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Anatomical and Functional Results of Inlay Tympanoplasty

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Abstract

Background: Tympanoplasty is the application of a graft to the perforated tympanic membrane due to several causes. It can be a complex medical procedure because the tympanic membrane covers an air-containing cavity; the graft must maintain its position and nourish itself from the edges. It is also not supported or receives nutrients from a flat surface and with little irrigation. Physiologically it is a challenge between the blood vessels that grow on the edges of the old perforation and the degeneration and degradation of the central graft, lacking support and poorly nourished.

Objective: To characterize the anatomical and functional outcomes of inlay tympanoplasty in patients with chronic otitis media.

Methods: A descriptive observational study was carried out with the objective of analyzing the outcomes of the inlay tympanoplasty in patients with chronic otitis media who attended the territorial consultation of Otorhinolaryngology and Head and Neck Surgery at the Dr. Octavio de la Concepción y la Pedraja Clinical Surgical Teaching Hospital in the province of Camagüey in the period from January 2017 to January 2019.

Results: In the study 35 patients were included, mostly of the 10 to 19 years age group, females and with excellent outcomes after the treatment.

Mostly they were europoids, with one to ten years of symptoms from onset to hospital admission. The main cause was the infection and the acute purulent otitis media as a predisposing factor. There were scarce complications and auditory improvement after the surgery, with an excellent general progress.

Conclusions: Female patients between 10 and 19 years were more frequent. The outcomes were excellent in the female sex. Most of them were europoid, with 1 to 10 years of symptoms before the surgical intervention and with central tympanic perforation. The most frequent cause was acute purulent otitis media as a predisposing factor and there were few complications and an excellent overall evolution.

Keywords: Chronic otitis media; Inlay tympanoplasty; Audiometry

Introduction

Tympanoplasty, a technique applied to a tympanic perforation, according to Smith AW, et al. [1] dates back to the 19th century, with the reports made by Toynbee in 1853. However, the absence of antibiotics and surgical microscopy favored the abandonment of the technique. Subsequently, with the description of tympanoplasty performed by Zollner F, [2] and Wullstein H [3] in the 1950s functional middle ear surgery began, as it is currently known. Although numerous techniques and various grafting materials have been proposed, in the 1960s Garcia-Ibañez E [4] proposed to close the tympanic perforation using the tragal perichondrium.

The inlay tympanoplasty is a surgical technique that is performed frequently and has various approaches, techniques and grafts to repair a tympanic perforation such as the retroauricular, intracanalicular and endoaural approaches; medial or lateral techniques; and fascia, perichondrium or perichondrial cartilage grafts. None in particular has been shown to be better and should be adapted to the type of perforation, the approach of the middle ear, whether it is a primary or secondary perforation and others [4].

In 1998, Eavey MD [5] carried out a study with nine pediatric patients in which they described a new technique for small and medium non-marginal perforations, which they called an inlay plug graft tympanoplasty, which we could translate as transtympanic tympanoplasty.

In 2000 Lubianca-Neto JF [6] published a study with 20 patients using the butterfly graft technique, adding some modifications in adult patients.



In primary health care, according to Ortiz J, [7] inflammatory ear conditions are a frequent reason for consultation. Globally, 20% of patients who come to the clinic with auditory symptoms have chronic otitis media and 8.3% show complications since the first visit. Many of these auditory affections cause alterations of the tympanic membrane whose loss of integrity determines a decrease in auditory capacity and conductive hearing loss, suppuration and other complications.

Tympanic perforation due to different causes is frequent in Latin American countries. In a study on the prevalence of ear and hearing disorders carried out in Ecuador in 2009 by Rodríguez P, et al. [8] sponsored by the World Health Organization (WHO), it was determined that around 750,000 Ecuadorians, 5% of the population, suffer from some degree of hearing impairment. This prevalence exceeds the world average of 4.2% and responds to postnatal disorders 74.5% of cases. In developed countries more resources are invested in the care of citizens; while 80% of people with hearing disabilities are concentrated in developing countries. It is a priority to change this reality, since 50% of these disabilities can be avoided through prevention, diagnosis and adequate treatment; because in the vast majority of patients there are long-term sequelae in the middle ear and perforations of the tympanic membrane.

Shetty S [9] found an incidence of acute otitis media in India of 2.2% out of 100 people, and in Colombia this is slightly higher, 4.1% .In Cuba, the incidence and prevalence of acute otitis media is not known exactly, but its frequency as a reason for consultation and complication of acute otitis media (AOM), makes this condition a relevant health problem.

