

A Study on Middle Ear Risk Indices in the Postoperative Outcome Following Tympanoplasty

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Abstract:

Background: A persistent inflammation of the middle ear and mastoid cavity known as chronic suppurative otitis media (CSOM) manifests as recurrent ear discharges or otorrhoea through a tympanic perforation. The distinguishing characteristics of CSOM from other types of chronic otitis media are persistent tympanic perforation and middle ear drainage. To evaluate MERI Score for the degree of AB gap closure and uptake of graft following tympanoplasty procedures in the study group. To assess the closure of perforations using Belluci criteria.

Methods: Based on the inclusion and exclusion criteria n=60 patients were prospectively enrolled for the study based on the convenient sampling technique. The following procedure was adopted for all participants. Detailed history taking followed by Clinical examination including General physical examination, Ear Nose, and Throat examination, and systemic examination. The following investigations were performed preoperatively on all patients Nasal endoscopy, X-Ray PNS, Water's view, and Belluci criteria to assess the degree of otorrhea, Pure tone audiometry, and air-bone gap.

Results: In the present study, among n=65 operated ears n=12 ears had ossicular necrosis. Ossicular necrosed (N=12) patients underwent type III tympanoplasty and the remaining patients (N=53) underwent type I tympanoplasty. In type I tympanoplasty, Graft acceptance was observed in n=51 patients (96.22%) In type III tympanoplasty, Graft acceptance was observed in only N=1 patient (8.33%) The graft acceptance was significantly affected by the presence of ossicular necrosis. The Hearing assessment is done for graft accepted patients.

Conclusion: In the present study the lower MERI risk categories were found to be associated with significantly better outcomes following the tympanoplasty in terms of both reduction of the A-B gap and Graft acceptance. Also, the presence of middle ear granulations and positive Belluci criteria were found to be significantly associated with the success of tympanoplasty in terms of graft acceptance.

Keywords: Belluci criteria, Chronic suppurative otitis media (COSM), Middle Ear Risk Index (MERI), Tympanoplasty.

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Introduction

A middle ear infection with inflammation that lasts for three months, or more is known as Chronic Otitis Media (COM). A persistent inflammation of the middle ear and the mastoid cavity is known as Chronic Suppurative Otitis Media (CSOM). It manifests as recurrent ear discharges or otorrhoea through a tympanic perforation. Middle ear drainage and a persistent tympanic perforation distinguish CSOM from other types of chronic otitis media.[1] Since the beginning of time, CSOM has been a known disease predominantly affecting individuals with Low living standards, poor personal hygiene,

and food contributing factors.[2] Trauma and middle ear conditions can both lead to tympanic membrane perforation (TMP). At least 0.5 percent of those who have chronic otitis media experience a rupture of the membrane (perforation). A major handicap, conductive hearing loss up to 60 dB, can be brought on by CSOM.[3] One therapy used to treat COM is tympanoplasty. It tries to repair the perforated eardrum and bring the middle ear back to full functionality. Tympanoplasty surgery can be performed endaurally, transmetally, post-auricularly, or superaurally. Underlay (medial)

