Trabajos originales

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Predictors of hearing outcomes in patients undergoing ossicular chain reconstruction in a developing country.

Factores predictores de desenlaces auditivos en pacientes llevados a reconstrucción de la cadena osicular en un país en vía de desarrollo.

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ABSTRACT

Objective: To explore the social and clinical factors that predict audiometric outcomes in patients undergoing ossicular chain reconstruction. Methods: A retrospective analytical cohort study was conducted, including patients 18 years of age or older with a history of chronic otitis media (COM) and/or any of its complications, who underwent ossicular chain reconstruction with Partial Ossicular Replacement Prosthesis (PORP) or Total Ossicular Replacement Prosthesis (TORP), at Hospital San José and Hospital infantile Universitario de San José between 2012 and 2020. We excluded patients with ossicular chain malformations and those with incomplete information. Information about sociodemographic and clinical factors was collected. Additionally, the surgery findings information was analyzed using the Ossiculoplasty outcome parameter staging (OOPS) index. *Results:* A total of 35 adult patients who underwent ossicular chain reconstruction were retrospectively studied. An improvement was evidenced in the Preoperative Pure-Tone Average (PTA) and postoperative PTA (p-value=0.036), as well as in the pre and postoperative air-bone gap (ABG) (p-value < 0.01). A moderate correlation coefficient was found between the OOPS index and the postoperative PTA (p= 0.429), and between the OOPS index and the postoperative (ABG) (p= 0.653). *Conclusion:* We found that a higher OOPS score is correlated with worse hearing outcomes postoperatively, and there was no association between the demographic or pathologic factors with a worse postoperative hearing outcome. Therefore, OOPS index can predict audiometric outcomes in patients undergoing ossicular chain reconstruction in a developing country, regardless of the demographic or pathologic factors.

Palabras clave (DeCS):
Osiculoplastia, reconstrucción de la cadena osicular, hipoacusia conductiva, otitis media crónica.

RESUMEN

Objetivo: Evaluar los factores sociales y clínicos que predicen los desenlaces audiométricos en pacientes llevados a reconstrucción de cadena osicular en un país en vía de desarrollo. *Métodos:* Se realizo un estudio de cohorte analítico retrospectivo donde se incluyeron pacientes mayores de 18 años, con antecedente de otitis media crónica y/o alguna complicación/secuela de esta, que fueron llevados a reconstrucción de la cadena osicular con prótesis PORP - TORP de la Fundación Universitaria de Ciencias de la Salud entre el año 2012 y 2020, se excluyeron pacientes con malformaciones de la cadena osicular y aquellos con informacion incompleta de su historia clinica y quirurgica. *Resultados:* La población estudiada fue 35 pacientes, en los cuales se compararon variables demográficas, antecedentes de rinitis o tabaquismo activo, parámetros audiológicos pre y postoperatorios, y hallazgos intraquirurgicos. Se evidenció una diferencia estadísticamente significativa entre el promedio tonal auditivo (PTA) preoperatorio y el PTA postoperatorio (p-valor=0.036), así como en el gap aéreo- oseo pre y post operatorio (p-valor < 0.01). Se reportó un coeficiente de correlación moderado entre el índice OOPS y el PTA post operatorio (p = 0.429), y entre el índice OOPS y el gap aéreo óseo post operatorio (p = 0.653), lo que indica que a mayor puntaje en el índice OOPS peores desenlaces auditivos. *Conclusión:* En este estudio un mayor puntaje en el índice OOPS se correlacionó con peores desenlaces auditivos. No se evidenció correlación entre los factores demográficos u otras comorbilidades descritas y un peor desenlace auditivo post operatorio. Aunque se obtuvo un GAO postoperatorio ≤20dB en el 48.5% de los pacientes, se observó una disminución en el GAO estadísticamente significativo.

Introducción

Chronic otitis media (COM) is a disease that affects the middle ear and can lead to problems in the microenvironment of the tympanic cavity, developing pathologies such as tympanosclerosis or cholesteatoma, with anatomical changes that lead to hearing loss, tinnitus, smelly discharge, and deterioration of the quality of life (1). Multiple risk factors for the development of COM have been studied, including socioeconomic status, education level, breastfeeding and

allergic disease (2, 3, 4) . In Colombia, there is an estimated prevalence of 0.131% for COM (5).