Hearing is important for development, communication, interaction and learning in children, and otitis media is known to occur in children, especially during the preschool years, when speech development is in the most dynamic phase. Language disorders occur due to hearing deficit, leading to permanent learning difficulties or psychological disturbances. In addition to hearing impairment, complications of otitis media could cause death or severe disability, especially in low-income countries [10].

It is important to avoid deterioration of the hearing organ, by eliminating the causes that could produce anatomical and functional alterations, either from a prophylactic point of view or through the intervention of the specialist.

The anatomy of the hearing organ is complex and in the external ear the conical, semi-transparent, pearly or translucent pearl gray color and elastic consistency of the tympanic membrane seals the cavity of the middle ear. This fine structure, 9 to 10 mm in diameter, is covered by skin on its outer side and mucosa on its inner side; it remains taut with a semi-oblique tilt. It produces vibrations in response to sound waves that come through the external ear canal. They are subsequently transmitted by the movement of the ossicles from the middle to the inner ear, transforming pressure variations into mechanical movement. The membrane isolates the pressure of the compartments (interior and exterior) and its vibration transmits the sound towards the interior, preventing the entry of liquids into the ear canal and the consequences that this would entail [8-11].

Under normal conditions and in the absence of alteration, the membrane allows us to see through its fine structure the elements of the resonance box, such as the stapes tendon and part of the long process of the anvil; upwards the handle and the short process of the hammer are distinguished, the two most constant anatomical references.

Most perforations resulting from AOM and trauma heal on their own, but if the infection persists or recurs, the chance of spontaneous improvement is reduced. Orji FT, et al. demonstrated that spontaneous membrane healing is significantly delayed depending on the size of the perforation (50% of the total extension is associated with a worse prognosis), the presence of otorrhea (indicative of infection), incorrect treatment and sustained contamination through the external ear canal [12].

Medical treatment is based on antimicrobials to prevent infection or to reduce infection already established. In the case of acute perforations, treatment is based on: penicillins, first and second generation cephalosporins, and macrolides. In chronic cases, second-generation quinolines and cephalosporins are used. Symptomatic treatment is based on the use of decongestants and nasal steroids as well as antihistamines in cases of allergy. The tympanic membrane will regain its integrity in AOM within two months after perforation in most cases, with the main goals of treatment being to relieve pain and prevent infection. In those patients with AOM or OMCS with central perforation and chronic non-cholesteatomatous otitis media (OMCNC), in whom the perforation is very wide, the closure of the perforation will be accomplished by tympanoplasty [11].

In 1951, Zollner F, [2] and Wullstein H, [3] one year later, introduced middle ear reconstruction surgery or tympanoplasty. Both classified the operations into types I to V, based on the principle of the round window sound protection. Type I is the grafting of a small tympanic membrane defect caused by a traumatic or infectious episode without additional surgery on the ear canal or middle ear. Type II is the repair of the tympanic membrane and small defects of the ossicular chain. Type III is when the supra structure and the stage remain mobile and intact. In type IV there is absence of supra structure with mobile stage so the graft rests on the stapes stage. In type V the stage is fixed and needs to be fenestrated. Type I tympanoplasty is performed in the case of dry central perforations. Tympanoplasty with mastoidectomy is indicated when the ear mucosa is congested, polypoid, wet or with discharge [4-12].

Therefore, tympanoplasty is the process of rebuilding the tympanic and ossicular system damaged by disease or removed to allow healing. It is a surgical technique aimed at reconstructing the transmission mechanism of the middle ear and is performed with or without grafting of the tympanic membrane. Depending on the magnitude of the intervention, it will be called: type I tympanoplasty or myringoplasty if it is a reconstruction of the tympanic membrane, ossiculoplasty if it involves total or partial reconstruction of the ossicular chain, and ossicular tympanic reconstruction, if both the membrane is reconstructed like the chain of ossicles [4,9].

According to La Fuente DA, [13] tympanoplasty is the procedure of choice for the treatment of sequelae of simple chronic otitis media. The main objective is to eradicate middle ear disease, to eliminate infection, mucosal injury that causes suppuration, and restore conduction mechanisms, including the tympanic membrane and ossicles. The main indication is in tympanic perforations without spontaneous repair and with hearing loss, however, it is not clear that tinnitus improves after the procedure.