and overlay grafting is the most popular procedure (lateral). The most common materials used as grafts are the perichondrium of tragal cartilage and the fascia of the temporalis muscle.[4] To understand their impact on the rate of tympanic membrane closure and hearing improvement, many factors have been examined. The results of numerous studies on tympanoplasty demonstrate that the success rate and success criteria differ from author to author. [3-5] According to certain research, the size and location of the perforation, the ossicular status, the type of surgical method, the type of graft, and the function of the eustachian tube all affect the surgical outcome. However, several authors assert that the outcome of surgery is unrelated to factors that are thought to be important.[6–10] Middle Ear Risk Index (MERI) is a numerical scale used to categorize the severity of the condition in CSOM patients. Each risk factor is given a specific number, and these values are summed to produce the MERI score. The risk factors include the otorrhea severity as determined by the Belluci criteria, the ossicular status as determined by the Austin/Kartush criteria, the presence of a perforation, middle ear cholesteatoma with granulations or effusion, and a history of prior surgery.[11] The following are the potential risk categories that can be determined from MERI: MERI 0 indicates normal, MERI 1-3 indicates mild disease, MERI 4-6 indicates moderate disease and MERI 7–12 indicates severe disease.[11] The cost of surgery and the time away from work are two key obstacles to two-stage surgery in developing nations. The cost-effectiveness of the surgery can be increased, and this will also increase patient compliance if we can forecast the outcome of the surgical procedure based on the pathologic state of the middle ear. The pathogenic factors influencing the surgical outcome of CSOM have been highlighted by several authors over time, but each study has only focused on one aspect at a time and each element has been evaluated independently.[12–14] The surgical, prosthetic, infection, tissue, and Eustachian tube (SPITE) technique is the sole study that combines these variables.[15] This makes it essential to investigate multiple middle ear pathological variables concurrently and to offer recommendations for their treatment. This study aimed to assess how middle ear risk indices (MERI) affect post-operative results after tympanoplasty surgeries.

Material and Methods

This Prospective interventional study was done in the Department of ENT, Rajiv Gandhi Institute of Medical Sciences, Adilabad, Telangana State. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study and possible outcomes in the local language.

Inclusion Criteria

1. All patients of CSOM undergoing Tympanoplasty procedures
2. Age between 15 and 60 years
3. Willing to participate in the study

Exclusion Criteria

1. Patients who have undergone Previous middle ear surgeries.
2. Patients with Cholesteatoma
3. Patients aged below 15 years and above 60 years
4. Patients with hypertension and diabetes mellitus
5. Patients on ototoxic drugs
6. Patients with complaints of tinnitus and vertigo

Based on the inclusion and exclusion criteria n=60 patients were prospectively enrolled for the study based on the convenient sampling technique. The following procedure was adopted for all participants. A Detailed history taking followed by Clinical examination including General physical examination, Ear Nose, and Throat examination, and systemic examination. The following investigations were performed preoperatively on all patients Nasal endoscopy, X-Ray PNS, Water's view, Belluci criteria to assess the degree of otorrhea, Pure tone audiometry, and air-bone gap. The following parameters were evaluated intraoperatively, Ossicular defects, Presence of granulations / middle ear effusions. The middle ear risk indices thus generated were used as indicators of the severity of the middle ear disease to stratify patients under study according to the severity of the disease. All patients who needed tympanoplasty type I and type III were performed as per the standard approach. The efficiency of MERI indices in predicting the outcome of tympanoplasty was evaluated during the follow-up of the patients. The graft status was examined on the 21st postoperative day by an Otoendoscope. On postoperative follow-up, an assessment of hearing was done by Puretone audiometry on the 3rd month of the postoperative day.

Statistical Analysis

Data was analyzed using SPSS 23.0 and MS Excel. The Chi-square test was used to analyze categorical variables. ANOVA and the paired Student's t-test were used to analyze the significance of differences in continuous variables of the study population before and after the surgical procedures. A value of $P < 0.05$ was considered significant and $P < 0.001$ was considered highly significant.

Results

Among the patients n=60(100%) in the study group, n=55(91.67%) patients were observed to have a unilateral perforation and n=5(8.67%) patients were observed to have bilateral perforations. For patients with bilateral perforation, both ears are operated

with a minimum interval period of 6 months, Total of n=65 ears are operated. Patients n=65 in the study group were assessed for graft uptake, average hearing threshold, and A-B gap. N=36(60%) males and n=24(40%) females were included in the study. The difference in gender of participants of the study group was not found to be statistically significant. (P>0.05) and the study group was observed to be comparable in terms of gender. The mean age of patients under study was observed to be 25.32 ± 8.43 yrs.

Classification of patients under study according to MERI

The patients in the study group were assessed on the following indices to calculate their MERI risk score. They are:

1. Otorrhea
2. Perforation

3. Ossicle status
4. ME pathology
5. Smoker

MERI risk categories

The categories were Mild for a MERI risk score of (1-3), Moderate for a MERI risk score of (4-6), and severe for a MERI risk score of (7-12). In the present study, the majority of the patients were categorized as mild, n=51(78.46%) followed by n=12 (18.46%) patients who were categorized as moderate, and n=2(3.08%) patients were categorized as severe risk category as shown in Figure 1.

