERI in the success of tympanoplasty.[16,17]

All patients 25 (100%) suffered from conductive hearing loss which is in accordance with all the studies compared so far. 21 patients (84%) had mild conductive hearing loss and 4 patients had (16%) had moderate conductive hearing loss. In the study done by Lima et al majority had moderate conductive hearing loss (46%) which maybe be due the late presentation of the patients due to low awareness compared to our state.[13] 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 mean post- operative 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. There was significant difference between pre and post op mean air bone gap in both mild and moderate risk groups.

According to our objectives in the mild MERI group (n=22), 13 patients were successful (59%), 7 patients had moderate improvement (31%) and 2 patients failed (10%). Whereas in the moderate MERI group (n=2), 1 patient had improvement (50%) and 1 patient failed

(50%). Overall in the mild MERI Group 90% and 50% in the moderate MERI group had improvement. Overall among 25 patients 21 (84%) had improvements. Lima et al had overall hearing improvements that is AB gap <20 db at 86% postoperatively and Kumar et al also had hearing improvements in 92.5% similar to our study.[13,16] The mean pre op and post op AB gap 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 is alignment with results seen in Sharma et al which was 12 dB.[14] Serviceable hearing (AB gap <20 dB–18.8 dB) was seen in 93.3% in the study by Naderpour et al which is also comparable to our study which was 84%.[18] Based on these findings it was concluded that MERI index was a good predictor of the hearing status.

Graft acceptance was seen in 22 patients (88%) and rejected in 3 (12%) patients. In patients in the mild MERI risk group n=22, graft was accepted in 21 (95%) patients and rejected in 1 patient (5%). In patients in the moderate MERI risk group n=2, graft was accepted and rejected in 1 patient (50%) each. In severe risk group none of the grafts were accepted (100%).Comparable results were observed in Kumar et al where overall acceptance was 80% and acceptance in mild MERI group was 86% and 75% in moderate group.[16] Becvarovski et al showed that all patients had graft uptake but delayed failure was observed in smokers about 20%.[19] Current study has no patients who were smokers.

According to belluci criteria, in dry ears n=11, there was no graft rejection. In occasionally wet ears n=9, graft rejection was observed in one patient (11%) and in persistently wet ears graft rejection was 2 in number (40%).This signifies that occasionally or persistently wet ears were more associated with graft rejection which concurred with the other studies compared so far.

Among the 25 patients operated 4 patients (16%) had ossicular fixity. Two patients had malleus fixity to promontory, one patient had incudostapedial joint fixity and another had stapes head fixity. All these patients underwent type I tympanoplasty and all were successful (75%) except for the patient who had stapes head fixity. Among the 25 patients only one patient had ossicular necrosis of the incus and this patient underwent type I tympanoplasty with cartilage ossiculoplasty of the incus and the graft uptake was successful. In studies like Ahmed et al the graft acceptance was comparatively low in patients with ossicular necrosis or fixity but since the patients with ossicular abnormality was very less in the current study further evaluation and data is necessary.[15]

CONCLUSION

Hence from the above results and observations it can be concluded that the MERI index is in fact a very useful and honest predictor of the 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 the 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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Ethical approval: The study was approved by the Institutional Ethics Committee

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