

## **Predictive Value of Middle Ear Risk Index (Meri) in Surgical Outcome of Tympanoplasty**

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Study Protocol

Conflict of Interest: None

### **Abstract:**

**BACKGROUND:** A mainstream otorhinolaryngeal issue worldwide is chronic suppurative otitis media, in developing countries precisely. This condition results in high morbidity rates. Deafness, academic loss and discontinuation of work triggers the fall of economy of nation. Despite the accessibility of a wide variety of antibiotics, improved surgical methods and procedures are available we are still not able to achieve 100 percent good results in tympanoplasty, which is the modality to reverse back hearing loss. Tympanoplasty, which is the modality to reverse back hearing loss depends on severity of the disease present preoperatively. The Middle Ear Risk Index constructed by Becvarovski and Kartush blends the conditions in the middle ear into a number to foresight tympanoplasty. Built on the risk factors, every patient is given a numerical score. The variables judged are otorrhea, perforation, cholesteatoma, ossicular status and perforation granulation of the middle ear and past surgical history. The overall score is 12. MERI-based, patients are scored as mild (1-3), moderate (4-6), and serious (4-6) diseases. The current study is being piloted to determine the MERI index's prognostic importance on the tympanoplasty result in terms of tympanic membrane graft uptake and audiological gain where the patients are followed for 6 months.

**OBJECTIVE:** To ascertain the Middle Ear Risk Index (MERI) in patients with CSOM doing tympanoplasty and to scrutinize the correspondence between MERI score and success of tympanoplasty.

**METHODOLOGY:** Patients (15yrs-60yrs) diagnosed with CSOM and willing to get operated for tympanoplasty to the sector of OTORHINOLARYNGOLOGY & Head and Neck Surgery (HNS).

**EXPECTED RESULT:** The data obtained will be analyzed statistically and will be discussed in light of literature available.

**CONCLUSION:** A better understanding of these factors is helpful for better prognostication of the factors affecting the disease and in planning the surgical procedure.

**Keywords:** CSOM, Middle ear risk index, Postoperative outcome, Tympanoplasty

## INTRODUCTION-

The main objective behind tympanoplasty in chronic otitis media (COM) is to eradicate pathology and to get a ear safe and dry and reversal of hearing loss to maximum extent. 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 <sup>[1]</sup>.

Tympanomastoidectomy is done for uprooting of pathology from middle ear cleft and tympanoplasty is the stratagem to reform the tympanic membrane and ear ossicles. The success of Tympanomastoidectomy with tympanoplasty is dependent not only upon the surgical principle but also on the pathological factors associated with disease. Although there is huge literature present explaining the techniques of Tympanomastoidectomy with tympanoplasty but the data about factors affecting the outcome is limited. The diseased situation of the middle ear to predictor outcome has been confusing issue in the literature. [2-4].

Middle Ear Risk Index (MERI) of a patient suffering from the COM is a numerical grading to stratify the toughness of disease and forecast the outcome of tympanoplasty in the particular patient. MERI is decided by assigning a specific value for each risk factor, which are added to get the MERI score. Determination of the Middle Ear Risk Index (MERI) for CSOM in patients planned for tympanoplasty, designate the patients mild, moderate and serious MERI score-based ailment and to research the relationship between the MERI score and the progress of tympanoplasty. The risk factors include Criteria of Belluci to determine the degree of otorrhea, Austin/Kartush criteria of ossicular status, presence of perforation, middle ear, middle ear granulations/effusion and history of previous surgery. MERI score is assigned as MERI 0 = Normal; MERI 1-3 = Mild disease; MERI 4-6 = Moderate disease; MERI 7-12 = Severe disease <sup>[5]</sup>. In the developing countries surgery cost and absence from the work are major drawback for multiple operation.