Patients with Cholesteatoma and previous ear surgeries were excluded from the present study, the effectiveness of MERI on the outcome after tympanoplasty in the above two conditions could not be studied.

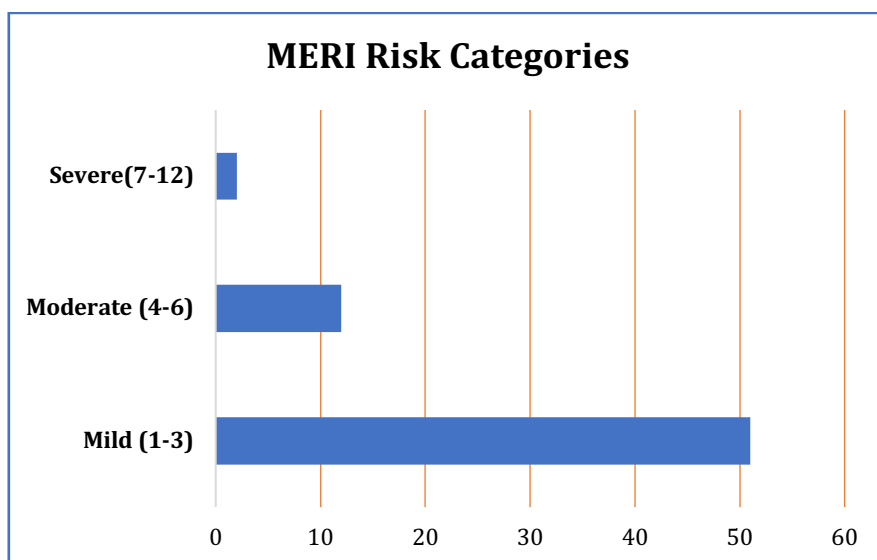


Figure 1: Distribution of cases based on MERI risk categories

The patients in the study group were also classified based on their hearing loss into three groups; Mild hearing loss, moderate hearing loss, and severe hearing loss based on the WHO- classification of hearing impairment. Half of the patients n=33(50.77%) suffered from a mean hearing loss of 26-40 dB and were classified as having Mild hearing loss (HL), followed by n=30(46.15%) patients who suffered from a mean hearing loss of 41-60 dB and were classified as having Moderate hearing loss

(HL) and n=2(3.08%) patients suffered from a mean hearing loss of 61-80 dB and were classified as having severe hearing loss (HL).Middle ear Granulation was observed in 2(100%) of patients in the severe MERI group; in the mild MERI risk group (n=51); 3 (5.88%) patients had middle ear Granulation and in the moderate MERI risk group; middle ear Granulation was observed in 4(33.33%) of patients. The presence of middle ear Granulation in the three MERI groups is depicted in Table 1.

Table 1: Presence of middle ear Granulation in the three MERI groups

MERI Score	Middle ear Granulation	
	Present N (%)	Absent N (%)
Mild	3 (5.88)	48 (94.12)
Moderate	4(33.33)	8(66.67)
Severe	2(100)	0(0.00)
Total	9 (13.15)	56 (86.85)

In patients in the mild MERI risk group; granulations were present in n=3 patients of whom graft was accepted n=1(33.33%) patient and rejected in 2(66.67 %) patients. In patients in the moderate MERI risk group (n=12) granulations were present in n=4 patients of whom graft was rejected in all n=4 (100 %) patients. In patients in the severe MERI risk group (n=12) granulations were present in n=2 patients of whom graft was accepted in 0 (0%) patients and rejected in n=2 (100%) patients depicted in table 2.