Depending on the histopathological changes and the disease sequelae in the middle ear, some patients require an ossicular chain reconstruction (ossiculoplasty) for conductive hearing reestablishment. An ossiculoplasty consists of the replacement the ossicular chain prosthesis that can be partial (Partial Ossicular Replacement Prosthesis: PORP) or total (Total Ossicular Replacement Prosthesis: TORP) (6). When the ossicles and joints are affected by the disease, ossicular chain reconstruction with a PORP or a TORP is indicated (7).

Previous studies have demonstrated that the condition of the middle ear microenvironment is the most important prognostic factor in an ossiculoplasty because the adequate mobility of the tympanic membrane (or neotympanum), ossicular chain vibration and consequently sound transmission depends on it (6, 8). Dornhoeffer et al., in 2001, proposed the Ossiculoplasty outcome parameter staging (OOPS) index to calculate the surgical success of ossiculoplasty, according to preoperative parameters, operative findings (middle ear mucosa and condition of the ossicular chain) and the type of surgery.

Surgical success is calculated with the audiometric air-bone gap (ABG), which is the difference between air-conduction (AC) thresholds and bone-conduction (BC) thresholds. A high value of ABG means a greater limitation in sound conduction and a worse postoperative outcome. Studies published in developed countries, which evaluated the capacity of the OOPS index to predict the prognosis of postoperative audiological results, showed that the higher the OOPS index, the higuer the postoperative ABG in the short and long term (6).

COM has been found to be one of the most common infectious diseases worldwide, affecting not only developing, but also developed countries (3). There are no studies that evaluate the OOPS index in Latin America or developing countries. Therefore, the aim of this study is to evaluate the social factors, clinical factors and surgical findings evaluated by the OOPS index that can predict audiometric outcomes in patients undergoing ossicular chain reconstruction in an institution located in a developing country such as Colombia, between 2012 and 2020.

Methods

A retrospective cohort study was conducted. Adult patients (>18 years old) with a history of COM and/or any complication or sequelae of COM, such as cholesteatoma and tympanosclerosis, who underwent ossicular chain reconstruction with PORP or TORP prosthesis at Hospital de San José or Hospital Infantil Universitario de San José, between 2012 and 2020 were included. Patients with history of ossicular chain malformations or disruption of the ossicular chain secondary to trauma were excluded, as well as patients with incomplete clinical data or surgical records.

A complete review of the clinical records and surgical descriptions of the patients who met the inclusion criteria was carried out in both institutions. The following variables were analyzed: age, sex, socioeconomic status, travel within the first postoperative month (changes in barometric pressure), diagnosis of allergic rhinitis, smoking, indication of surgical management, as well as preoperative and postoperative audiometric studies (two or three months after surgery). The audiometric values for frequencies (0.5-4 kHz) were used to calculate pure-tone average (PTA) and ABG.

Intraoperative findings used to calculate the OOPS index score were middle ear mucosa status, presence of otorrhea, ossicular chain status given by presence of the malleus, posterior wall preservation or not, and revisional surgery or not (9). Each finding was quantified according to the score established in table 1, and the total score was calculated. The greater the alteration, the higher the score. The table 1 provides the grading system (OOPS) index (9). Other variables considered were the type of prosthesis used (TORP or PORP), the technique of ossiculoplasty (microscopic or endoscopic), lateral support of the prosthesis and postoperative complications.

Table 1. Ossiculoplasty outcome parameter staging index

Risk factor			Risk value
Middle ear factors	Drainage	None	0
		Present >50% of time	1
	Mucosa	Normal	0
		Fibrotic	2
	Ossicles	Normal	0
		Malleus +	1
		Malleus –	2
Surgical factors	Type of surgery	No mastoidectomy	0
		Canal-wall-up mastoidectomy	1
		Canal-wall-down mastoidectomy	2
	Revision surgery	No	0
		Yes	2

The Ethics Committee from both hospitals approved this study. The confidentiality of the medical records was guaranteed, the personal data of the patients included in the study was protected, through a codification system in a database (Microsoft Excel 2016).