Matthew LH [14] shows promising results, achieving hearing improvement and infection control or prevention, with an increase in hearing acuity in 85%.

Tympanoplasty can be performed by an intracanalicular, endoaural, or retroauricular approach, using a microscopic or an endoscopic technique. The graft will be placed at the tympanic perforation site; the



graft material as well as the selected technique according to surgeon's preferences.

The approach will be intra-canal or endoaural, being necessary in the endoaural approach the closure with stitches, which are removed seven days later. After the intervention, a tamponade with hemostatic material is placed in the external auditory canal and a circular bandage. The surgery is ambulatory and the patient will remain in the hospital for hours or days depending on his post-operative evolution.

Tympanoplasty with tragal perichondrium has shown less morbidity and a 40% reduction of costs. It is recommended for small or medium perforations that do not exceed 3mm. The transcanal myringoplasty with tragal inlay perichondrium, that is the object of this study, is described as a technique that consists of reviving the edges of the perforation, filling the middle ear with absorbable sponge and placing the graft through the perforation, ending with a packing of the external auditory canal. The great advantage is that it is a simple procedure, which can be performed under local anesthesia, does not require canaloplasty, and either fascia or fat can be used. It is a technique that shortens the effective clinical course as well as being a simple method for closing small or medium central perforations [15].

It is performed through a transcanal approach, without the need for incisions in the external auditory canal (only the incision in the tragus is required for the extraction of the graft), using a cartilage graft and tragal perichondrium that is carved in the shape of a butterfly or cap and placed similarly to a transtympanic vent tube [16].

Unlike the inlay technique, both the underlay technique, in which the graft is placed medial (below) the fibrous layer, and the overlay, in which the graft is placed lateral (above) the layer, require incisions in the external auditory canal and support material in the tympanic box [13].

Among the advantages of the inlay technique, the following stand out: average surgical time of 45 minutes, the possibility of performing it on an outpatient basis, reducing hospital stay and local anesthesia and sedation [15,16].

The high incidence of chronic middle ear infections, their anatomical and functional sequelae and considering that tympanic perforations reduce hearing capacity, we characterized the patients who underwent inlay tympanoplasty according to anatomical and functional results.

Methods

A descriptive observational study was carried out with the objective of analyzing the outcomes of inlay tympanoplasty in patients with tympanic perforation from different causes, who attended the territorial (Central and Eastern provinces) consultation of Otorhinolaryngology and Head & Neck Surgery Otorhinolaryngology and Head and Neck Surgery at the Octavio de la Concepción y la Pedraja Teaching Military Hospital in Camagüey province, from the Central and Eastern provinces of the country, in the period from January 2017 to January 2019. A total of 35 patients with tympanic perforations from different causes and who underwent inlay tympanoplasty were studied.

Inclusion criteria

- Patients aged from 10 to 70 years, with tympanic perforations of up to 4mm, dry ear, and who in the audiological studies showed complete ossicular chain and conductive, perceptual or mixed hearing loss

Exclusion criteria

- Patients who did not Research during the study period

- Patients with discontinuity of the ossicular chain
- Patients with marginal perforations or cholesteatomas.

The surgical technique used for inlay tympanoplasty included the following sequence:

Extraction of the fibrous ring at the edges of the tympanic perforation. Removal of the epithelium at the perforation edges and the perforation is measured with the help of the scalpel or with an angled micro ruler made by us. Location, dissection, measurement and carving of the tragal graft with cartilage and perichondrium, with a diameter of 1 mm greater than that of the perforation. Circumferential incision of the edge of the graft, achieving the separation of the cartilage and the perichondrium, which when separated resemble the wings of a butterfly. The transtympanic graft is placed similarly to that of a ventilation tube; its fit and stability are checked, avoiding tearing of the tympanic membrane or falling into the middle ear. Finally, the spongostán is placed on the graft, occluding the entire external auditory canal.

To evaluate tympanoplasty outcomes the following variables were considered: anatomical outcomes, according to the neo-eardrum state; and functional, by means of audiometric tests. The outcomes were assessed in relation to the following variables: age groups, sex, skin color, history of ear discharge before the surgical treatment in years (less than 1,1 to 5, 6 to 10,11 to 20 and more than 20), tympanic membrane characteristics (marginal, all quadrants, central, and epitympanic perforation), etiology (infectious, traumatic, iatrogenic), predisposing factors (vesicular myringitis, bimeric eardrum, trauma, acute purulent otitis media, acute secretory otitis media, chronic cholestaetomatous otitis media), complications (infectious, persistent tympanic rupture, tympanic membrane retraction, auditory), and preoperative audiometry (10-20dB, 21-30dB, 31-40dB, 41-60dB).