Table 2: Association of the presence of middle ear granulation tissue/effusion and graft uptake/acceptance

Risk Category (MERI)	Granulation Tissue Present	Graft Accepted	Graft Rejected	P Value
Mild (N=51)	3	1(33.33)	2(66.67)	>0.05
Moderate(N=12)	4	0(0.00)	4(100.0)	
Severe(N=2)	2	0(0.00)	2(100.0)	

In the present study, the graft was accepted in n=52 (80%) patients and rejected in n=13 (20%) patients. In patients in the mild MERI risk group, n=51 graft was accepted in n=44 (86.27%) patients and rejected in n=7 (13.73 %) patients. In patients in moderate MERI risk group (n=12) graft was accepted in 8 (66.67 %) patients and rejected in n=4 (33.33 %) patients. In patients in severe MERI risk group

(n=12) graft was accepted in 0 (0%) patients and rejected in 2 (100%) patients. This difference in graft acceptance in the three MERI risk groups was found to be statistically significant. (P<0.05) In patients in the low MERI risk group; graft acceptance was observed to be significantly higher as compared to patients in the moderate and severe MERI risk group.

Table 3: Status of graft in the three MERI risk groups

Risk Category	No of Ears	Result of Tympanoplasty				P Value
		Graft Accepted		Graft Rejected		
		N	%	N	%	
Mild	51	44	86.27	7	13.73	<0.05*
Moderate	12	8	66.67	4	33.33	
Severe	2	0	00.00	2	100.0	

* Significant

According to Belluci criteria, in dry ears (n=49) cases, graft rejections were observed in n=1 (2.04%) ear. In the Occasional Wet ears (n=14) cases, graft rejection was observed in n=10(71.43%) of them. In the Persistently wet ears (n=2) cases graft rejection was observed in n=2(100%) of them. The presence of occasionally wet and persistently wet ears was found to be significantly associated with graft rejection (p<0.05) given in table 4.

Table 4: Association of Belluci criteria and graft uptake/acceptance in the study group

Belluci Criteria	Graft Accepted	Graft Rejected	Total	P Value
Dry	48(97.96)	1(2.04)	49(100.0)	<0.05*
Occasional Wet	4(28.57)	10(71.43)	14(100.0)	
Persistently Wet	0(00.00)	2(100.0)	2(100.0)	

* Significant

Improvement in Hearing Following Surgery in postoperative follow-up hearing assessment done for the graft accepted patients. As discussed earlier in the mild MERI group (N=51) graft was accepted in 44 patients, in the moderate MERI group (N=12) graft was accepted in 8 patients, and in the severe MERI group (N=2) Graft rejection was observed in 2 patients. Assessment of hearing was done for only mild and moderate MERI groups. Preoperative Air

Bone (AB) Gap: The mean preoperative AB gap in the mild MERI (N=44) group was 26.34 (\pm 4.14) dB; in the moderate MERI (N=8) group it was 37.04 (\pm 3.72) dB. The difference in the mean preoperative AB gap among the two MERI groups was found to be significant. The difference in mean AB gap pre- and post-operatively; in the study group was found to be highly significant on analysis. (P<0.001) in the mild and moderate MERI group shown in figure 2.