Using the G*- power program, a minimum sample size of 35 patients was calculated considering a fixed effect of 0.8 (8) and a power of 80% for a linear regression model.
The analysis was performed using Stata © 15 statistical software. A bivariate analysis was done both with the overall data and by subgroups. This analysis was done using the Wilcoxon test in qualitative variables. An association was determinate with a p-value <0.05. A multiple linear regression

analysis was performed to the variables with a p-value<0.20 in the bivariate analysis. Finally, a Pearson correlation coefficient was calculated to evaluate the correlation between the OOPS index, the ABG and the PTA. A correlation greater than 0.7 was defined as a good correlation.

Results

Atotal of 78 patients at the otorhinolaryngology division of Hospital de San José and Hospital Infantil Universitario de San José in Bogota, underwent ossicular chain reconstruction with partial (PORP) or total (TORP) prosthesis between 2012 and 2020. Of these 43 patients were excluded due to missing data related to diagnosis, surgery, and clinical or audiometric information. Finally, 35 patients were included in the study, and a total of 35 ears were analyzed. The mean age was 44.9 years (SD 13.4) and 62.9% were women. The follow-up range was from 2 to 79 months with a median of 5 months. Demographic characteristics are described in **Table 2**.

Table 2. Demographic and clinical characteristics

Sex	Female	22 (62.9)
	Male	13 (37.1)
Age*		44.9 ± 13.4
BMI*		24.2 (22.2-27.3)
Socioeconomic level	1	1 (2.9)
	2	10 (28.6)
	3	17 (48.6)
	4	5 (14.3)
	5	2 (5.7)
Operated ear	Right	18 (51.4)
	Left	17 (48.5)
Postoperative travel	No	28 (80)
	Yes	7 (20)

*Quantitative variables were represented by mean standard deviation.

An audiometric improvement was found between preoperative PTA PTAs (p=0.036) and a statistically significant closure in the ABG was found (p-value<0.01). These results are shown in **Figure 1.**

In the multivariate analysis no statistical significance was found, which means there were no variables related to better or worse hearing outcomes. However, in the subgroup analysis an improvement of postoperative PTA was found in all the subgroups. Patients without history of allergic rhinitis (p =0.004), non-smokers (p = 0. 009), patients with history of chronic otitis media in childhood (p = 0.0003), history of tympanic perforation (p = 0.003), patients who underwent primary ossiculoplasty (p = 0.0002) and patients in which a PORP prosthesis was used (p = 0.0029), all showed PTA improvement. These results are shown in **Table 3**.

Table 3. Bivariate analysis by subgroups and hearing outcomes with preoperative and postoperative pure tone averages.

	Preoperative PTA	Postoperative PTA	p-value*
Rhinitis	Median (IQR)	Median (IQR)	
Yes (n = 6)	50 (36.25-80)	36.25 (27.5-57.5)	0.423
No (n = 29)	56.25 (50- 62.5)	41.25 (28.75-50)	0.004
Travel			
Yes (n = 7)	60 (46.25-61.7)	43.75 (27.5-50)	0.018
No (n = 28)	55 (46.47-62.9)	40 (27.5-55)	0.006
Smokers			
Yes (n = 5)	60 (45.62-80.85)	43.75 (38.75-55)	0.2087
No (n = 30)	55.6 (43.12 - 80.8)	44.37 (29.37 - 59.37)	0.009
Chronic otitis media			
Yes (n = 30)	56.25 (45.25-80.85)	42.5 (26,25 - 59.37)	0.0003
No (n = 5)	52.5 (50-58.75)		
43,75 (36.25-80)	0,6015		
Tympanic perforation			
Yes (n = 17)	55.25 (46.225- 63.3)	31.25 (23.75 -40)	0.0003
No (n = 18)	55,62 (43.3 - 70)	46.47 (32.5 -57.5)	0.1736
Technique			
Endoscopic (n = 14)	57.5 (46.25-71.25)	40.62 (28.75-51.25)	0.0455