The outcomes were evaluated according to the following criteria:

Anatomic success

Moderate: Reduction in the size of the perforation. Good: full tympanic membrane, but withdrawn.

Excellent: Full tympanic membrane and normal position.

Functional evaluation: When the audiometric results show hearing loss (bad), hearing gain ≤ 10 dB (moderate, 11-15dB (good), > 15dB (excellent).

In addition, closing of the gap between air conduction and bone $\leq 10 \text{dB}$ was considered in the average of pure tones (APT) of the frequencies (0.5, 1, 2 and 3KHz). The value of the difference between the airway and the bone pathway and the closure of both were also evaluated, using 20dB as the cut-off point. Postoperative audiometry was performed at three months, six months, and one year, as recommended by the American Academy of Otorhinolaryngology and Head and Neck Surgery guidelines [17].

Data sources were the medical records, the surgery reports and data sources containing the variables under study. Data processing was done with SPSS (version 15 for Windows), descriptive statistics for distribution of absolute and relative frequencies. Summary of results is shown in tables and graphics. Written informed consent was obtained from all study participants.

Results

Tympanoplasty by endoaural inlay approach with cartilage graft



in the shape of a butterfly (butterfly technique) or in the form of a plug, is a new and innovative technique, initially described for central perforations with comfortable ducts; however, its utility has been demonstrated in larger perforations and, even, in conjunction with more extensive otological procedures, such as mastoidectomy. Its effectiveness in treating retraction pockets and adhesive middle ear disease has also been reported [18].

Table 1 distributed the patients according to age groups and outcomes; it was observed that the 10 to 19 years age group prevailed with 14 cases, 40%. In general, of the 35 operated, 22 (62.85%) had an excellent outcome, 3 (8.57%) good, 5 (14.28%) moderate and 5 (14.28%) a bad outcome. Of these, the results were satisfactory in 30 patients (85.71%) of those who showed excellent, good or moderate results. As will be observed at a younger age, the outcome were better, which may be due to the extremely thorough care of mothers facing (or confronted with) scary complications that chronic otitis media can cause, in addition to the auditory and social limitations imposed (or produced to the child) on the child by a tympanic perforation.

Mothers care facing scary complications that chronic otitis media can cause, together with the auditory and social limitations imposed on the child by the existence of a tympanic perforation. In the adult, social responsibilities, cultural aspects, the minimization of ambulatory and reduced access surgery lead to limiting the care required by the evolution and the anatomical and functional outcomes of the patient.

In table 2, when analyzing the outcomes according to sex, a clear predominance of the female gender is observed with 21 patients, 59, 99% and of them 13 (37.14%) excellent, 2 (5.71%) good, 4 (11.43%) moderate and 2 (5.71%) bad. In males, 14 patients underwent surgery, 39.99%, and 11 had results between excellent and moderate, 31.42% of the total number of men who underwent surgery.

Table 3 shows the outcomes in relation to complexion of the operated patients and, as will be seen from the total of the operated patients, 24 (68.57%) cases correspond to the Europoids; Europoid-Negroids (copper) 7 (20%) and Negroids 4 (11.43%). Of the 24 Europoid patients, 23 (95.83%) had excellent to fair outcomes. Of the negroids, 4 were operated (11.43%) and only one showed poor outcomes.

Table 1: Anatomical and functional outcomes of inlay tympanoplasty. Distribution according to age groups. January 2017-January 2019.

| | | _ | _ | | | • | | | | | |
|-----------|-----|--------|-------|------|---|---------|---|-------|----|--------|--|
| Age group | | | T-4-1 | | | | | | | | |
| (Years) | Exc | ellent | (| Good | М | oderate | | Bad | | Total | |
| 10-19 | 9 | 25.71 | 3 | 8.57 | 2 | 5.71 | 0 | 0.0 | 14 | 40.00 | |
| 20-29 | 7 | 20.00 | 0 | 0.00 | 1 | 2.85 | 2 | 5.71 | 10 | 28.57 | |
| 30-39 | 3 | 8. 57 | 0 | 0.00 | 0 | 0.00 | 2 | 5.71 | 5 | 14.80 | |
| 40-49 | 1 | 2.85 | 0 | 0.00 | 0 | 0.00 | 1 | 2.85 | 2 | 5.71 | |
| 50-59 | 1 | 2.85 | 0 | 0.00 | 1 | 2.85 | 0 | 0.00 | 2 | 5.71 | |
| 60-69 | 1 | 2.85 | 0 | 0.00 | 1 | 2.85 | 0 | 0.00 | 2 | 5.71 | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | |