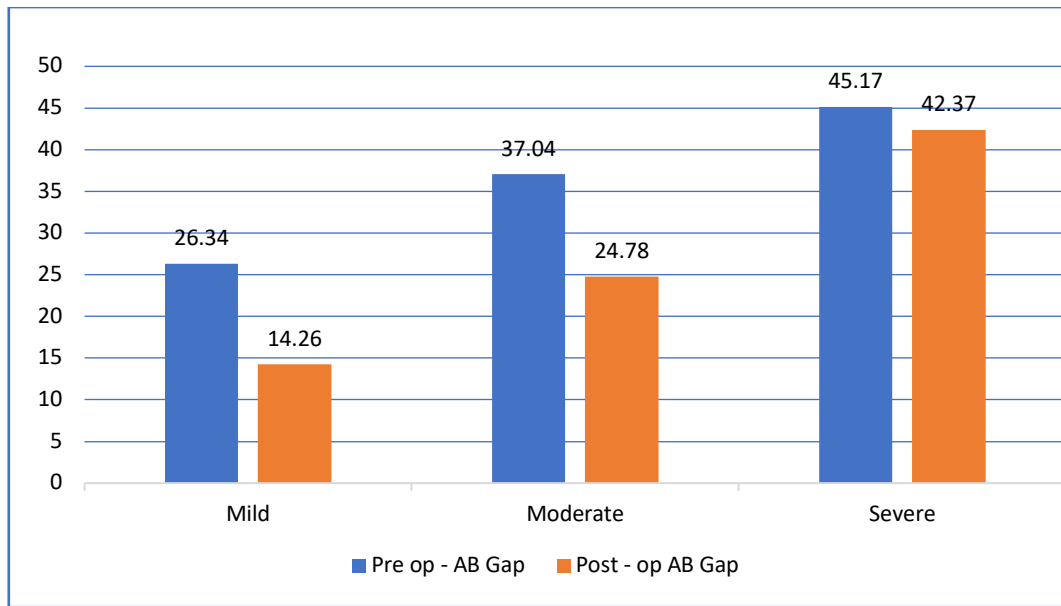


Figure 2: Comparison of pre and post-operative AB gap in the three MERI groups

As mentioned in the objectives considering post-operative AB gap >20 dB as a failure, 11-20 dB as markedly improved, and 0-10 dB as Successful following tympanoplasty procedures. In the present study, a mild MERI group of n=8/44 patients are successful; n=33 patients are moderately improved, and n=3 patients failed. In the moderate MERI group, N=4/8 patients are moderately improved and n=4 patients failed.

In the present study, among n=65 operated ears n=12 ears had ossicular necrosis. Ossicular necrosed (N=12) patients underwent type 3 tympanoplasty and the remaining patients (N=53) underwent type I tympanoplasty. In type I tympanoplasty, Graft acceptance was observed in n=51 patients (96.22%) In type 3 tympanoplasty Graft acceptance was observed in only n=1 patient (8.33%) The graft acceptance was significantly affected by the presence of ossicular necrosis. A hearing assessment is done for graft accepted patients. Considering post-operative AB gap >20 dB as a failure, 11-20 dB as Markedly improved, 0-10 dB as Successful following tympanoplasty procedures. In Type I tympanoplasty (N=51), n=14 patients were successful, n=33 patients were markedly improved, and n=4 patients failed. In Type III tympanoplasty (N=1), only one patient with graft acceptance in this category was assessed for hearing, results come as failure (AB gap >20 dB).

Discussion

The presence of a persistent tympanic perforation and middle ear discharge differentiates CSOM from other forms of chronic otitis media. CSOM can cause conductive hearing loss up to 60 dB, which is considered a serious disability. [3] The MERI has been revised in 2001. [16] Smoking is added as a middle ear risk and is given 2-risk points. Significant

granulation of tissue or effusions added 2-risk points. Furthermore, the cholesteatoma risk value had been increased to 2-risk points. The risk factors include Belluci criteria to assess the degree of otorrhoea, Austin/Kartush criteria for ossicular status, presence of perforation, cholesteatoma middle ear granulations/effusion, and history of previous surgery. The suggested risk categories can be derived from MERI as follows: MERI 0 = Normal; MERI 1-3 = Mild disease; MERI 4-6 = Moderate disease; MERI 7-12 = Severe disease. [11] In the present study, the mean age of patients under study was observed to be 25.32 ± 8.43 yrs. N=25 (41.66%) patients were observed to be smokers and n=35 (58.33%) were non-smokers. Among the patients n=60 (100%) in the study group, n=55 (91.67%) patients were observed to have a unilateral perforation and n=5 (8.67%) patients were observed to have bilateral perforations. Sharma A et al., [17] found the mean age of the patients was 22.66 (SD 9.16) years with the minimum and maximum ages of 7 and 50 years respectively. There was no significant difference among the genders of the study patient. In this study, most of the patients were categorized as mild, n=51 (78.46%) followed by n=12 (18.46%) patients who were categorized as moderate, and n=2 (3.08%) patients were categorized as severe risk category. Kumar N et al., [18] in a similar study observed that the maximum number of ears n=36 (72%) falls under MERI 1-3 mild disease followed by 12 (24%) ears with MERI score of 4-6 moderate disease and then by 2 (4%) ears with MERI score of 7-12 Severe disease. Sharma A et al., [17] in n=50 patients planned for tympanoplasty for chronic otitis media and evaluation done by MERI (Middle Ear Risk Index) and pure tone audiometry found that most of the patients had mild MERI (64%), followed by severe MERI (20%) and then moderate MERI (16%). In this study, all n=65

