Acta Otorrinolaringol Esp. 2009;**60(3):**169-75

Acta Otorrinolaringológica Española

www.elsevier.es/otorrino

ORIGINAL ARTICLE

Myringoplasty: auditory follow-up and study of prognostic factors

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Received August 25, 2008; accepted December 11, 2008

KEYWORDS
Myringoplasty;
Hearing evolution;
Prognostic factors

Abstract
Objective: To perform a 5-year study of hearing evolution in patients undergoing myringoplasty to determine whether eardrum repair correlates with improved hearing. We also studied factors that might predispose to failure and their usefulness as prognostic factors.
Material and method: In a serial case study, we reviewed all myringoplasties performed at our centre during 2000, 2001, and 2002. We reviewed 83 case histories and studied the closure of the perforation, auditory function pre-operatively, post-operatively and after 5 years, as well as different associated factors.
Results: The perforation was closed in 75.9%of cases. The mean gain of auditory function was 1.5 dB at 5 years, without statistical significance. The hearing evolution presented a post-surgical improvement and a subsequent deterioration, both statistically significant. We found a statistically significant relationship between the size of the perforation and the condition of the contralateral ear.
Conclusions: Perforation closure in our series (75.9%) is similar to that reported in the literature. We found contralateral ear pathology and the perforation extension to be associated with poor prognosis after myringoplasty.

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PALABRAS CLAVE
Miringoplastia;
Evolución auditiva;
Factores pronósticos

Miringoplastia: seguimiento auditivo y estudio de factores pronósticos

Resumen
Objetivo: Realizar un estudio a 5 años de la audición de los pacientes sometidos a miringoplastia a fin de probar si la restitución timpánica tiene correlación con la mejora auditiva. Se investigan también posibles factores predisponentes al fracaso y averiguar si podemos describirlos como factores pronósticos.
Material y método: Se realiza estudio tipo serie de casos y una revisión de las miringoplastias realizadas en nuestro centro en los años 2000, 2001 y 2002. Se revisaron 83 historias y se estudió el cierre de la perforación, la función auditiva prequirúrgica, posquirúrgica y a 5 años, así como diferentes factores relacionados.
Resultados: Se obtiene un cierre de la perforación en el 75,9% de los casos. En cuanto a la función auditiva, obtenemos una ganancia sin significación estadística de 1,5 dB a los 5 años. La evolución auditiva presenta una mejora posquirúrgica y un empeoramiento posterior, ambos estadísticamente significativos. Se ha obtenido una relación estadística en el tamaño de la perforación y el estado del oído contralateral.
Conclusiones: Se presenta un resultado de cierre de la perforación acorde con la mayoría de las series. El estado patológico del oído contralateral y la extensión de la perforación son factores de mal pronóstico de la miringoplastia.

Introduction

The eardrum graft or myringoplasty is one of the most frequent interventions in otology. In 1878, Berthold proposed the term *myringoplastik*, but the modern era of myringoplasty arrived in the decade of the nineteen-fifties with the work of Zollner and Wullstein, who performed a classification of different types of surgery of the tympanic cavity.[1]

Myringoplasty is a surgical procedure with the primary aim of repairing the tympanic membrane through skin grafts without other surgical manipulations in the middle ear.[2]

According to Sheehy et al[3], myringoplasty is the technique that is limited to the repair of the tympanic membrane. Implicitly, this definition means that the ossicular chain is intact and mobile, as well as the absence of affection in the middle ear.

Its most common indication is to treat perforations of the eardrum, but it is also used to strengthen weak and withdrawn areas, such as the retraction pockets, or to remove any myringosclerosis plaques that are preventing a good mobility of the membrane; if it is possible to close the perforation, it is also possible to achieve the functional objective with an improvement in the patients tonal hearing.[2]

In many cases, the tympanic perforation is no more than the natural resolution of a problem of negative pressures with a long evolution in the middle ear, due to an alteration in the ventilation of the cavity through the Eustachian tube or to a disease of the mucosa that alters gas exchange.

