

ORIGINAL STUDY

Results of tympanoplasty and its association with the Middle Ear Risk Index in a tertiary care hospital

Diana Laura Reyes-Fernandez¹, Juan Antonio Lugo-Machado¹

¹Mexican Institute of Social Security, Ciudad Obregón, Sonora, Mexico

ABSTRACT

OBJECTIVES. To assess the association between tympanoplasty outcomes and the Middle Ear Risk Index (MERI).

MATERIAL AND METHODS. Observational, retrospective, analytical, and cross-sectional study. The files of the operated cases were reviewed, and demographic, clinical and MERI parameters were included. Descriptive statistics and measures of dispersion were used. To assess associations, Pearson's chi-square test was applied, with a significance level set at $p \leq 0.05$.

RESULTS. A total of 82 files were included, with an average age of 43.12 ± 16.9 ; 67% of the patients were women and 51.2% had comorbidities. The most used technique was overlay in 76.8%, with the temporal fascia being the most frequently used graft in 81.7%. The degree of middle ear disease was mild in 41 patients (50%), moderate in 28 (34.1%), and severe in 13 ears (15.9%). An association was found between the degree of MERI and surgical success, with a p -value of 0.02.

CONCLUSION. It seems that the index is associated with the graft outcome at 6 months. Moderate MERI appears to be linked to lower success rates.

KEYWORDS: tympanoplasty, middle ear, tympanic membrane perforation, association, Middle Ear Risk Index.

INTRODUCTION

The causes of chronic otitis media (COM) have a multifactorial origin, both environmental and genetic, determined by the anatomical and functional characteristics of the Eustachian tube, which has the functions of ventilation, protection and cleaning of the middle ear¹. COM can lead to multiple complications, in which conductive hearing loss related to tympanic perforation or involvement of the ossicular or sensorineural chain due to the toxicity of the organ of Corti stands out². One of the goals, considered the most important of tympanoplasty surgeries for non-cholesteatoma otitis media, is to eradicate the disease and make the ear safe and dry. The second goal of surgery is to restore hearing to useful levels³. Uncomplicated tympanic membrane perforation closure has been reported to have a good success rate^{4,6}. Several studies report a success rate of 60 to 99% in adults and 35 to 94% in children^{7,8}. Nonetheless, differences of opinion persist on the staging of the COM surgical procedure. Some studies support single-stage surgery for both disease removal and

tympanoplasty, while others advocate a two-stage procedure to achieve the different goals^{5,6,9}.

The treatment of COM is mainly surgical, with the main objectives of eradicating the disease, preventing recurrence and preserving or improving hearing⁹⁻¹³. The success of this surgery depends not only on the surgical principle but also on the pathological factors associated with the disease. Although there is a great deal of literature on surgical techniques, data on factors affecting outcomes are limited.

There are authors, such as Salvador et al.¹¹ and Black¹⁴, who emphasize that pathological conditions of the middle ear can be predictors of surgical outcomes. Several classifications have been described for the evaluation of tympanoplasty outcomes, including the Bellucci classification, the five-part system of Wullstein and Austin, the Kartush factor and the Black system^{9,11,15,16}.

Chronic otitis media is a common problem in developing countries, representing one of the main causes of otologic surgery in public hospitals in populations of low socioeconomic status^{17,18}. Tympanic perforation is an indi-

Corresponding author: Juan Antonio Lugo-Machado, Mexican Institute of Social Security, Ciudad Obregón, Sonora, Mexico

Address: Prolongación Hidalgo, Bellavista, Cajeme 85130. Ciudad Obregón. Sonora, Mexico

ORCID: <https://orcid.org/0000-0003-4864-8546>

e-mail: otorrinox@gmail.com; juan.lugo.imss@gmail.com

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cation for tympanoplasty. However, it is important to predict the outcome and give appropriate advice to the patient. Kartush proposed a numerical indicator of middle ear pathology, which he called the Middle Ear Risk Index (MERI). The importance of this indicator turned out to be a useful tool for predicting the outcomes of otologic surgery^{16,19}.

The Middle Ear Risk Index is one of several methods used to stratify the severity of the disease. This stratification is determined by assigning a specific value to each risk factor, and these values are then summed to obtain the MERI score: MERI 0 = normal; MERI 1-3 = mild disease; MERI 4-6 = moderate disease; MERI 7-12 = severe disease¹⁷. Risk factors include the following: Bellucci criteria for assessing otorrhea grade, Austin/Kartush criteria for ossicular status, presence of perforation, middle ear granulations/effusion, and history of previous surgery.