Table 2: Outcomes of patients in relation to sex.

| | Outcome | | | | | | | | | | | | |
|--------|---------|--------|----|------|----|--------|----|-------|----|--------|--|--|--|
| Sex | Exc | ellent | G | ood | Мо | derate | ı | Bad | | Total | | | |
| | No | % | No | % | No | % | No | % | No | % | | | |
| Female | 13 | 37.14 | 2 | 5.71 | 4 | 11.43 | 2 | 5.71 | 21 | 59.99 | | | |
| Male | 9 | 25.71 | 1 | 2.86 | 1 | 2.85 | 3 | 8.57 | 14 | 39.99 | | | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | | | |

Table 4 distributes the patients according to time of symptoms from onset to hospital admission and, as will be seen, the largest numbers of operated patients were in the groups of 1 to 5 years and 6 to 10 years with 12 cases (34.29%) in each group respectively. Majority of patients of the 1-5 years and 6-10 age groups had excellent outcomes. While most patients over 21 years old had moderate or bad outcomes.

Table 5 shows the characteristics of the perforation of the tympanic membrane in the patients studied. There was a predominance of central perforations. With excellent outcomes there were 20 patients (57.14%); good 3 (8.57%); moderate 4 (11.43%) and bad 5 (14.28%). Epitympanic perforations ranked second with 3 cases (8.57%); 2 (5.71%) with excellent outcomes and 1 (2.86%) fair.

Table 6 summarizes the outcomes in relation to the etiology of the tympanic perforation. There was a clear predominance of infectious etiology with a frequency of 27 (77, 13%) cases of the total number of operated patients. Overall of the 35 operated, 19 cases (54.28%) were of infectious etiology and 3 cases (8.57%) of traumatic etiology, all with excellent results. 2 (5.71%) and 3 (8.57%) showed poor results, for infectious and traumatic causes, respectively.

Table 7 shows the outcomes the results according to predisposing factors and it will be observed that in the greatest number of cases the factor that predisposed tympanic perforation was purulent AOM in 24 cases (68, 57%) of the total number of patients and trauma in 8 cases (22.86%). Of the 24 cases of purulent AOM, 22 (62.85%) had excellent, good and fair results. Of the 8 (22.85%) trauma cases, 5 (14.28%) had excellent and fair results.

According to table 8, there was a predominance of patients who showed audiometry with losses between 31 and 40 dB.

Table 9 shows the postsurgical audiometric results and, as will be seen, 30 (85.71%) patients had hearing gain between 1 and 15db and results between excellent and moderate; 25 (71.42%) gain between 11 and more than 15 dB, with results between excellent and good, and finally, 22 cases (62.85%) of the operated patients had excellent results, who showed hearing gain above 15dB.

We observed 9 complications in 5 patients five. Hearing loss was more frequent in 4 patients (11.43%); tympanic membrane rupture and graft necrosis in 2 cases for 5.71%, respectively, and increased diameter of the perforation after graft necrosis in one patient for 2.86% of complicated cases. [Table 10]

Discussion

Tympanoplasty results were similar to reports by Shetty S [9] and Farhad M [10] who reported in their population series up to 50% of operated patients under 20 years of age, with sequelae of chronic otitis media or trauma, with excellent results in up to 60% of cases, and good in at least 85% of those operated on.

Table 3: Distribution of patients according to complexion.

| | | T-4-1 | | | | | | | | |
|----------------------|-----|--------|----|------|----|--------|--------|-------|-------|--------|
| Complexión | Exc | ellent | G | ood | Мо | derate | te Bad | | Total | |
| | No | % | No | % | No | % | No | % | No | % |
| Europoid | 17 | 48.57 | 2 | 5.71 | 4 | 11.43 | 1 | 2.86 | 24 | 68.57 |
| Negroid- europoid | 3 | 8.57 | 1 | 2.86 | 0 | 0.00 | 3 | 8.57 | 7 | 20.00 |
| Negroid | 2 | 5.71 | 0 | 0.00 | 1 | 2.86 | 1 | 2.86 | 4 | 11.43 |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 |



