ORIGINAL ARTICLE

Ossiculoplasty in chronic otitis media: Surgical results and prognostic factors of surgical success

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KEYWORDS
Ossiculoplasty; Ossicular chain reconstruction; Surgical results; Prognostic factors

Abstract

Background and objectives: The goal of ossiculoplasty is to improve hearing. Successful ossiculoplasty depends on several factors. This retrospective study was carried out to analyze hearing results of ossiculoplasty in ears with chronic otitis media (COM) and evaluate clinical outcomes and factors predictive of hearing improvement.

Subjects and methods: We reviewed the results of 153 patients with COM (with cholesteatoma (COMC) and without cholesteatoma (COMWC)) who underwent ossiculoplasty between January of 2002 to December of 2011. Several potential prognostic factors were evaluated: cholesteatoma present vs absent; type of surgical procedure, state of the middle ear mucosa, state of the ossicular chain, type of prosthesis.

Results: We analyzed 153 ossiculoplasties: 96 patients presented COMWC and 57 patients presented COMC. The ossiculoplasties were performed using autologous ossicles for the most part. All ossiculoplasties were carried out in one-stage surgery. In 38% of cases ossiculoplasty was combined with mastoidectomy; in the remaining 62% of cases, ossiculoplasty was performed without mastoidectomy. Ossiculoplasty was successfully achieved in 113 patients (74%). The presence of the stapes superstructure and normal mucosa were significant predictive factors of surgical success.

Conclusion: The majority of the ossiculoplasties improved hearing status satisfactorily. Multivariate analysis should be performed to investigate prognostic factors of favorable short-term hearing outcomes after ossiculoplasty. Better knowledge of these predictive factors may contribute to the surgeon’s judgment and the information given to patients.

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PALABRAS CLAVE
Ossiculoplastia; Reconstrucción de la cadena osicular; Resultados quirúrgicos; Factores pronósticos

Osiculoplastia en otitis media crónica: resultados quirúrgicos y factores pronósticos de éxito quirúrgico

Resumen

Introducción y objetivos: El objetivo de osiculoplastia es mejorar la audición y sus resultados funcionales dependen de varios factores. Se ha realizado un estudio retrospectivo para analizar los resultados funcionales de la osiculoplastia en enfermos con otitis media crónica (OMC) y evaluar los resultados clínicos y los factores pronósticos que influyen en la recuperación auditiva.

Sujetos y métodos: Revisión de los resultados de 153 pacientes con el diagnóstico de OMC (con cólesteatoma [COMC] y sin cólesteatoma [COMSC]) sometidos a osiculoplastia entre enero de 2002 y diciembre del 2011. Los factores pronósticos evaluados fueron: la presencia o no de cólesteatoma, el tipo de técnica quirúrgica, el estado de la mucosa del oído medio, el estado de la cadena osicular y el tipo de prótesis.

Resultados: Se han analizado 153 osiculoplastias: 96 pacientes presentaron COMSC y 57 pacientes presentaron COMC. En la mayoría de las osiculoplastias se utilizó material autólogo. Todas las osiculoplastias se realizaron en un único tiempo quirúrgico. En el 38% de los casos de las osiculoplastias se añadió la mastoidectomía; en el 62% restante de los casos la osiculoplastia se realizó sin mastoidectomía. Se ha logrado una mejora de la audición en 113 pacientes (74%). La presencia de la supraestructura del estribo y de una mucosa normal fueron los factores pronósticos estadísticamente significativos en el suceso quirúrgico.

Conclusión: La mayoría de las osiculoplastias mejoró la audición de forma satisfactoria. El análisis multivariado permite evaluar cuáles los factores pronósticos de mejoría auditiva a corto plazo tras la realización de la osiculoplastia. Un mejor conocimiento de estos factores contribuye para la decisión del cirujano y la información a los pacientes.

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Introduction

Ossicular chain reconstruction (OCR) represents an attempt to restore the mechanical transmission of sound from the tympanic membrane to the oval window (inner ear) when the ossicular chain has been affected by a pathological process or trauma. In the last three decades, various ossiculoplasty methods have evolved and good results were achieved. Nevertheless OCR continues to be a process in evolution.1-3

Successful ossiculoplasty depends on several factors, including Eustachian tube function, middle ear pathology, ossicular chain status, surgical skill, and technique of OCR.2 Surgeons should recognize these factors before surgery to counsel their patients properly.3 There are many studies about prognostic factors which affect short and long-term results of ossiculoplasty, but standardization between studies is negatively affected by a variety of follow-up parameters.3

Ossiculoplasty can be a part of many surgical procedures in the middle ear such as tympanoplasty, surgery of ear trauma, congenital abnormalities of the middle ear and stapedectomy. This retrospective study was carried out to analyze hearing results of ossiculoplasties that were realized in the ENT department at Alto Ave Hospital Center, in Guimarães, for patients with chronic otitis media (COM); and evaluate clinical outcomes and factors predictive of hearing improvement.