The MERI is a prognostic tool to predict the results of tympanoplasty. By applying it to a patient with chronic otitis media prior to otologic surgery, we can provide more comprehensive and accurate advice on the expected results in terms of the success of their surgery²⁰⁻²². Currently, there are few studies using the Middle Ear Risk Index tool in Mexico, particularly in the northwest region of the country. We aim to analyze the correlation between this grading system and our tympanoplasty outcomes, which will help future research in predicting the potential success of surgery for patients with certain characteristics.

MATERIAL AND METHODS

An observational, retrospective, analytical, and cross-sectional study was conducted. The records of patients who underwent tympanoplasty surgery in a non-probabilistic manner from January 2019 to December 2023 were reviewed. The inclusion criteria were: patient records of any sex, age 10-75 years, patients with a diagnosis of chronic otitis media and/or sequelae of otitis media and undergoing tympanoplasty.

Demographic, clinical, surgical and MERI parameters were included.

Descriptive statistics were used to measure central tendency (mean and median) and dispersion (standard deviation, range, and variance), as well as relative and absolute frequencies. Pearson's Chi-square test or Fisher's exact test for qualitative variables were used to assess the associations. A value of $p \leq 0.05$ was considered significant. The variables were coded in a Microsoft Excel 2010 template for Windows in Spanish version 2010, and the IBM Statistical Package for the Social Sciences, SPSS version 24 in Spanish, was transferred for analysis. We used graphs and tables for their interpretation.

RESULTS

From the 92 files identified during the study period, a total of 82 were included; 10 files were eliminated because they were incomplete. The mean age of the patients was 43.12 ± 16.9 years (minimum: 10 years, maximum: 71 years); 27 patients (33%) were men and 55 (67%) were women (Table 1).

40 patients (48.8%) did not have comorbidities, 7 patients (8.5%) had a diagnosis of isolated diabetes mellitus, 20 (24.4%) had only arterial hypertension, while in 10 patients (12.2%) both comorbidities were present. 2 patients (2.4%) had a diagnosis of hypothyroidism and 3 (3.7%) had other comorbidities (Table 1).

Before surgery, 2 patients (representing 2.4%) had an intact but thinned tympanic membrane, 15 cases (18.3%) had a tympanic perforation $\leq 15\%$, 41 (50%) between 16 and 50%, and 24 patients (24.3%) had a perforation $>50\%$ (Table 1).

Regarding the graft placement technique, we found that the most commonly used method was overlay tympanoplasty, performed in 63 patients (76.8%). Underlay tympanoplasty was used in 9 cases (11%), and other techniques, such as the cartilage butterfly wing technique, were used in 12.2% of patients (Table 1).

Regarding the type of tissue used for the graft, temporal fascia was used in 67 patients (81.7%), cartilage in 14 patients (17.1%) and fat grafting in 1 patient (1.2%). Of the 82 patients who underwent tympanoplasty, 74 (90.2%) had been otorrhea-free for 3 months or more, while 8 (9.8%) had otorrhea within the 3 months prior to their surgery (Table 1).

The presence of cholesteatoma was confirmed by histopathological study in 16 cases (19.5%), and no cholesteatoma-like tissue requiring confirmatory evaluation was observed in 66 cases (80.5%) (Table 1).

In 24 cases (29.3%), granulation or effusion tissue was found in the middle ear during surgery, while 58 cases (70.7%) showed no abnormalities.

The ossicular chain was intact in 60 cases (73.2%); an incus defect was identified in 7 cases (8.5%), a combined incus and stapes defect in 6 cases (7.3%), and a combined incus and malleus defect in 9 cases (11%). No ossicular chain abnormalities or stapedia fixation were found in any of the 82 patients operated on.

Of the total number of patients operated on, 58 (70.7%) had not undergone surgery before, while 24 patients had a previous mastoidectomy.

Based on the MERI (Middle Ear Risk Index) score before tympanoplasty, the degree of middle ear disease was mild in 41 patients (50%), moderate in 28 patients (34.1%), and severe in 13 patients (15.9%) (Table 1).

The graft condition was reviewed 6 months after surgery and found intact in 55 patients (67%) and perforated in 27 (33%) (Table 1).