This study is aimed towards answering the questions: "What happens with hearing after the resolution of the perforation?," "What hearing levels do successfully operated patients have after 5 years?," and "Is there a factor that we can study to establish the prognosis of myringoplasty?"

The aim of our study was to evaluate the hearing of patients who had undergone myringoplasty to test whether the tympanic restitution is correlated with hearing improvement.

Different concomitant factors are studied and a univariate analysis is performed in order to determine whether they are related to the failure of the myringoplasty.

Material and methods

We carried out a case series study and a review of the myringoplasties practised in our centre over 3 years (2000, 2001, and 2002), performed by the same surgeon, always using the underlay technique.

We reviewed a total of 83 medical records. We studied the following parameters: age, gender, type of anaesthesia (local or general); audiometric values (tonal audiometry) at frequencies of 500, 1000, 2000, and 4000 Hz pre- and post-operatively (3 and 6 months after surgery), and at 5 years.

Reason for consultation: predominant symptom for which the patient was referred to the otolaryngology specialist (hearing loss, otorrhea, or otodynia); contralateral ear status (normal or pathological); approach (endoaural or retroauricular); extension of the perforation (classified as greater or lesser than 50% of the surface of the membrane); involvement (marginal or non marginal) of Gerlach's annular tendon; predominant location of the perforation (anterior or posterior); graft material; and achieving anatomic restitution (success or failure).

The air and bone pathways are mentioned to present the study and the air-bone differential hearing threshold (DHT). There is also a quantification of the mean loss per year in each.

Exclusion criteria were:

— Audiometric loss not consistent with sole involvement of the tympanic membrane. We excluded patients with losses greater than 40 dB.
— Patients in whom the myringoplasty was a reintervention.
— Patients who underwent reintervention during the study period (5 years).
— Aetiology other than affectation of the ventilation of the middle ear (trauma, etc).
— Patients whose history was incomplete or where there was no complete audiometric testing.

Statistical analysis

Descriptive analysis: the description of the variables was conducted using the mean and the standard deviation for continuous variables and absolute and relative frequencies for categorical variables.

Univariate analysis: the comparison of the groups was done using the non-parametric Mann-Whitney *U* test for continuous variables and the χ^2 test for categorical variables.

For the evaluation of audiometric changes in patients with anatomic restoration of the tympanic membrane perforation, a multivariate analysis of variance (MANOVA) was carried out for repeated measurements of a factor. To adjust the assessment of evolution by prognostic variables, a MANOVA was conducted on 2 factors.

The accepted statistical significance was $P \leq .05$.

Data analysis was conducted using the statistic package SPSS version 12.0 for Windows (SPSS Inc. Chicago, United States).

Results

Closure of the perforation

Out of a total of 83 operated ears, anatomical restoration was achieved in 75.9%(63) of cases.

Study of the hearing function (Table 1)

Bone pathway: the study population shows an average gain of 1 dB after surgery which worsens to a level of 5 dB at 5 years.

Air pathway: there is a final mean increase of 1.5 dB, without statistical significance ($P = .3$). In studying the progression of this improvement, we see a clear increase (7.75 dB), confirmed statistically, from the pre-operative to the post-operative audiometry ($P = .03$) which then deteriorates, also in a statistically significant way ($P < .0001$), from post-operative to the 6.25 dB of the 5 year follow-up. The mean annual loss over the 5 years following surgery is 1.25 dB.

It is important to mention that despite the overall gain, the study shows a 46% of patients (n=29) who do not experience any degree of improvement.

Air-bone DHT: as occurred in the study of the air pathway, there is a closure of 8.75 dB in the DHT between the pre-operative and post-operative audiometries and a worsening eof 1.25 dB between the post-operative audiometry and that conducted 5 years later. The improvement between the pre-operative and post-operative audiometries is statistically significant ($P < .0001$). We calculate the annual loss as 0.25 dB. Between the pre-operative audiometry and the one 5 years after surgery we see a closure of 7.5 dB in DHT ($P = .01$) (Figure 1).