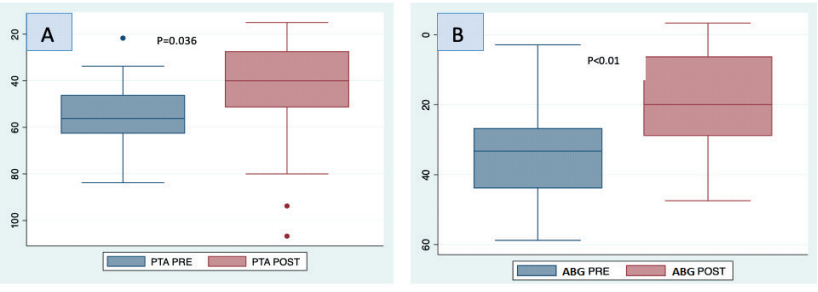

Figure 1. A. Preoperative and postoperative PTAs; B. Preoperative and postoperative ABG.

Microscopic (n = 21)	53.75 (46.7-61.7)	40 (26.25-50)	0.0045
Ossiculoplasty			
Primary (n = 32)	56.25 (51-62.9)	40 (26.87-48.5)	0.0002
Secondary (n = 3)	55 (32.5-57.5)	43.75 (36.25-46.25)	0.5127
Prosthesis			
PORP (n = 26)	56.25 (46.25-62.5)	39.37 (25-47.5)	0.0029
TORP (n = 9)	55 (50-61.7)	46.25 (32.5-55)	0.0922
Support			
Malleus (n = 13)	56.25 (46.25-62.5)	40 (25-51.25)	0.0329
Neotympanum (n = 22)	55 (46.7-63.3)	41.25 (28.75-50)	0.0047
Tympanoplasty			
Yes (n = 33)	56.25 (46.25-62.5)	41.25 (28.75-51.25)	0.0013
No (n = 2)	54.12 (52-56.25)	29.37 (22.5-36.2)	0.1213
Graft			
Both (n = 15)	56.25 (43.7-62.3)	40 (31.7-47.5)	0.0143
Cartilage (n = 15)	56.25 (52.5-63.3)	42.5 (23.7-55)	0.0512
Fascia (n = 5)	55 (42.34-80)	31.25 (27.5-57.5)	0.1745

Two patients presented extrusion of the prosthesis. Both patients had undergone ossicular reconstruction with TORP prostheses. Three patients needed secondary ossiculoplasty, two of which had received ossicular reconstruction with TORP prostheses. Regarding the surgical technique used, both microscopic (p = 0.045), and endoscopic technique (p = 0.004), had an audiometric improvement (**Table 3**).

In the correlation analysis, a moderate positive coefficient was found between the OOPS index and the postoperative PTA (p = 0.429), postoperative ABG (p = 0.653) and the OOPS index (**Figure 2**). This means that the higher the OOPS index score, a worse hearing outcome is expected.

Discussion

COM is defined as the presence of an irreversible inflammatory disease in the middle ear. It usually affects the ossicular chain, resulting in conductive hearing loss (10). Total or partial erosion of the ossicular chain is observed in approximately 80% of patients with COM with cholesteatoma, while, in the absence of cholesteatoma, it may be present in approximately 20% (10).

In patients with COM, the surgery main goal is to provide a dry ear, ensure Eustachian tube function and restore the middle ear sound conduction system (10). The success of the ossiculoplasty is determined by technical skill and, to a large extent, the selection of surgical candidate patients. Much of the variability in the literature on hearing outcomes after ossiculoplasty is due to a lack of understanding and uniform reporting of middle ear factors that influence the outcomes (11).

The literature describes that the male sex is more likely to suffer from COM in childhood (4). However, Kotzias and colleagues (10), found a higher percentage of women than men with a diagnosis of COM, who underwent ossiculoplasty, without differences in the morbidity of the disease between the two genders. In our study, we found a higher prevalence of women (22) 62.9%, and there was no association between gender and hearing outcomes, which is consistent with the literature.