## RATIONALE

The main aim of operation for COM is to remove the pathology, get a dry ear 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. Tympanomastoidectomy is the surgery for making the middle ear cleft disease free and tympanoplasty is the procedure for rebuilding of the middle ear. The benefit from the 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 tympanomastoidectomy with tympanoplasty but the data supporting the factors affecting the outcome is limited. [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 the need of the hour 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. If we can foresee the end point of the surgical procedure based upon the middle ear diseased condition, the cost effectiveness of the surgery can be improved and this will also improve the patients compliance. The pathological factors affecting the surgical outcome of COM has been highlighted by different authors time by time but determinants have been seen separately and each study has used only on one factor at a time <sup>[7-9]</sup>. There is only one study combining these factors, the surgical, prosthetic, infection, tissue and Eustachian tube (SPITE) method which is an exception <sup>[2]</sup>. This makes it imperative for studying various pathological factors of middle ear disease simultaneously and to provide guidelines for their management.

The main target of this analysis is, to gauge a diagnosed group of patients undergoing tympanomastoidectomy with tympanoplasty with reference to the prognostic significance of Middle ear risk index (MERI) and other components in determining the consequence.

## **AIM-**

To optimize the surgical outcome in severe disease in terms of graft uptake and audiological gain

## **OBJECTIVES-**

1. Interconnection of hearing loss with TM perforation and ossicular destruction depending on size and position of the pathology.
2. MERI research and the outcome of tympanoplasty by category of risk.
3. To test the outcome of tubotympanic CSOM surgical treatment and its association with MERI.
4. Analysis of the outcome of the Eustachian tube feature on tympanoplasty outcomes.

## **METHODOLOGY**

### **STUDY DESIGN**

This is a cross-sectional prospective observational study.

### **STUDY SETTING**

Study will be executed in the province of OTORHINOLARYNGOLOGY & Head and Neck Surgery (HNS) in AVBRH, DMIMS, WARDHA.

Study duration-NOV 2020 – NOV 2022

## **PARTICIPANTS**

Patients of severe stage of CSOM in the age group 15–60 years attending OTORHINOLARYNGOLOGY & HNS OPD who have given consent are to be included in this study.

### **Inclusion Criteria**

1. Patients presenting with unilateral or bilateral COM with or without cholesteatoma.
2. Patients between 15 to 60 years of age.
3. Patients with satisfactory cochlear reserve.

### **Exclusion Criteria**

1. Patients with sensorineural deafness.
2. Patients with co-morbidities e.g. hypertension, diabetes mellitus.
3. Patients with adenotonsillitis, cleft palate and nasal polyp.
4. Patients with intracranial complications of chronic otitis media e. g Bezolds abscess
5. Patients not willing for surgery.

## **VARIABLES**

All the cases will undergo detailed history taking and examination according to the proforma. Details will be saved .Otological tests included are-

### **1. Audiological check**

1. Pure tone audiometry (PTA).
2. Speech discrimination score (SDS).
2. Eustachian tube function (ETF).

Eustachian tube function was assessed by three ways:

1. Instillation of antibiotic ear drop.
2. Auscultation tube test.
3. ET functions by tympanometry.
3. Otomicroscopy.
4. To determine the size of the perforation, thin and transparent plastic paper will be used to measure the size of the perforation and over it graphs of 1 mm<sup>2</sup> 2mm will be drawn, oval sections of approximately 9x8 mm will be cut and sterilized by holding in cidex, with magnification under working microscope ~15 sterile plastic over the t.m. with the graph imprinted on it is kept. Number of occupying Square by the perforation would be directly

counted, whether half or more of any square is within, it is taken to be a single square perforation and if less than half, its left.

All patients with ear discharge will receive conservative treatment with antibiotics, antihistaminic, decongestants and topical ear drops and when a dry ear is seen, the patients will be treated with tympanoplasty or myringoplasty. Preoperative ear test(quiescent/inactive) status before surgery, ET function workup(type of hearing loss conductive/mixed/SNHL) will be carried out .MERI score and severity will be noted.

Depending on the extent of the perforation, surgical procedures will be scheduled.

- The modified inlay method can be used for tiny perforations.
- The routine underlay approach will be used for small to moderate perforations.
- The Interlay approach would be done for broad to subtotal perforations or complete perforation.
- The Anterior tucking technique will be used for anterior perforations with a wide margin.