Table 1 Average audiometric values in the pre-operative, post-operative, and 5-year audiometries

	Pre-operative	Post-operative	5-year
Bone pathway	−13 (11.6) dB	−14 (13) dB	−19 (13) dB
Air pathway	−31.5 (14) dB	−23.75 (15) dB	−30 (16) dB
DHT	18.5 (6.4) dB	9.75 (7) dB	11 (9) dB

DHT indicates differential hearing threshold.
The data are presented as mean (standard deviation).

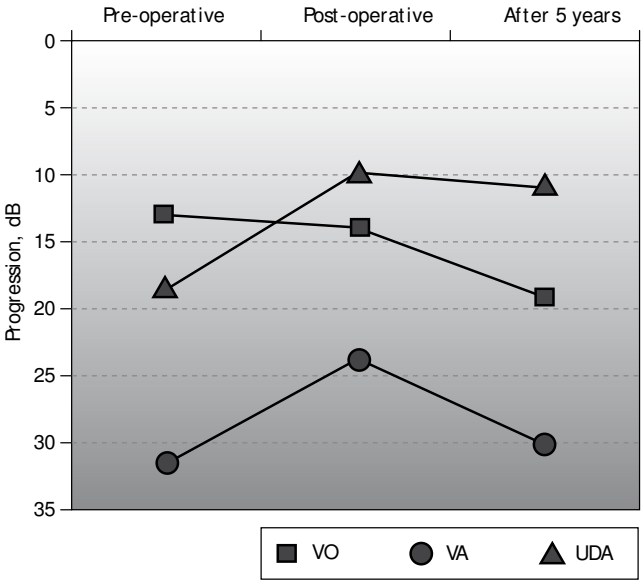

Figure 1 Representation in dB of the average progression of the bone pathway (VO), the air pathway (VA), and the differential auditory threshold (UDA) in pre-operative, post-operative, and 5-year audiometry.

Descriptive analysis

The age of the patients in the study was 9-65 years, with a mean (standard deviation) of 34.5 (17.5).

By gender, 57.83%(n=48) were female and 42.16%(n=35) male.

Women presented a 70.83% success rate and a 29.17% failure rate. Males presented an 82.85%success rate and a 17.15%failure rate.

Table 2 Statistical relationship between the factors studied and the result of the intervention

Variable	*P*
Age	NS
Gender	NS
Laterality	NS
Main symptom at consultation	NS
Approach	NS
Marginal involvement of the perforation	NS
Location of the perforation	NS
Material used	NS
Size of the perforation	.019
Status of the contralateral ear	.021
Type of anaesthesia	NS

NS indicates no statistical significance.

Table 3 Percentage of closure of perforation according to the literature reviewed

Author, y	Patients, n	Closure, %
Puhakka et al[4] (1979)	98	88
Lau et al[12] (1984)	124	92
Adkins et al[6] (1984)	71	89
Halyk et al[5] (1998)	605	81
Sakagami et al (2007)	554	77.7
Caye et al[9] (2007)	52	94
Yuasa et al[8] (2008)	75	76

Perforation was present in the right ear for 59% of patients (n=49), while 41%(n=34) presented perforation in the left ear.

The group of patients affected in the right ear had a 71.42% success rate and 28.58% failure rate. The group of patients affected in the left ear showed an 82.35% (28) success rate and a 17.65%(6) failure rate.

The hypoacusis group presented 79.54%(35) of success and 20.46%(9) of failure. The otorrhea group presented 67.64% (23) of success and 32.36%(11) of failure. The outcome was successful for all patients (n=6) in the otodynia group.

In 93.9%(78) of cases, the approach was endoaural and in 6.1%(5), retroauricular. Patients intervened through the endoaural route showed 76.92%(60) of success and 23.08% (18) of failure. The patients intervened by the retroauricular route presented 60%(3) of success and 40%(2) of failure.