We considered audiological success to be the improve-

Table 1. Characteristics of the population included in the study (Source: Otorhinolaryngology Service of the Specialty Hospital No. 2).

| | | | |
|---|---------------|----------|--|
| Age | 43.12±16.9 SD | | |
| Sex | Number | % | |
| Male | 27 | 33 | |
| Female | 55 | 67 | |
| Clinical features | Number | % | |
| No comorbidities | 40 | 48.8 | |
| With comorbidities | 42 | 51.2 | |
| Diabetes mellitus | 7 | 8.5 | |
| Blood pressure | 20 | 24.4 | |
| Diabetes mellitus and high blood pressure | 10 | 12.2 | |
| Hypothyroidism | 2 | 2.4 | |
| Other | 3 | 3.7 | |
| Condition of the tympanic membrane before surgery | Number | % | |
| No drilling | 2 | 2.4 | |
| ≤ 15% | 15 | 18.3 | |
| Between 16% and 50% | 41 | 50 | |
| ≥ 51% | 24 | 29.3 | |
| Graft placement technique | Number | % | |
| Overlay | 63 | 76.8 | |
| Underlay | 9 | 11 | |
| Other (fat placement) | 10 | 12.2 | |
| Type of tissue for the graft | Number | % | |
| Fascia temporalis muscle | 67 | 81.7 | |
| Concha cartilage | 14 | 17.1 | |
| Grease | 1 | 1.2 | |
| Duration of dry ear in the months leading up to surgery | Number | % | |
| ≤ 3 months | 74 | 90.2 | |
| ≥ 4 months | 8 | 9.8 | |
| Presence of cholesteatoma and confirmed by histopathological study | Number | % | |
| YES | 16 | 19.5 | |
| NO | 66 | 80.5 | |
| Degree of middle ear disease according to the MERI, prior to tympanoplasty | Number | % | Pearson's chi-square test p = 0.020 |
| Normal | 0 | 0 | |
| Mild | 41 | 50 | |
| Moderate | 28 | 34.1 | |
| Severe | 13 | 15.9 | |
| Successful surgery at 6 months | Number | % | |
| NO | 27 | 33 | |
| YES | 55 | 67 | |
| Audiological success | Number | % | |
| No changes | 45 | 54.9% | |
| Improvement | 30 | 36.6% | |
| Worsened | 7 | 8.5% | |

ment in hearing levels when comparing preoperative and postoperative audiometry. Postoperative audiometry revealed an improvement in 30 patients (36.6%), no change in 45 patients (54.9%) and a worsening in 7 patients (8.5%). In terms of decibel changes, recovery ranged from 5 to 15 decibels, while the 7 patients who experienced hearing loss shifted from a mild to a moderate level.

When looking for an association between tympanoplasty success and MERI outcome, Pearson's chi-square test was applied. A statistically significant association was found, with a p -value of 0.020.

To assess the changes between preoperative and postoperative audiometry, the McNemar test was used for two related samples, and it was found that the postoperative hearing level improved significantly compared to the preoperative level, with a p -value of 0.02.

A mild to moderate MERI score was more strongly associated with failure.

DISCUSSIONS

Our sample had a lower average age than those found by Nallapaneni et al.²³ with 33.12 ± 8.1 years and Indorewala et al.²⁴ with 35 ± 15.79 years, but it was similar to the average age described by Sevil et al.²⁵, who reported 36.79 years, close to our own average age.

Our population consisted of both adult and pediatric patients, similar to the studies of Verma et al.²⁶ and Mathri et al.²⁷ in India. With respect to gender, in our series there was a female predominance (67%), similar to what was found by Verma et al.²⁶ and Mathri et al.²⁷ in India (54% and 62% respectively), as well as Murcia et al.²⁸ in Colombia (62%) and Pinar et al.²⁹.

Among the characteristics of the population, arterial hypertension and diabetes mellitus were the most frequent comorbidities, similar to the findings of Jung et al.³⁰. The inclusion of these variables helped us estimate their potential impact on our results, as there are authors who point out that these factors play a key role and can influence the postoperative outcome of patients^{29,31}.

Regarding the graft placement technique in our series, the overlay procedure predominated, being used in 76.8% of the patients, similar to the findings of Pinar et al.²⁹, who reported 76%. In a study published in 2014, Patil et al.³² evaluated 100 patients who underwent type 1 interlay tympanoplasty with temporalis fascia for graft placement focusing on graft uptake, complications, and hearing improvement. They concluded that this surgical technique is both successful and safe. Zhu et al.³³ reported using all three surgical techniques, with a predominance of underlay (93.5%), followed by overlay (5.1%) and inlay (1.4%). Although research indicates that both techniques are effective³⁴, the preference is related to the skill and experience of the surgeon.