Materials and methods

We performed a retrospective study of all data obtained from patients, diagnosed with COM, undergoing OCR at our department from 2002 to 2011, which included 153 cases/ossiculoplasties. Ninety-six patients presented chronic otitis media without cholesteatoma (COMWC) and 57 patients presented chronic otitis media with cholesteatoma (COMC) (Fig. 1).

In every cases, OCR was undertaken in a primary manner (that is, without staging), even the presence of cholesteatoma. Temporalis fascia was used as the graft material for the tympanic membrane. Ossiculoplasty was performed using autologous ossicles, cortical bone, cartilage or titanium prosthesis. Parcial ossicular replacement...
prosthesis (PORP) were used in the absence of an incus, or when it was eroded, and there were stapes superstructures. Total ossicular replacement prostheses (TORP) were used in the absence of the incus and of stapes superstructures.

The tympanoplasties are presented according to the Portland Classification. The mean patient age, considering the time of surgery, was 37 years (range, 13–67 years), with a male predominance (85 male; 68 female) (Fig. 2).

All patients had a minimum follow-up of at least one year, with audiological evaluation. The mean follow-up was 43 months (range, 12–87 months).

We determined the pure-tone average (PTA) through the mean increase in air conduction at 4 frequencies (0.5, 1.2, and 4 kHz). For the purposes of this report, and according to prior reports, the criteria for a successful ossiculoplasty were defined as a postoperative ABG of 20 dB or less, with a minimum follow-up of 6 months. We also calculated the closure in ABG as the difference between pre- and post-operative ABG. Variables that could influence hearing outcomes, including the presence of cholesteatoma, the status of the middle ear mucosa, the presence of a malleus handle, the presence of stapes superstructure and surgical methods were collected and analyzed.

All group comparisons were analyzed using SPSS software (version 22.0). Average hearing level was described as mean ± standard deviation (SD), Pearson’s Chi-square test and Fisher’s exact test were used for comparisons of categorical variables, and the Mann–Whitney test, the Kruskal–Wallis test and the Spearman correlation test for comparisons of continuous variables. We also performed multiple logistic and multiple linear regression analyses to assess the contribution of various factors to surgical success. A p value of less than 0.05 was considered statistically significant.

Results

We performed 153 ossiculoplasties: 38% without mastoidectomy; 62% with mastoidectomy: 70 canal wall-up mastoidectomies (CWUM) and 24 canal wall-down mastoidectomies (CWDM). Were realized 48 tympanoplasties type II and 11 tympanoplasties type III (Fig. 3).

The most widely used prostheses was autologous incus (n=78). Cortical bone was used in 30 surgeries, autologous malleus in 20 surgeries, cartilage in 6 patients and titanium prosthesis in 19 patients (TORP: n=16; PORP: n=3) (Fig. 4).

The mean preoperative ABG was 35.3 ± 10.6 dB and the mean postoperative ABG was 14.0 ± 10.5 dB. These measurements represented a significant improvement over the preoperative values (p<0.05). In conducting the review of our results based on the ABG, we found that ossiculoplasty was successfully achieved in 113 patients (74%) (Figs. 5 and 6).

Multivariate analysis of the effects of several variables on hearing success is summarized in Table 1. The presence of stapes suprastructure was significantly associated with success rate, whereas only the middle ear mucosa status was significantly associated with closure ABG.

Status of ossicles

The mean postoperative ABG in the 70 patients with intact malleus handles was 12.2 ± 10.7 dB, with 56 patients...
showing postoperative hearing success (Table 1). In contrast, the average postoperative in the 83 patients without intact malleus handles was 15.6 ± 10.0 dB with 57 patients showing postoperative hearing success. There was no significant difference in closure of ABG (p = 0.593) or success rate (p = 0.140).

The mean postoperative ABG in the 93 patients with the presence of a stapes superstructure was 11.6 ± 10.2 dB, with 75 (80.6%) patients showing postoperative hearing success (Table 1). In contrast, the average postoperative in the 60 patients without a stapes superstructure was 17.7 ± 9.91 dB with only 38 patients showing postoperative hearing success, and thereby the presence of stapes superstructure was significantly associated with success rate (p = 0.023). On the other hand, the effect of stapes superstructure on closure of ABG (p = 0.561) was not significant.