Marginal involvement affected 22.8% (19) of cases. The non-marginal perforation group presented 80% (52) of success and 20% (13) of failure, while the marginal perforation group presented 61.1% (11) of success and 38.9%(7) of failure.

Regarding the location of the perforation, we divided them into anterior and posterior according to the predominant area involved. A percentage of 28.92% (24) presented anterior involvement and 71.08%(59), posterior involvement.

Anterior perforations showed 66.6%(16) of success and 33.3%(8) of failure. Posterior perforations showed 79.66% (47) of success and 20.34%(12) of failure.

Regarding the material used, 79.5% (66) were performed with fascia temporalis muscle, 16.8%(14) with perichondrium, and 3.6%(3) with temporalis muscle fascia and cartilage.

The cases done with temporalis muscle fascia presented 77.28% (51) of success and 22.72% (15) of failure. Myringoplasties made with the perichondrium showed 71.43%(10) of success and 28.57%(4) of failure.

Finally, the cases performed with fascia and cartilage presented 66.6%(2) of success and 33.3%(1) of failure.

Depending on the extent of the perforation, 42.1%(35) presented a perforation greater than 50%and the remaining 57.9%(48) less than 50%

Patients with perforation of more than 50% presented 54.54%(18) of success and 45.46%(15) of failure. Patients with a perforation of less than 50%presented 90%(45) of success and 10%(5) of failure.

Pathology was present in the contralateral ear 62.65%(52) of patients, whereas 37.35%(31) had a healthy contralateral ear.

The group with a pathologic contralateral ear presented 65.38%(34) of success and 34.62%(18) of failure. The group with healthy contralateral ear presented 93.54% (29) of success and 6.46%(2) of failure.

A percentage of 83.1% (69) of the interventions were performed under general anaesthesia, while the remaining 16.9%(14) received local anaesthesia.

The group operated under general anaesthesia presented 79.7%(55) of success and 20.3%(14) of failure.

The myringoplasties performed under local anaesthesia presented 57.14%(8) of success and 42.86%(6) of failure.

The univariate analysis of the variables collected in connection with the failures is presented in Table 2.

Discussion

The results of perforation closure presented (63 patients, 75.9%) are comparable with other series (Table 3).

The auditory function did not follow any linear evolution as there was a clear improvement between the pre-operative and post-operative audiometries ($P=.03$) and a worsening, also significant ($P<.0001$), in the audiometry after 5 years compared to the post-operative results (Figure 1).

According to Lau et al,[12] we must take 30 dB in the air pathway as the limit for "social" hearing. In our case, before surgery, 50.79%(32) of the patients were above this limit, while after 5 years this figure had become 55.55% (35); ie the myringoplasty improved the 30 dB level for 4.76%of patients.

The mean of the pre-operative air pathway was 31.5 dB, which improved slightly after 5 years to 30 dB, without statistical significance.

With regard to the closure of the DHT, the direct value indicating the correctness of the ear's transmissive function, the mean gain was 7.5 dB. It has previously been commented that this difference is statistically significant ($P=.01$).

When studying DHT by frequencies, it is observed that in the three audiometries it is highest for low frequencies and that the improvement at 5 years was more pronounced at high frequencies. We should bear in mind that the bone pathway deteriorates 1 dB/ year (Figure 2).