(100%) patients/ears suffered from conductive hearing loss. This study found mild MERI group (N=44) n=8(18%) patients were successful, n=33(75%) patients are moderately improved, and n=3(6%) patients failed. In this study, moderate MERI group 50% of patients improved moderately and 50% failed to improve. In mild MERI group cases, 18% were successful, and moderately improved were 75% were cases. In the Moderate MERI category, no case was successful, and moderately improved were 50% of cases. Lima et al.,[4] found hearing improved in most patients by 72%. It did not change in n=11 patients (28%) and did not worsen in any of the cases. Preoperatively, all 100% of patients had conductive hearing loss (in line with the clinical picture of COM alone and most patients (18 cases, 46%) had moderate hearing loss. Naderpour M et al.,[19] the average air-bone gap improvement for all 60 tympanoplasty procedures was 18.8 dB±5.62 SD. Satisfactory hearing (air-bone gap<20 dB) was achieved in 93.3% of the 60 tympanoplasties postoperatively. In the current study post-operative AB Gap <20 dB was achieved in 80%. In the study by Ahmed A et al.,[20] to assess audiological Gain Pure tone audiometry following tympo-mastoid surgery was done at 3 and 6 months, and audiological improvement (taken as the closure of air-bone conduction gap) was measured in all patients undergoing the surgery for chronic otitis media. Chrobok V et al.,[21] found patients with lower MERI had a significantly better pre-op and post-op air and bone conduction than patients with a higher MERI. Patients with a generally lower MERI had better pre-op and post-op air and bone conduction than patients with a higher MERI ($p < 0.05$). In this study presence of granulations significantly affected the graft outcome in the mild MERI group n=3 patients had middle ear granulations, graft accepted in one patient, in moderate MERI group n=4 patients and severe MERI group n=2 patients had granulations, in all these n=6 patients graft was rejected. In the current study, graft in the mild MERI risk group (n=51) graft was accepted in n=44 (86.27 %) patients and rejected in n=7 (13.73 %) patients. In patients in moderate MERI risk group (n=12) graft was accepted in n=8 (66.67 %) patients and rejected in n=4 (33.33 %) patients. In patients in severe MERI risk group (n=12) graft was accepted in 0 (0%) patients and rejected in n=2 (100%) patients. This difference in graft acceptance in the three MERI risk groups was found to be statistically significant. ($P<0.05$). In the current study according to Belluci criteria, in dry ears n=49 graft rejection was observed in 1 (2.04%) in the Occasional Wet ears graft rejection was observed in n=10(71.43%) of them; in the persistently wet ears graft rejection was observed in 2(100%) of them. occasionally wet and persistently wet ears were found to be significantly associated with graft rejection. The presence of granulation tissue was

highly significantly associated with graft rejection. ($P<0.001$).

Conclusion

In the present study, the lower MERI risk categories were found to be associated with significantly better outcomes following the tympanoplasty in terms of both reductions in AB gap and Graft acceptance. Also, the presence of middle ear granulations and positive Belluci criteria were found to be significantly associated with the success of tympanoplasty in terms of graft acceptance.