Table 4: Patients outcomes according to preoperative clinical evolution time.

| Presurgical | | | | Out | come | • | | | Total | | |
|--------------|-----------|-----------|------|------|----------|-------|-----|-------|-------|--------|--|
| evolution | Excellent | | Good | | Moderate | | Bad | | iotai | | |
| time (years) | No | % | No | % | No | % | No | % | No | % | |
| < 1 | 2 | 5.71 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 2 | 5.71 | |
| 1-5 | 9 | 25.71 | 1 | 2.86 | 1 | 2.86 | 1 | 2.86 | 12 | 34.29 | |
| 6-10 | 8 | 22. 86 | 1 | 2.85 | 2 | 5.71 | 1 | 2.85 | 12 | 34.29 | |
| 11-20 | 2 | 5.71 | 1 | 2.85 | 1 | 2.86 | 1 | 2.85 | 5 | 14.28 | |
| > 21 | 1 | 2.86 | 0 | 0.00 | 1 | 2.86 | 2 | 5.71 | 4 | 11.43 | |
| Total | 22 | 62. 5 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | |

Table 5: Outcomes according to the characteristics of the tympanic membrane perforation.

| Characteristics | | | | Tatal | | | | | | | |
|-------------------------------------|-----|---------|----|-------|----|----------|----|-------|----|--------|--|
| of the | Exc | cellent | | Good | | Moderate | | Bad | | Total | |
| tympanic membrane perforation | No | % | No | % | No | % | No | % | No | % | |
| Central | 20 | 57.14 | 3 | 8.57 | 4 | 11.43 | 5 | 14.28 | 32 | 91.43 | |
| Epitympanic | 2 | 5.71 | 0 | 0.00 | 1 | 2.86 | 0 | 0.00 | 3 | 8.57 | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | |

Table 6: Distribution of patients 'outcomes in relation to the etiology.

| | Outcome | | | | | | | | | | | |
|------------|---------|-------|------|--------|----|--------|----|-------|----|-------|--|--|
| Etiology | (| Good | Exce | ellent | Мо | derate | E | Bad | | Total | | |
| | No | % | No | % | No | % | No | % | No | % | | |
| Infectious | 19 | 54.28 | 3 | 8.57 | 3 | 8.57 | 2 | 5.71 | 27 | 77.13 | | |
| Traumatic | 3 | 8.57 | 0 | 0.00 | 2 | 5.71 | 3 | 8.57 | 8 | 22.85 | | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 99.98 | | |

For their part, Tawab HMA, et al. [19] reflect up to 58% of operated patients under the age of 25 and up to 70% of results rated as excellent. Other studies carried out in Mexico, by Sánchez Hernández CM, et al. [20] reveal that of a group of 13 operated patients and made up of 14 ears, five right (35.7%) and nine left (64.3%) of 13 patients, five were women and eight men, with an average age 40.07 years (limits from 11 to 62).

In investigations carried out by Durán-Padilla C, et al. [21] in Mexico, they showed that of 69 patients with high-risk tympanic membrane perforations,33 patients in the inland cartilage tympanoplasty group (group I), and 36 in the tympanoplasty with temporal fascia group (group II), showed a slight redominance in both groups of female patients. These results coincide with the findings presented in this study where there was a clear predominance of the female gender in the operated patients in a ratio of 1.5:1.

In the population that attends the territorial consultation of Otorhinolaryngology and Head and Neck Surgery, there is a predominance of white, Caucasian or Europoid patients, according to data revealed by the population census, which explains its greater frequency [22,23,11].

Pollak N, et al. [24] allege that more than a third of their patients have at least 5 to 10 years of evolution prior to surgery. Similar results were obtained by Hyeoggi C, [24] who observed 90% of patients with identical characteristics of their tympanic membrane.

In similar studies carried out by De la Paz PF, et al. [25] following patients for 5 years, they observed that nine out of ten patients had central tympanic perforations.

Lacovou E, et al. [26] and Cavaliere M, et al. [27] observed 33.3% of central perforations, 23.8% anterior, 21.4% posterior, 19.1% inferior and 2.4% aticales. They authors observed that in patients with tympanic membrane perforation, the degree of presurgical hearing loss depends on the location of the perforation. The greatest hearing loss was related to the posterior location of the perforation and 3 of them were traumatic that did not heal: one of them due to fracture of the skull base, which represented 21.4%; which was in correspondence with our findings.