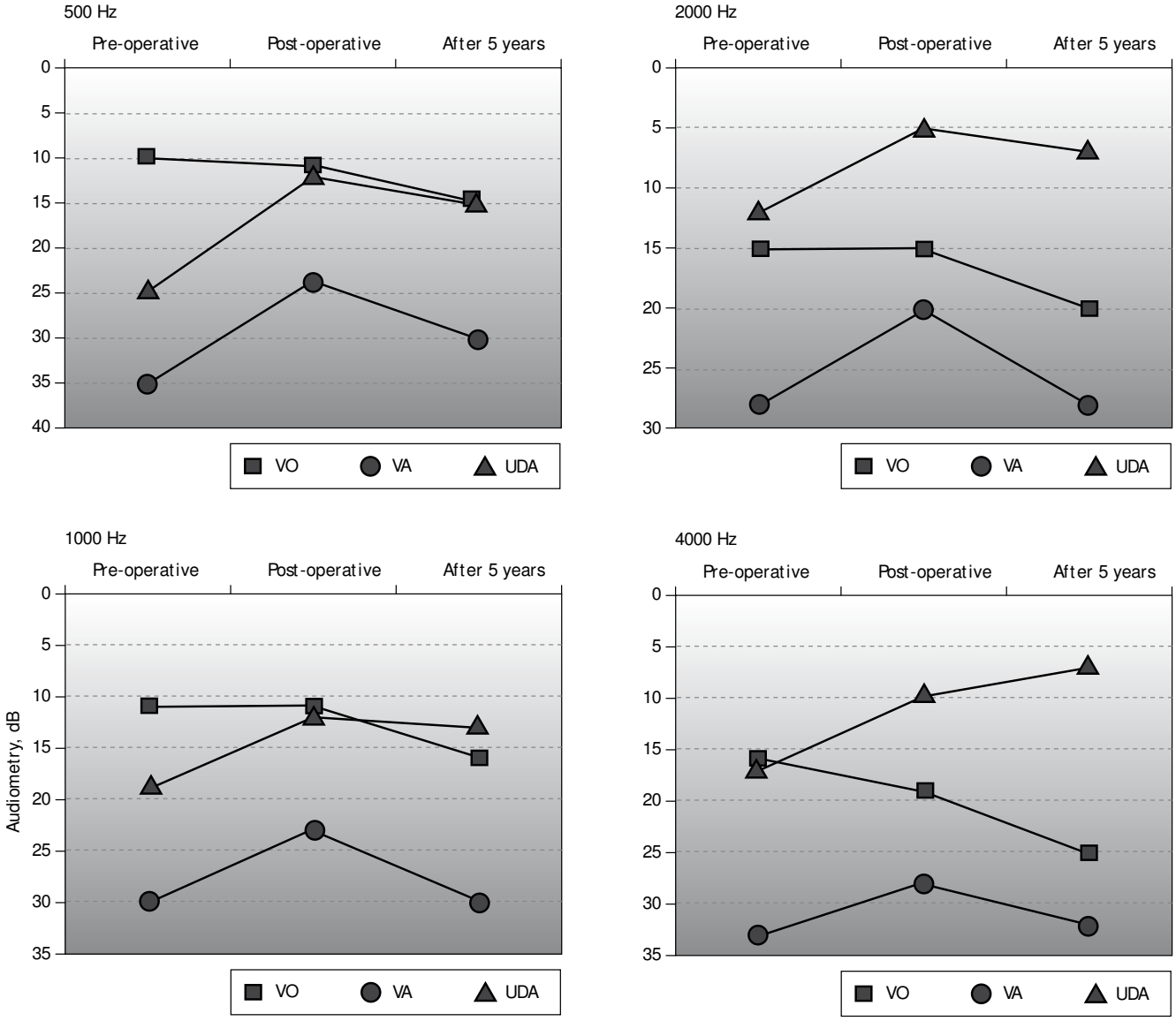

Figure 2 Graphical representation in dB depending on the frequency studied of the average values of the bone pathway (VO), the air pathway (VA), and the differential hearing threshold (UDA) in pre-operative, post-operative, and 5-year audiometry.

We noted that the air-bone DHT is the most studied factor of the audiometric tests in the series reviewed.[7,10,11]

Sakagami et al[7] presented an evolution of the pre-operative and post-operative DHTs of 15.2 (8.3) and 5.1 (8.5), respectively, in which 77.2%are below 20 dB.