The 134 patients who received autologous prosthesis had an average postoperative ABG of 13.5 ± 10.3 dB, with the majority (101 patients) showing postoperative hearing success. In comparison, the 19 patients who received synthetic prosthesis had an average postoperative ABG of 17.9 ± 11.2 dB, with 12 patients showing postoperative

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Overall hearing results, determined using multiple variables.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
<td>Cases (n = 153)</td>
</tr>
<tr>
<td>Malleus handle</td>
<td></td>
</tr>
<tr>
<td>Present (%)</td>
<td>70</td>
</tr>
<tr>
<td>Absent (%)</td>
<td>83</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.045</td>
</tr>
<tr>
<td>Stapes superstructure</td>
<td></td>
</tr>
<tr>
<td>Present (%)</td>
<td>93</td>
</tr>
<tr>
<td>Absent (%)</td>
<td>60</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.000</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td></td>
</tr>
<tr>
<td>Absent (COMWC) (%)</td>
<td>96</td>
</tr>
<tr>
<td>Present (COMC) (%)</td>
<td>57</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.002</td>
</tr>
<tr>
<td>Middle ear mucosa</td>
<td></td>
</tr>
<tr>
<td>Normal (%)</td>
<td>56</td>
</tr>
<tr>
<td>Diseased (%)</td>
<td>97</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.001</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
</tr>
<tr>
<td>Ossiculoplasty only (%)</td>
<td>59</td>
</tr>
<tr>
<td>With mastoidectomy (%)</td>
<td>94</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.001</td>
</tr>
<tr>
<td>Type of prosthesis</td>
<td></td>
</tr>
<tr>
<td>Autologous (%)</td>
<td>134</td>
</tr>
<tr>
<td>Synthetic (%)</td>
<td>19</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.080</td>
</tr>
</tbody>
</table>

Bold: the p value of less than 0.05.
hearing success. Neither the success rates nor the closure of ABG (7.8 ± 7.6 dB versus 10.1 ± 9.6 dB, p = 0.298) differed significantly between the autologous and synthetic prosthesis.

Presence of cholesteatoma

The preoperative ABG in 57 patients with cholesteatoma was 17.4 ± 9.59 dB and the preoperative ABG in the 96 patients without cholesteatoma was 12.0 ± 10.5 dB. The average postoperative ABG in patients with cholesteatoma was 8.3 ± 7.6 dB and 39 patients showed postoperative hearing success. In comparison, the average postoperative ABG in patients without cholesteatoma was 8.3 ± 7.6 dB and 74 patients showed postoperative hearing success. Neither the success rates (p = 0.258) nor the closure in ABG (p = 0.859) differed between patients with and without cholesteatoma.

Status of middle ear mucosa

We considered middle ear mucosa "diseased" when inflammatory, edematous, or granulation tissues were found during surgery. About 56 patients with healthy mucosa had an average postoperative ABG of 10.3 ± 6.7 dB with 45 patients showing postoperative hearing success. In comparison the 97 patients with "diseased mucosa" had an average postoperative ABG of 16.2 ± 9.7 dB, with 68 cases showing postoperative hearing success. Closure of ABG was 7.1 ± 5.6 dB in patients with healthy mucosa and 10.2 ± 8.6 in patients with diseased mucosa, and the difference was statistically significant, indicating the importance of the status of middle ear mucosa in the reconstruction (p = 0.019).

Surgical procedures

The mean postoperative ABG in the 94 patients who underwent mastoidectomy plus ossiculoplasty was 15.8 ± 9.9 dB, with 68 showing postoperative hearing success. In contrast, the average postoperative ABG in the 59 patients whom mastoidectomy were not performed was 11.2 ± 10.8 dB, and 45 of these patients showed postoperative hearing success, similar to success rate in patients who underwent mastoidectomy (77.3%). Closure of ABG was 7.4 ± 7.7 dB in patients who underwent mastoidectomy plus ossiculoplasty and 9.5 ± 8.1 in patients who underwent only ossiculoplasty, and the difference was not statistically significant (p = 0.115).

Multivariate analysis of variables affecting postoperative hearing outcome

Univariate analysis showed that the presence of stapes superstructure was significantly associated with success rate (p = 0.017). The status of middle ear mucosa was the only factor significantly associated with closure ABG (p = 0.003) (Table 2). Multivariate analysis showed that the presence of stapes superstructure (R = 0.192) was independently associated with surgical success rate.