Tympanic membrane perforations are often sequelae of middle ear infections or traumatic events. In most cases, these perforations are close spontaneously. When this does not occur, tympanoplasty is a surgical procedure used to restore hearing in affected ears. The procedure is generally performed in cases of chronic otitis media without cholesteatoma, atelectic otitis media, and tympanosclerosis and may fail when there are alterations in ventilation of the middle ear, with or without a persistent inflammatory process [21,23].

Our findings coincide with Shwan HM, et al. [28] and Ramírez A [29] who found between 68% and 75% of cases with tympanic perforations of infectious cause.

Lee JC, et al. [30] assert that the perforations of the studied patients were, for the most part, of infectious origin (11 subjects, 78.6%); and iatrogenic, 3 (21.4%) after the placement of transtympanic ventilation tubes. In none of the individuals was the cause traumatic. Regarding the size of the perforations, in 25.7% of the patients it was between 5 and 40% of the total membrane; of these, the majority was from 20 to 40% (N = 6, 42.8%), followed by those of less than 20% (N=5, 35.8%). Those of 40 to 60% (N=3, 21.4%), and in no case were the perforations subtotal.

According to Gómez-Rodriguez E, et al. [31] the most frequent preoperative diagnosis was non-cholesteatomatous OMC (82%), followed by fibro adhesive otopathy (18%). Of the total sample, 60% corresponded to surgeries in the right ear, with primary tympanoplasties in 79% of all cases. 22.22% of the patients had non-cholesteatomatous OMC in the contralateral ear, and only 3.7% had fibro adhesive otopathy.

The most frequent germ found in chronic suppurations of the middle ear, as quoted by Lyons SA, et al. [32], is the Streptococcus pneumoniae, 30-35%; followed by the Haemophilus influenzae, 20-25%; Moraxella catarrhalis, 10-15%; Streptococcus pyogenes, 3-5%; Staphylococcus aureus, 1-3%, and others (anaerobes, E. coli or Pseudomonas aeruginosa) 1-3%. According to the authors, the isolation is sterile in 20-30% of the studies carried out, discussing whether it is due to a viral etiology or anaerobes; however, studies carried out in Spain confirm the causes in this order, except for Moraxella catarrhalis, which is isolated only in 1-3% of AOM cases.

Our findings are similar to those of Mane R, et al. [16] whose postsurgical audiometric results revealed a higher hearing gain in the group that was studied, with a threshold of 2.5 dB (p=0,03). In these patients, the hearing gap (GAP) was closed in 58.3% of subjects of the study group, while only in 25% in the control group.

Dundar R, et al. [33] found improvement in hearing with a significant difference when comparing pre-surgical hearing loss with



Table 7: Distribution of patient's outcomes in relation to predisposing factors.

| | | | | Out | tcome | | | | _ | Tatal | |
|------------------------|------|-------|-----|-----------|-------|----------|----|-------|-------|--------|--|
| Predisposing factors | Good | | Exc | Excellent | | Moderate | | Bad | Total | | |
| | No | % | No | % | No | % | No | % | No | % | |
| Traumatism | 3 | 8.57 | 0 | 0.00 | 2 | 5.71 | 3 | 8.57 | 8 | 22.86 | |
| Purulent AOM | 17 | 48.57 | 2 | 5.71 | 3 | 8.57 | 2 | 5.71 | 24 | 68.57 | |
| OMCS (w/central perf.) | 1 | 2.86 | 1 | 2.86 | 0 | 0.00 | 0 | 0.00 | 2 | 5.71 | |
| OMC Cholesteatomatous | 1 | 2.86 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 | 1 | 2.86 | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | |

Table 8: Distribution of patient's outcomes in relation to the preoperative audiometry.

| | Outcome | | | | | | | | | | | |
|---------------------------|---------|-------|-----------|------|----------|-------|-----|-------|-------|--------|--|--|
| Presurgical Audiometry | Good | | Excellent | | Moderate | | Bad | | Total | | | |
| Addiometry | No | % | No | % | No | % | No | % | No | % | | |
| 10-20dB | 7 | 20.00 | 0 | 0.00 | 2 | 5.71 | 1 | 2.86 | 10 | 28.57 | | |
| 21-30dB | 1 | 2.86 | 2 | 5.71 | 2 | 5.71 | 2 | 5.71 | 7 | 20.00 | | |
| 31-40dB | 14 | 40.00 | 1 | 2.86 | 1 | 2.86 | 2 | 5.71 | 18 | 51.32 | | |
| Total | 22 | 62.85 | 3 | 8.57 | 5 | 14.28 | 5 | 14.28 | 35 | 100.00 | | |