The main objective of surgical management of COM is the achievement of a dry and safe ear, the interruption of recurrent ear drainage and, on the other hand, the improvement of hearing. Therefore, tympanic membrane integrity and the ossicular chain status are important (8, 12). The status of the ossicular chain as a determinant factor of hearing outcome has been somehow controversial in the literature. With respect to the malleus handle, it has been described that the mean ABG is improved when present with a statistically significant p-value (p = 0.05), which indicates the importance of the integrity and presence of the malleus handle for ossicle reconstruction (9, 11) . This differs from our results. We observed an improvement in the postoperative PTA (p <0.05), whether the prothesis was supported in the malleus or in the neotympanum.

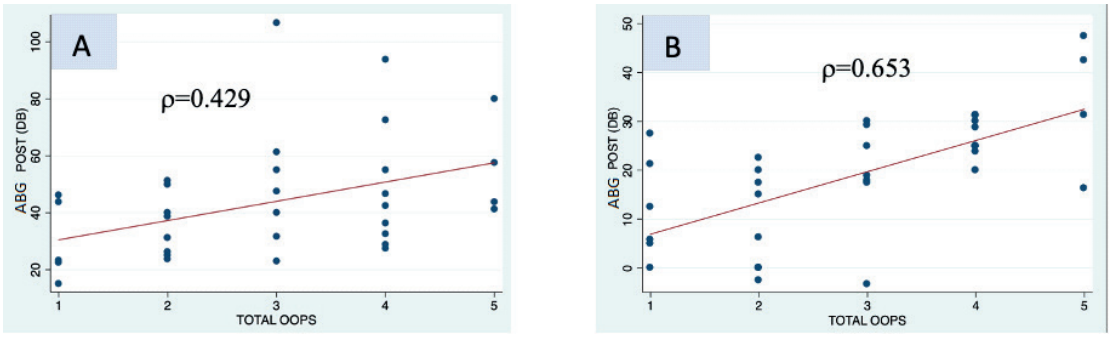

Figure 2. A. Correlation between total OOPS and postoperative PTA; B. Correlation between total OOPS and postoperative ABG.

Dornhoeffer and colleagues (9) proposed the OOPS index, which is calculated based on surgical findings. The index goal is to predict the postoperative audiometric outcomes in relation to the air-conduction thresholds and ABG closure in patients undergoing ossiculoplasty (9). In our study, when performing a bivariate correlation analysis between the OOPS Index score and postoperative PTAs, a moderate correlation was found ($p = 0.429$), which indicates that a higher index score, that is, a middle ear in worse condition, predicts a less favorable audiometric outcome with a higher postoperative PTA. Also, when compared with the postoperative ABG, a moderate correlation was found ($p =0.653$), which indicates that the higher the OOPS index, the higher the postoperative ABG, that is, it predicts worse audiometric outcomes in the study population. These results are similar to those that have been previously described in the literature (9).

COM is a very common medical problem worldwide, affecting 2% of the population (13). Its prevalence varies considerably among populations, but it is more common in low and middle-income countries (1). The health system in Colombia is centralized in large cities and access to health services is limited in rural areas. Therefore, this study aimed to evaluate socio-demographic factors, other than the OOPS index, that could be related to better or worse audiological outcomes in this population. Socioeconomic status was determined on a scale from 1 to 6 based on the family income. It was not possible to determine an association between socioeconomic status and hearing outcomes because most of the patients in the study were classified as status 3 (48.6%), probably secondary to the small sample size and a nonrandomized distribution among the subgroups.

In addition, the place of residence and whether or not the patient had to travel in the first postoperative month were evaluated. Since the geographic distribution by thermail floors in Colombia makes the atmospheric pressure vary considerably, even in very short distances, these travels could impact the middle ear pressure and, thus, have some effect on the position of the prosthesis. However, no correlation was found between these variables and the hearing outcomes; the two patients who reported prosthesis extrusion resided in Bogota and had not traveled in the first postoperative month.