Caye et al[9] presented a series of 26 patients intervened for bilateral myringoplasty that achieved a closure of the DHT in 100%to less than 20 dB and in 92%to less than 10 dB, with a follow up of 12 months.

Albera et al[10] reported an average improvement in the DHT of 8 (13) dB, similar to our study.

When considering the percentage difference of pre-operative and 5-year DHT, we concur with Sheehy et al,[3] who present a series of DHTs with a closure to less than 20 dB in 93% Strahan et al[13] presented 83%with a DHT below 10 dB and finally Mendel et al,[14] 90%with DHT below 20 dB. Our series provides a closure of the DHT to less than 20 dB in 92%(58) of cases. One must keep in mind that prior to the intervention, 69.8% (44) presented a DHT≤20 dB, so we attribute 22.2%of the closures of DHT to the operations.

We found no studies which quantified the annual loss in decibels, so we cannot compare. In our case, following myringoplasty, 1.25 dB/ year are lost in the air pathway and the DHT becomes worse by 0.25 dB/ year.

However, the loss in the bone pathway has been quantified, with 1 dB/ year attributed to natural loss,[15] which fully agrees with our study, as has been mentioned previously.

Through an analysis of the failures, we intend to find possible prognostic factors.

We found no differences with regard to age. However, in the literature reviewed we found many different conclusions. Most show that the results are less satisfactory

in children than in adults; probably due to the frequency of high respiratory tract infections, otitis and the unpredictable role of the Eustachian tube.[16]

Moreover, in a recent paper, Yung et al[17] concluded that there was no difference in outcome at 12 months when comparing groups of children of 4-8 years and 9-13 years.

Due to the difficulty of determining the physiology of the pressures from the tube, some authors[18] propose "frontier ages," some talk about 8 years of age, others 10, and a minority 12. Unfortunately, it is very difficult to compare these studies because they assume disparate selection criteria.

In any case, it seems that myringoplasty is predominant in children, since exposure of the middle ear makes recurrent infections very frequent, with progression to middle ear diseases, and consequent loss of hearing and impact on development.

There were no statistically significant differences relating gender with a negative result of the intervention. Nor did we find statistically significant differences with regard to the main symptom for consultation.

We do not have significant results in terms of the approach. There are various opinions as to the choice of approach[10]; at our centre we agree with most authors in saying that both techniques are appropriate and offer good results if one is scrupulous in the selection of patients.

Marginal perforation involvement: unlike what is described by most authors, we found no significant differences between those cases that had preserved Gerlach's annular tendon and those in which it was affected.

Marginalization has been separated from the perforation of the extension and location, although it is very likely that all these factors co-exist in the poor prognosis presented by the papers consulted.[19]

Regarding the location of the perforation, many authors[6,19] have commented on the difficulty of correcting previous perforations, although there are differing views.

The frequency of reperforation in this area can be explained by the lower vascular contribution of the anterior area of the tympanum.[19] In our work we have found no differences according to location, as opposed to that presented by Koch et al[20] who found a higher rate of failures in posterior perforations, and others, where the rate is higher in anterior perforations, mainly due to poor visualization and the anatomical characteristics of the area.[4]

Over 80% of our myringoplasties were performed with temporalis muscle fascia, therefore we cannot draw conclusions on the results obtained with one material or another.

Depending on the material used, Strahan et al[14] show a recovery of 10 dB in DHT in 90% with perichondrium and 82% with fascia. We cannot compare our results with those studies as there are not enough cases with perichondrium.

Furthermore, Glasscock et al[21] present a closure rate of 91% with temporal muscle fascia.

Extension of the perforation: this factor is shown as predictive of the outcome of the intervention, since it shows statistically significant differences in the results according to the extension of the perforation.

To eliminate possible bias in the results of the univariate calculation, the study of the extent of affectation was separated from that of Gerlach's annular tendon. Even so, the size of the perforation showed significance even without marginal involvement.