Table 9: Distribution of patients' postsurgical audiometric results.

| After surgery Audiometric results | No | % |
|-----------------------------------|----|--------|
| Hearing loss(Bad) | 5 | 14.28 |
| ≤ 10dB (Moderate) | 5 | 14.28 |
| 11-15dB (Good) | 3 | 8.57 |
| >15dB (Excellent) | 22 | 62.85 |
| Total | 35 | 100.00 |

Table 10: After surgery complications.

| Complications | No | % |
|-----------------------|----|-------|
| Rupture of the TM | 2 | 5.71 |
| Auditory | 4 | 11.43 |
| Graft necrosis | 2 | 5.71 |
| Increased perforation | 1 | 2.86 |
| Total | 9 | 25.71 |

postoperative gain in two groups of cases studied (45dB to 31dB using temporal fascia and 42dB to 28dB, using perichondrium; with a p<0.05).

In Italian series, Marchioni D, et al. [34] distributed the patients according to the level of hearing before and after surgery, despite the fact that in other studies, hearing gain was measured by the average of the auditory GAP (difference between bone and air conduction). These authors measured hearing by averaging dB at all frequencies; however, hearing gain was similar comparing their results (84% of patients achieved normal hearing, compared to 16% who maintained hearing loss).

Alicandri-Ciufelli M, et al. [35] obtained hearing gain in 50 patients, with a sample very similar, in which they compared hearing one week after myringoplasty, performed with local anesthesia and endoaural approach as in the cases described in this investigation, although the approach and anesthesia were different. In the sample used by the authors there was a reduction in the gap, which showed hearing

improvement; just as it happened in the patients operated in our study.

We consider that these results force a revision of the current knowledge on the physiology of hearing, especially to revoke the dogma, that the tympanic membrane must be thin and easily displaced by sound waves. The hypothesis that could explain the transmission of the sound wave seems to lie in its physical properties. In vitro studies on the mechanical properties of cartilage show that with a thickness of 500 micrometers that is half a millimeter, the acoustic behavior is similar to that of the tympanic membrane, which in turn means that large displacements or vibrations are not required for the transmission of sound. This explains why a structure as thick as cartilage can favor sound transmission, although it should always be taken into account that rigidity will favor high-frequency transmission and that the increase in mass prevents it; occurs in reverse with low frequencies.

Kim CW, et al. [36] and Kozin ED, et al. [37] declare very few complications in patients operated with this novel technique, with a limited range of 12-15% at the expense of local complications such as granulomas of surgical wound and infections.

For their part, Daneshi A, et al. [38] report between 10% and 15% of infectious and local complications in the sample studied, which coincides with the results of this study.

In other studies consulted, such as that of Surmelioglu O, et al. [39] they did not report major complications, except for one patient with a granuloma in the middle ear in whom temporal fascia was used as a graft. Patients with otorrhea due to postsurgical infection were treated with topical antimicrobials, the condition remitting eight days after treatment. In our study, no postoperative infections were reported, which was in relation to the measures taken in the pre, Trans and postoperative period was, since it is an organ of extreme sensitivity for the patients' lives.

Luaces YR, et al. [40] in Cuba describe trauma to the external auditory canal as a frequent postoperative complication in their series (28.6%); followed by hematomas of the pinna in (4.8%), plasty infections in 2.4%, as well as necrosis of the plasty and cartilage lateralization in 2.4%. These complications are infrequent in other series described worldwide and were not found in our study, except



graft necrosis. We consider that hematomas and trauma to the duct are avoided with adequate hemostasis and with the use of gentle maneuvers during the execution of the technique.

Rai AK, et al. [41] found among the complications of type I tympanoplasty, tympanic membrane retraction and graft lateralization. In all cases, they were managed surgically, while most of the rest of the complications were minor and could be managed conservatively.

We consider that in many cases the complications of type I tympanoplasty depend on inexperience, poor selection, manipulation and inadequate placement of the graft; as well as on not taking the best care to prevent nosocomial infections.

Conclusions

The results of the inlay tympanoplasty in patients with perforations of the tympanic membrane, showed a predominance of patients between 10 and 19 years of age, female sex and infectious etiology. We found few complications and hearing improvement after surgery.

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