It is well known that the pathogenesis of COM is multifactorial and that the most relevant factor in the evolution of this disorder is the Eustachian tube function. Allergic rhinitis, which affects 10%-30% of adults and up to 40% of children, has a well-known effect on the Eustachian tube function. However, there is still no consistent evidence of the effect of allergic rhinitis on the development of COM (3). In this study, we evaluated whether there was an association between COM patients with allergic rhinitis and postoperative hearing outcomes. As previously mentioned, no association was found between patients with a history of allergic rhinitis and worse hearing outcomes, but when bivariate analysis by subgroups was performed, better hearing outcomes measured with the PTA were found in patients without a history of allergic rhinitis ($p = 0.004$). It would be interesting to develop a prospective study with a larger sample size to elucidate this association between allergic rhinitis and postoperative hearing outcomes.

Tobacco exposure is also described in the literature as a risk factor for otitis media in children.

Several studies suggest that nicotine and other tobacco components could lead to ear infections and increase the possibility of invasion of microorganisms into the middle ear. Also, smoke exposure could affect the mucociliary function of the Eustachian tube leading to nasopharyngeal airway obstruction. The adhesion of microorganisms to the surface of epithelial cells and the depression of local immune function were investigated as a pathogenic mechanism for the occurrence of middle ear disease caused by passive smoking (4). Despite this, there are no studies in adult population where smoking is associated with COM hearing outcomes. This association was evaluated in this study, and even though there was no statistically significant association between smoking and hearing outcomes, in the bivariate analysis by subgroups an improvement in postoperative AC was found to be statistically significant in non-smoking patients ($p = 0.009$). Again, a prospective study with a larger sample size to elucidate this association would be important, especially in the preoperative patient education scenario.

Given the advent of endoscopic surgery and its good results in chronic middle ear pathology surgeries, an association between this technique and hearing outcomes was analyzed. Endoscopic ear surgery improves the visualization of the tympanic spaces in comparison with traditional microscopic techniques (14) and, therefore, facilitates the elimination of the disease in the anterior and posterior epitympanic spaces, areas of difficult access and often the reason for recurrence or failures of conventional microscopic approach (15). In addition, the correct placement of the prosthesis is important to maximize the acoustic benefit and this is possible when the working area can be clearly visualized, as in the endoscopic technique (15). However, we could not find differences in auditory outcomes according to the technique used, microscopic or endoscopic ossiculoplasty. Both the use of the endoscope ($p = 0.0455$) and the use of the microscope ($p = 0.0045$) presented statistically significant differences in the pre-and postsurgical PTA, showing improvement in the postoperative PTA. Nonetheless, when evaluating the pre- and postoperative ABG, the results showed a greater decrease in the ABG with the endoscopic technique compared to the microscopic technique, but it did not reach statistical significance ($p = 0.5379$). Das et al, (15) investigated ABG closure in patients undergoing microscopic versus endoscopic PORP and TORP prosthesis ossiculoplasty, finding that there was no significant difference with TORP ossiculoplasty between the two techniques over time. However, endoscopic PORP ossiculoplasty resulted in significant ABG closure at 1 month compared to the microscopic technique, but with no benefit of the endoscopic procedure when followed up at 3 and 6 months postoperatively (15).

Many techniques of ossiculoplasty have been described over the years, and today there is no single technique that guarantees better audiometric results (4). As mentioned above, the success of the ossiculoplasty depends on several factors. The most important are the type of the prosthesis, the reconstruction techniques, and the severity of the middle ear disease. In this study, 48% of the patients reached an ABG ≤20dB. There was no association between the type of prosthesis used and hearing outcomes. However, in the bivariate analysis by subgroups, statistically significant differences were observed between pre-and postoperative PTAs when PORP was used ($p = 0.0029$). Further, 50% of patients (13/26) who were taken to ossiculoplasty with PORP had a postoperative ABG <20 dB compared to the patients taken to ossiculoplasty with TORP, in which 33% of them (3/9) had a postoperative ABG <20 dB.

These results are consistent with those reported in the literature by Rondini-Gilli, who found that the ABG remained within 20 dB in 67% and 50% of ears with PORP and TORP, respectively ($p < 0.05$) (8), and Yung et al, who calculated the 5-year successful ABG closure rate for PORPs and TORPs to be, approximately, 66% and 33%, respectively (8). Many other studies also confirm better outcomes with PORPs compared to TORPs (4).