Discussion

The primary goal of surgery for COM is the achievement of a safe, dry ear, and hearing improvement. Ossicular reconstruction has always been a challenge for the otosurgeon. More than half of chronic middle ear diseases are reported to have ossicular involvement. Success in ossiculoplasty is determined by technical skill and case selection. In the literature, surgical results were considered successful when postoperative ABG was less than or equal to 20 dB. In our study the postoperative ABG was between 0 and 20 dB in 74% (n = 113) of the cases. The difference between preoperative ABG and the postoperative ABG was statistically significant (p < 0.05), noting a significant improvement in hearing results in the postoperative. The long-term (5 years) results of ossiculoplasty were not analyzed in this study. It was generally accepted that short-term results would be better than long-term results in ossiculoplasties, and absorption and/or extrusion of ossiculoplasty materials were among the reasons cited.

The ideal prosthesis for ossiculoplasty should be bio-compatible with surrounding tissues, stable, cost-effective, capable of optimal sound transmission, easy to harvest, and easy to handle during surgery. Implant design, stability, ease of use, and functional results are all accounted for in prosthesis selection. The limitations of ossiculoplasty are well known, most distressing are extrusions and the long-term deterioration in functional result. Comparative study on outcome of ossiculoplasty using different materials in different ossicular status of middle ear had already been done by various authors previously. The efficacy of a prosthesis and of the surgical procedure are usually evaluated 2–3 months post-surgery, with overall clinical outcomes assessed after at least 1 year, and up to 3–5 years postoperatively.

We analyzed the hearing results only 2 months after surgery. In this study we compared the autograft prosthesis (ossicles, cortical bone and cartilage) with allograft prosthesis.

### Table 2 Statistical results of univariate analyses.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Difference in success rate (p)</th>
<th>Difference in closure of ABG (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malleus handle</td>
<td>NS (0.114)</td>
<td>NS (0.520)</td>
</tr>
<tr>
<td>Staples suprastruture</td>
<td>$ (0.017)$</td>
<td>NS (0.831)</td>
</tr>
<tr>
<td>Presence of cholesteatoma</td>
<td>NS (0.241)</td>
<td>NS (0.627)</td>
</tr>
<tr>
<td>Middle ear mucosa status</td>
<td>NS (0.167)</td>
<td>$ (0.003)$</td>
</tr>
<tr>
<td>Combining mastoidectomy versus ossiculoplasty only</td>
<td>NS (0.593)</td>
<td>NS (0.131)</td>
</tr>
<tr>
<td>Type of prosthesis (autologous/synthetic)</td>
<td>NS (0.260)</td>
<td>NS (0.251)</td>
</tr>
</tbody>
</table>

S: significant; NS: not significant.
Bold: the p value of less than 0.05.
(titanium – PORP and TORP) and it was found not statistically significant difference between the two groups, in relation to surgical success or closure of ABG. Because of sample heterogeneity (autograft prosthesis: n = 134 cases vs. allograft prosthesis: n = 19 cases), there is a chance of statistical error. Good and Nishihara\(^5\) reported that the “ideal” ossiculoplasty should have the following characteristics: prostheses mass <40 mg; proper tension of the prostheses; angle between tympanic membrane (TM) and the stapes <45°; prostheses with a head angulated at about 30° to increase the surface area connected to the TM.

Much of the variability in the literature concerning hearing results after ossiculoplasty is due to a lack of understanding and uniform reporting of those middle ear factors that influence the results. The factors that seem to be associated with successful hearing results after ossiculoplasty include the presence of a stapes superstructure, the presence of a malleus handle, the status of the middle ear mucosa, perforation of the tympanic membrane, the presence of cholesteatoma, the type of prosthesis, Eustachian tube function and revision surgery. Among these, the presence of a malleus handle, the presence of a stapes superstructure and the status of the middle ear mucosa, have been found to be most important.\(^3,5,11\) Mills\(^4\) reported that the loss of the stapes arch was a factor causing a significantly worse outcome, but only 55 ossiculoplasties were analyzed. Albu et al.\(^11\) examined prognostic factors in 544 ossiculoplasties and concluded that the presence of the malleus handle and the mucosal status were the most important predictors in COMWC. Dornhoffer and Gardner\(^14\) reported the prognostic factors of 200 ossiculoplasties and concluded that mucosal status, presence of the malleus handle, otorrhea, mastoidectomy, and revision surgery were significant prognostic factors. Yung and Vowler\(^9\) reported the long-term outcomes of 145 ossiculoplasties and concluded that the presence of the malleus handle was the only significant factor. In our patient series, mucosal status and the presence of the stapes superstructure were significant predictors, which is similar to most of the previous reports.