References

1. Acuin J. Chronic suppurative otitis media: burden of illness and management. 1st ed. Switzerland: World Health Organization, Geneva; 2004: 9-10.
2. Malik S, Ashrafi K, Sohail Z, Afaq S, Nawaz A. Determinants of variable hearing loss in patients with chronic suppurative otitis media. Pak J Otolaryngol 2012; 28: 45-47.
3. Bhusal CL, Guragain RP, Shrivastav RP. Frequency dependence of hearing loss with perforations. J Nepal Med Assoc 2007; 46(168):180-84.
4. Lima JCB, Marone SAM, Martucci O, Gonzalez F, Silva Neto JJD, Ramos ACM. Evaluation of the organic and functional results of tympanoplasties through aretro-auricular approach at a medical residency unit. Brazilian journal of otorhinolaryngology 2011; 77(2): 229-36.
5. Pfammatter A, Novoa E, Linder T. Can myringoplasty close the air-bone gap? Otolaryngology & Neurotology 2013; 34(4):705-10.
6. Karela M, Berry S, Watkins A, Phillipps JJ. Myringoplasty: surgical outcomes and hearing improvement: is it worth performing to improve hearing? European Archives of Oto-Rhino-Laryngology 2008; 265(9): 1039-42.
7. Shetty S. Pre-operative and post-operative assessment of hearing following tympanoplasty. Indian Journal of Otolaryngology and Head & Neck Surgery 2012; 64(4): 377-81.
8. Onal K, Uguz MZ, Kazikdas KC, Gursoy ST, Gokce H. A multivariate analysis of otological, surgical, and patient-related factors in determining success in myringoplasty. Clinical Otolaryngology 2005; 30(2): 115-20.
9. Emir H, Ceylan K, Kizilkaya Z, Gocmen H, Uzunkulaoglu H, Samim E. Success is a matter of experience: type 1 tympanoplasty. European archives of otorhinolaryngology 2007; 264(6): 595-99.
10. Lee P, Kelly G, Mills RP. Myringoplasty: does the size of the perforation matter? Clinical Otolaryngology Allied Sciences 2002; 27(5): 331-34.

11. Kartush JM. Ossicular chain reconstruction. Capitu-lum to Malleus. *Otolaryngol Clin North Am.* 1994; 27(4): 689-715.
12. Wasson JD, Papadimitriou CE, Pau H. Myringoplasty: impact of perforation size on closure and audiological improvement. *J Laryngol Otol.* 2009; 123: 973-977.
13. Pignataro L, Berta LGD, Capaccio P, Zaghis A. Myringoplasty in children: anatomical and functional results. *J Laryngol Otol.* 2001; 115: 369-373.
14. Holmquist I. The role of the eustachian tube in myringoplasty. *Acta Otolaryngol (stockh).* 1968; 66: 289.
15. Black B. Ossiculoplasty prognosis: the spite method of assessment. *Am J Otol.* 1992; 13: 544-551.
16. Becvarovski Z, Kartush JM. Smoking and tympanoplasty: implications for prognosis and the Middle Ear Risk Index (MERI). *Laryngoscope* 2001; 111:1806-11.
17. Sharma A, Saxena RK, Verma LR, Bhandari S. Correlation Between MERI and Hearing After Tympanoplasty. *JNGMC;*2015 (13) 6-9.
18. Kumar N, Madkikar NN, Kishve S, Chilke D, Shinde KJ. Using Middle Ear Risk Index and ET Function as Parameters for Predicting the Outcome of Tympanoplasty. *Indian Journal of Otolaryngology and Head & Neck Surgery.* 2012; 64(1):13-16.
19. Naderpour M, Jabbari Moghadam Y, Ghanbarpour E, Shahidi N. Evaluation of Factors Affecting the Surgical Outcome in Tympanoplasty. *Iranian Journal of Otorhinolaryngology.* 2016;28(85):99-104.
20. Ahmed A, Sharma SC. Middle Ear Risk Index [MERI] as Prognostic Factor in Tympanomastoidectomy with Tympanoplasty. *Madridge J Otorhinolar.* 2016; 1(1): 15-22
21. Chrobok V, Pellant A, Meloun M, et al. Prognostic Factors for Hearing Preservation in Surgery of Chronic Otitis Media. *Int. Adv. Otol.* 2009; 5(3): 310-317.