Although this study included patients operated from 2012 to 2020, the follow-up of those patients at 1 and 5 years was not rigorously possible due to loss of the follow-up. Future studies could consider analyzing audiometric outcomes in patients who were fitted with PORP or TORP prostheses on a long-term follow-up postoperatively.

Limitations

Among the limitations of this study is the sample size, even though the cohort was collected in two institutions, which could limit the representativeness of the population. Therefore, we suggest that multicenter studies be carried out at a national level.

Another limitation was the follow-up of the patients, considering deficiencies in the provision of the health service by the insurers, which do not guarantee a medium to long-term followup in the same institution where the patients were operated. Despite the period studied, prospective studies with long-term follow-up are required, comparing hearing results according to the types of prosthesis and surgical techniques in the short - and long- term, and obtaining results with higher scientific quality.

Conclusions

The ossiculoplasty is one of the treatments of choice for conductive hearing loss reestablishment when the ossicular chain is affected by COM. A successful outcome after ossiculoplasty depends on different variables, especially the condition of the middle ear microenvironment. No predictors of worse hearing outcomes were found to be associated with the demographic or pathological variables described. However, the OOPS score seems to be a useful scale for clinical practice to predict hearing loss after ossiculoplasty in developing countries such as Colombia, regardless of the demographic or pathologic factors.

Ethical Considerations

The aim of the study described is to evaluate which social and clinical factors predict audiometric outcomes in patients undergoing ossicular chain reconstruction performed by the otology group, in order to know the applicability and prognostic value of the OOPS index in our social environment, projecting it to developing countries, so that the OOPS index can be used in future interventions to predict results and to be able to perform education and pre-surgical counseling to patients. The information will be taken from the electronic medical records of the hospitals in question, and will be collected and codified in an Excel database.

Considering that this is an observational study (a description of a cohort of patients), and not an experimental study, whose methodology is based solely on the review of medical records, no interventions that modify the patient's state of health are required and therefore, the patient is not at risk of suffering or unnecessary harm.

In Resolution 8430 of 1993 of the Colombian Ministry of Health, Article 4, it is mentioned that health research includes the development of actions that contribute to: the knowledge of biological and psychological processes in human beings; the knowledge of the links between the causes of disease, practice and social structure; the prevention and control of health problems; the study of techniques and methods that are recommended or used for the provision of health services and the production of inputs for health. Our study fully complies with these criteria. Article 11 defines our study as a risk-free research, additionally in Article 15, Paragraph one, it is determined that in this type of risk-free research, it is not necessary to obtain an Informed Consent. However, when we encountered the difficulty of clinical records of operated patients where the paraclinical reports do not have all the data, it was decided to make phone calls where the missing data were requested with prior authorization by the patients of the use of their information, making an informed consent through the phone call, which would be recorded.

The present study is governed by national and international bioethical standards for human research studies. In the Nuremberg Code (1947), it is stated that "the experiment should be conducted with the aim of obtaining fruitful results for the good of society, should be conducted in such a way as to avoid unnecessary suffering or harm, and should be conducted only by scientifically qualified persons". On the other hand, the Declaration of Helsinki (2008) determines that "the duty of the physician is to promote and safeguard the health, welfare and rights of patients, including those

involved in medical research", ensuring the health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information.

Taking into account the Belmont Report and the Resolution 1581 of 2012, the information collected was handled with confidentiality and will only be used for academic purposes. It was be collected and codified in an Excel database, and will be available to be reviewed and approved by the Human Research Ethics Committee (CEISH) of the Society of Surgery of Bogota, Hospital de San José and Hospital Infantil Universitario de San José.

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Conflict of interest statement

The researchers declare that they have no conflict of interest.

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Declaration of authorship

The authors declare that we have reviewed and validated the manuscript submitted for your consideration and approve its publication. As authors of this work, we certify that none of the material contained herein is included in any other manuscript, is not under consideration for any other publication, has not been accepted for publication, and has not been published in any language. We further certify that we have contributed to the scientific and intellectual material, data analysis and writing of the manuscript and are responsible for its content. We have not conferred any right or interest in the work to any third party. We also certify that all figures and illustrations accompanying this article have not been digitally altered and faithfully represent the facts reported.

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