The status of the ossicular chain as a determinant of hearing results has been somewhat controversial in the literature. In the current study, the stapes superstructure was the only factor with a significant relation with hearing results. The presence of stapes superstructure is a very important factor to improve hearing in ossiculoplasty. Brackmann reported long term results as 86% of success rate in adults with a postoperative air-bone gap of 15 dB or less, when the stapes was intact.\(^12\) On the other hand, Vartiainen and Nuutinen reported Kuopio experience as 59% of success rate with a postoperative air-bone gap of 0–20 dB when the stapes was intact after a long term follow-up period.\(^12\) Recently, Fayad et al.\(^13\) showed that in the absence of the stapes superstructure the presence of a “cavity” was associated with poorer hearing results.

In our study the presence of malleus handle not found a significant predictor. However, in the present series, this factor will not good evaluate since the prosthesis was not always placed under the handle but, parallel to the handle. In addition, the handle was missing in 54% of cases. Bared and Angeli\(^15\) reported significantly better outcomes were observed in patients with malleus handle, in particular in closure of ABG. The presence of a malleus handle seems to allow a proper adaptation of the tympanic graft and optimizes the stability of the reconstructed ossicular chain. Moreover, it probably prevents significant lateralization of the tympanic graft and extrusion of the prosthesis. Furthermore, the malleus contributes to the acoustic mechanism through its action as a catenary lever and impedance matcher.\(^2\)

The pathologic condition of the middle ear as a predictor of outcome is a very confusing issue in the literature. As shown in earlier reports, atelectasis of the MT is a major reason for poor hearing results after tympanoplasty, especially for children. Estimation of the future middle ear ventilation of the patient before surgery is a challenge for the otosurgeon. Selection of the right patient to offer an implant may be as important as the correct surgical technique. Swelling of the middle ear mucosa or the presence of granulation tissue may interfere with normal aeration of the middle ear cavity. We found that the status of the middle ear mucosa was a prognostic factor for closure of ABG.

The type or complexity of the surgical procedure had a significant impact on the hearing results, both in the performance of a mastoidectomy and, more important, in the removal of the canal wall. The decision whether to perform a CWD mastoidectomy or an CWU technique depends upon the severity of disease, mastoid size/aeration, and often, surgeon preference. Several authors have reported better hearing results in CWU mastoidectomy than in CWD mastoidectomy, while others have reported similar results in both techniques when the ossicular chain was reconstructed.\(^14\) In our study, the success rate was identical in the two groups (ossiculoplasty with mastoidectomy/ossiculoplasty without mastoidectomy) (77–72% Table 1) and the closure of ABG between the two groups was not statistically significant (p = 0.115). Besides that, the patients who underwent CWU mastoidectomy tended to have better results than those who underwent CWD mastoidectomy. The detrimental importance of removing the canal wall has not, however, been universally shown. Patients who did not require mastoidectomy usually had healthy middle ear mucosa and a pneumatic, well-aerated mastoid cavity. Furthermore, patients who underwent CWD mastoidectomy had more severe disease than those who underwent CWU mastoidectomy.\(^12\) Conceptually, patients with CWD mastoidectomy may have poorer hearing results because a shallow middle ear cleft is less acoustically efficient, and preservation of the canal wall favors a more physiologic ossiculoplasty, with less chance of contraction or fibrosis of the prosthesis to the promontory or the facial nerve.\(^3\)

**Conclusion**

Ossicular reconstruction still presents challenges. In this study we obtained surgical success in 74% of surgeries. The presence of the stapes superstructure and normal middle ear mucosa were significant predictive factors for successful hearing results after ossiculoplasty. With the continuing advances in our understanding of middle ear mechanics, the outcome of ossiculoplasty is improving. By paying careful attention to the principles of ossicular

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**Table 1**

<table>
<thead>
<tr>
<th>Prosthesis Type</th>
<th>Successful Closures</th>
<th>Total Closures</th>
</tr>
</thead>
<tbody>
<tr>
<td>CWD</td>
<td>77%</td>
<td>72%</td>
</tr>
<tr>
<td>CWU</td>
<td>72%</td>
<td>77%</td>
</tr>
</tbody>
</table>
reconstruction and the lessons from basic sciences and applying them in clinical practice, it is possible to give more desirable hearing results for the patients.

Conflicts of interest

No conflict of interest was declared by the authors.

Bibliografía