45<sup>th</sup> day, 3 months and 6 months follow up visits are required to evaluate graft assimilation by otoscopy, subjective evaluation (hearing, tinnitus, and any other complaints); otoscopy and repeat PTA and ETF were done. The findings are then related with preoperative findings

#### MERI SCORE

S.NO	RISK FACTOR	RISK VALUE
1	OTORRHOEA	
	I DRY	0
	II OCCASIONALLY WET	1
	III PERSISTENTLY WET	2
	IV WET,CLEFT PALATE	3
2	PERFORATION	
	I ABSENT	0
	II PRESENT	1
3	CHOLESTEATOMA	
	I ABSENT	0
	II PRESENT	1
4	OSSICULAR STATUS(AUSTIN/KARTUSH)	
	O:M+I+S	0
	A:M+S+	1
	B:M+S-	2
	C:M-S+	3

	D:M-S-	4
	E:OSSICULAR HEAD FIXATION	2
	F:STAPES FIXATION	3
5	MIDDLE EAR GRANULATION/EFFUSION	
	NO	0
	YES	1
6	PREVIOUS SURGERY	
	NONE	0
	STAGED	1
	REVISION	2

MERI 0 Normal

MERI 1–3 Mild diseases

MERI 4–6 Moderate disease

MERI 7–12 Severe disease

## BIAS

Study will be conducted through a proper study design and data analysis to combat with any source of bias arising at any given point of time in the allotted duration of the study.

## STUDY SIZE

In research term a sample is a group of people that are taken from a large population for tabulation of data .The sample should be representative of the population to ensure that we can generalize the findings from the research sample to the population as a whole.

Sample size formula with designed error of margin:

$$n = \frac{Z(\alpha/2)^2 \times P(1-P)}{d^2} \quad [10]$$

where,

$Z(\alpha/2)$  is the level of significance at 5%

Level of significance i.e 95% confidence interval-1.96

P=prevalence of CSOM=4%=0.04

d=desired error of margin=7%=0.07

Sample size required=30 patients

## STATISTICAL METHOD

Data will be analyzed by using simple statistical methods (t-test) and will be tabulated with the help of MS Office software.

## EXPECTED OUTCOMES/RESULTS

The collected data will be tabulated and statistical analysis will be done by estimating means and standard deviations for various measurements. Statistical analysis will be done using standard t test. Direct relation between preoperative meri score and postoperative outcome of tympanoplasty will be derived.

## DISCUSSION

CSOM has been elucidated as infection of the middle ear and mastoid cavity with or without ear discharge through a tympanic membrane perforation present for months to years. The main aim of operation 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.<sup>[11]</sup> 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.<sup>[12,13]</sup> Whereas others advocate two stage procedure for achieving the different objectives.<sup>[14-15]</sup>

The diseased atmosphere of the middle ear as a factor of outcome has been clouding issue in the past.<sup>[16-18]</sup> The choice between 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 put forward, known as middle ear risk index (MERI). MERI of a patient suffering from chronic suppurative otitis media is a numerical grading to stratify the ferocity of the disease. MERI is determined by assigning a specific value for each risk factor which are added to get the MERI score. For each risk factor, MERI is calculated by assigning a particular value. To get the MERI ranking, connect. Belluci parameters are included in the risk factors to determine the degree of Otorrhea, Austin/Kartushossicular disorder criterion, presence of perforation, cholesteatoma, middle ear granulation/ effusions and experience of prior surgery. The risk categories proposed MERI can be derived as follows: (0= normal; 1-3= mild illness; 4-6= moderate illness; 7-12=Severe)<sup>[19]</sup>. There are very less studies to correlate the surgical outcome of the disease taking into account all pathological factors of the disease as most of the studies concentrate on one factor exclusively.<sup>[20-22]</sup> Few of the related studies were reviewed <sup>[23-27]</sup>. The present study is being conducted to assess the prognostic value of the various pathological and the technical factors associated with the outcome of the surgery.

45<sup>th</sup> day, 3 months and 6 months follow up visits are required to evaluate graft assimilation via various proposed tests. The findings are then related with preoperative findings.

## CONCLUSION

All data collected will be evaluated and conclusion will be derived for better understanding of the etiopathological factors affecting the outcome of tympanoplasty and regaining of hearing to a serviceable level.

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Received 15 December 2020; Accepted 05 January 2021.

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