As for the type of tissue used for grafting, there is con-

trovery about which tissue is best. Kouhi et al.³⁵, in Iran, made a comparison between the use of temporal fascia and auricular cartilage, observing that temporal fascia grafts resulted in better hearing outcomes. However, cartilage grafts achieved higher anatomical success rates³⁵. In our series, the most commonly used graft tissue was temporalis fascia (81.7% of cases), followed by the auricular concha cartilage (17.1% of cases), similar to the findings reported by Mohamed et al. in Egypt³⁶ and Zhu et al.³³ in China. In a review published in 2020, Bayram et al.³⁷ evaluated the success rate of different types of grafts in tympanoplasty. They found that temporal fascia is the most commonly used graft material. However, poor graft stability can lead to failure. On the other hand, cartilage grafts have a superior resistance to infections, pressure, and insufficient vascular supply. This means that cartilage grafts are particularly suitable for revision cases³⁷.

A large portion of our sample had a dry ear period of 3 months or more (90.2%), similar to what Mohamed et al.³⁵ reported.

According to the MERI staging, middle ear involvement was mild in half of the cases included in our study and moderate in 34.1% of the cases, similar to the findings reported by Sharma et al.²⁰ in Nepal (64% of 50 patients), Saidha et al.⁴ (64% of 50 patients), Risvana et al.³⁸ (74% of 96 patients). Mohamed et al.³⁶ reported a slight risk of middle ear involvement in 39 of the 100 patients included in their study, with 52 patients classified as having moderate risk and 9 as having severe risk. Of the 413 patients included in Zhu et al.³³ study, 37.8% had moderate MERI and 32.7% had mild MERI.

Our series presented a 67% success rate in graft integrity at 6 months, lower than that reported by Zhu et al.³³ with 91.3% (377 out of 413 patients) and Saidha et al.⁴ with 92% (46 out of 50 patients). However, our results were similar to those of Mohamed et al.³⁶, who reported a success rate of 68.4%. A literature search reveals that the success rates, defined as graft integrity, show significant variation: Bayram et al.³⁷ reported a range of 75% to 98%, Ferlito et al.³⁹ found an overall variation between 82% and 97% in adult patients, while other authors such as Lau et al.⁴⁰ and Kessler et al.⁴¹ indicated a variation between 35% and 92% in paediatric patients. These findings underscore the importance of separating success rates by age group to avoid bias from combining pediatric and adult patients, providing more accurate and precise data.

Considering audiological success as a qualitative improvement in the postoperative audiogram compared to the preoperative one, we found improvement in a third of our sample (30 out of 82 patients, 36.6%), while 54.9% showed no change and 8.5% worsened. Tang et al.⁴² reported a postoperative audiometric success rate of 59.49% and no successful hearing outcomes in 40.51% of patients. Other authors reported audiometric success rates between 23.7% and 79.5%^{43,44}.

When analyzing the association between tympanoplasty

success and MERI outcomes, Pearson's chi-square test was applied, revealing a significant association with a p -value of 0.020. Moderate MERI grades were associated with tympanoplasty failure.

CONCLUSIONS

Our findings align with those of several researchers regarding population and they also coincide with other studies in terms of MERI grading, but they differ from the outcomes reported in other authors. We can point out that our sample demonstrated an association between a moderate MERI classification and less successful tympanoplasty. The proportion of anatomical graft success observed in our study was similar to that reported by other international studies, as was the proportion of audiological success.

The MERI is a useful indicator for predicting success in patients undergoing tympanoplasty. However, a larger sample size is required to allow for the generalization of our findings.

Study limitations: Undoubtedly, the number of patients represents one of its main limitations, which restricts the ability to generalize the results; additionally, the non-probabilistic selection of patients further limits the generalizability of the findings.

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Authors' information

Diana Laura Reyes-Fernández, Otorhinolaryngology Resident, Mexican Institute of Social Security, Ciudad Obregón, Sonora, Mexico. E-mail: dianalrf4@gmail.com. ORCID: <https://orcid.org/0009-0007-9523-131X>.

Juan Antonio Lugo-Machado, Otorhinolaryngology Specialist, Mexican Institute of Social Security, Ciudad Obregón, Sonora, Mexico. E-mail: otorrinox@gmail.com. ORCID: <https://orcid.org/0000-0003-4864-8546>.

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