There are different series reported which coincide with our results, such as that of Ophir et al[22], which shows 155 myringoplasties with 79% of closure. However, most authors do not coincide with us.[11,23]

One of the prognostic factors, confirmed statistically, which we found is the higher rate of failures when the contralateral ear presented pathology.

There is broad consensus about the importance of tubal function in the outcome of the myringoplasty. It is proposed that the state of the contralateral ear is a prognostic factor because it may indicate tubal dysfunction, and thus it would mark a predisposition to failure.[10] Therefore, we believe that tubal assessment should be carried out systematically in all patients.

However, there are no affordable and accessible means to evaluate tubal function; for this reason we include the condition of the contralateral ear as indicative of this function.

Different ways have been proposed to evaluate the tubal function: Takahashi et al[16] proposed exploring this function through indirect methods; they found that the relevant factors to assess the function of the Eustachian tube are: DHT>20 in the frequencies 500, 1000, and 2000 Hz; spontaneously perforated eardrum 6 months after surgery, and finally, persistently wet ear. Their results showed a directly proportional correlation with the presence of one or more of those factors.

In the literature reviewed we found no unanimity of views on the prognosis provided by the condition of the contralateral ear. It is considered as a prognostic factor by Ophir et al[22], Koch et al[20], Gersdoff et al,[18] and Onal et al[11]; the latter present an interesting study, through a univariate analysis (P=.029) and another multivariable study (logistic regression) (odds ratio [OR] =5; 95% confidence interval [CI], 1.3-19.9). However, Albera et al[10] and Chandrasekhar et al[24] found no statistical relationship between the condition of the contralateral ear and the prognosis.

In the material we reviewed, we found different actions depending on the ear to be operated on. Our centre opts for conservative treatment, repeated aspirations and antibiotic therapy before surgery. As a rule, "active" ears are not operated on and it is customary to wait 3 months before surgery.

Nevertheless, there are published series[1,10,18] which do not believe it necessary to wait in cases of dry ears.

The underlay technique is used in all our myringoplasties. Like Mendel et al[14], we believe that this technique is the most suitable in our hands, because it allows an inspection of the middle ear, it provides more ease to preserve the anterior angle and it decreases the risk of graft lateralization.

Other authors introduce a number of aspects to be studied in relation to the failure of the intervention: Onal et al[11] conducted a multivariate study and introduced consideration of smoker/non-smoker status and provided a statistically significant relationship, as well as OR=11.4 (95% CI, 2.1-62.2) for failure.

Some authors show that the result is more dependent on other factors such as the experience of the surgeon. Onal et al[11] showed a significant relationship between experience and outcome (P<.0001; OR=14.3, 95% CI, 2.9-71.2).

However, Palva et al[25] studied this association in 452 ears, 142 intervened by otolaryngologists in training, 114 by a senior specialist and 196 by different team members, and found no significant differences in outcomes ($P>.05$).

Conclusions

The initial results of myringoplasties in experienced hands, with strict indications, show good rates of anatomical and functional results which vary between 74% and 96%. This study shows a success rate of 75.9%

With an audiometric study after 5 years, a slight improvement in hearing is observed, but is not statistically significant.

Although improvement is found, it does not always occur or is just a few dB; thus the main objective of the myringoplasty is the closure of the perforation, not hearing improvement.

The audiometric curve shows a clear early improvement and a clear worsening after 5 years, both significant.

The state of the contralateral ear appears as a prognostic factor for predicting the success of the myringoplasty. The observation of the contralateral ear can provide an indirect assessment of the condition of tubal function.

We see that the size of the perforation has a clear impact on the outcome of the myringoplasty.

It would be necessary to increase the number of cases in order to study the rest of the prognostic factors.

In the literature reviewed, we found, great heterogeneity in the study of myringoplasty and its prognostic factors, as well as a lack of follow-up in the long/very long term.

Conflict of interests

The authors have indicated there is no conflict of interest.

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