Risk Factors Leading to Failure in Myringoplasty: A Case-Control Study

Leonardo E. Ordóñez-Ordóñez, Esther S. Angulo-Martínez, José A. Prieto-Rivera, Jorge E. Almario-Chaparro, José E. Guzmán-Durán, and José G. Lora-Falquez
Servicio integrado de Otorrinolaringología, Hospital Militar Central-Hospital Universitario Clínica San Rafael, Universidad Militar Nueva Granada, Bogotá, Colombia

Introduction and objectives: To determine the risk factors associated with myringoplasty failure among the study population, a case-control study was carried out in 2 tertiary hospital centres.
Patients and method: Patients undergoing tympanic membrane perforation or atelectasis within 3 to 6 months following surgery were considered as cases, otherwise, they were considered to be controls. Patients having undergone any type of ossiculoplasty were excluded. Seventy cases and 210 controls were included, a sample size calculated for the following variables: inflammation at time of surgery, place and size of the tympanic membrane perforation, presence of tympanosclerosis, presence of cholesteatoma, and surgical technique. Odds ratio was calculated as main association measure, a stratified analysis was performed to rule out possible confusion factors.
Results: No significant differences were found between the 2 groups respect to the variables for which the sample was calculated. Although in total group the addition of a modified radical mastoidectomy showed better operative results (95% CI OR=0.13-0.72; *P*=.002), in isolated tympanic membrane perforation this association it was loosed (95% CI OR=0.06-7.44; *P*=.81*).*
Conclusions: Results in this study suggest that the variables for which the sample size was calculated are not associated with myringoplasty failure in this population.

Key words: Tympanoplasty. Myringoplasty. Case-control study. Risk factors. Tympanic membrane perforation.

Factores de riesgo de fracaso de la miringoplastia: un estudio de casos y controles

Introducción y objetivos: Para determinar los factores de riesgo asociados con el fracaso de la miringoplastia en la población estudiada, realizamos un estudio de casos y controles en dos hospitales de tercer nivel.
Pacientes y método: Se consideró casos a los pacientes que presentaron perforación o atelectasia de la membrana timpánica entre 3 y 6 meses después de la cirugía, y a los demás se los consideró controles. Se excluyó a los pacientes a quienes se realizó cualquier tipo de osciculoplastia. Se incluyó a 70 casos y 210 controles, un tamaño de muestra calculado para las siguientes variables: inflamación al momento de la cirugía, lugar y tamaño de la perforación timpánica, presencia de timpanosclerosis, presencia de colesteatoma y técnica quirúrgica. La principal medida de asociación utilizada fue la razón de ventajas. Se realizó un análisis estratificado para descartar posibles factores de confusión.
Resultados: No se encontraron diferencias significativas entre los dos grupos respecto a las variables para las que se calculó la muestra. Aunque en el grupo total la adición de una mastoidectomía radical modificada mostró mejores resultados (intervalo de confianza [IC] del 95% de la *odds ratio* [OR] = 0,13-0,72; p = 0,002), al analizar las perforaciones timpánicas aisladas, esta asociación se perdió (IC del 95% de la OR = 0,06-7,44; p = 0,81).
Conclusiones: Los resultados de este estudio indican que las variables para las que se calculó el tamaño de muestra no se asocian con fracaso de la miringoplastia en esta población.

Palabras clave: Timpanoplastia. Miringoplastia. Estudio de casos y controles. Factores de riesgo. Perforación de la membrana timpánica.

INTRODUCTION

Myringoplasty is indicated for atelectases or permanent perforations of the tympanic membrane (TM).[1-3] The aims of this surgery are to restore the integrity of the TM, avoid

The autors declare not to have financing sources.

Correspondence: L.E. Ordóñz-Ordóñez.
Servicio de Otorrinolaringología. Hospital Militar Central.
Transversal 3 # 49-00, tercer piso norte. Bogotá. Colombia.
E-mail: leoorl@gmail.com

Received October 23, 2007.
Accepted for publication February 12, 2008.

possible otological or intracranial effects or complications and improve the sound transmission mechanism.

The history of otology is full of controversy regarding the risk factors related with myringoplasty failure. The surgical results in children were, for a long time, considered to me worse than those expected in adults.[1,5] The risk factors described for this age group are linked to a higher rate of upper respiratory and inner ear infections, smaller diameter of the external auditory meatus (EAM), and technical difficulties during surgery.[1,5,6] The results of a meta-analysis of this seem to show that age may be a risk factor, without other variables being significantly associated with a poor surgical outcome.[7] On the other hand, some authors have presented good results, both in children[8,9] as well as in elderly patients.[10] For other variables the results are also contradictory: some say that possible risk factors include the location of the perforation,[1,6] its size,[2,11] the surgeon's experience,[6] the swollen tissue at the time of surgery,[9] the surgical technique,[12] and the presence of myringosclerosis,[13] tympanosclerosis,[2] or cholesteatoma.[2] Other studies, however, show that there is no link between surgical failure and the variables mentioned[2,5-7,12,14,15] nor with the surgery class (primary or revision), the type of surgery (isolated myringoplasty or combined with some sort of mastoidectomy),[7,16] the graft type (temporal fascia, perichondrium, cartilage),[3,6] the aetiology (infectious or traumatic),[2,3,12] or infections in the upper airway or of the surgical wound.

Even though there are abundant publications on this subject most are cross studies on series of cases. In order to offer an improved clinical practice more studies are needed that provide a higher level of evidence. This is why we use case-control design in order to identify risk factors, if any, that are associated with myringoplasty failure.

PATIENTS AND METHOD

A case-control study was done with patients who had undergone a myringoplasty in the Otorhinolaryngology services at 2 tertiary hospital centres. Approval was granted from the research committee of each institution before beginning the study.

Those patients who had a TM perforation or atelectasis for the last 3-6 months and that went ahead with the surgery were included as cases and the rest of the patients were considered to be the control group. For each case 3 controls were chosen. Those patients who had undergone any type of ossiculoplasty were excluded, as well as those who did not have a follow-up evaluation in the 3-6 months (1 month) following surgery or had incomplete medical records.

The information was obtained in retrospect. Since before starting it was not known who were cases and who were controls the search for cases started in November 2006 and finished once the proposed number was reached, in January 1999 (see "Sample Size"). The rest of the medical histories, that were for the controls, were randomized in order to reach the proposed number of controls. Information was taken regarding pertinent demographic, clinical, and surgical variables. The inflammation at the time of surgery was defined as otorrhea or inflammatory mucosa/epithelium in the EAM or TM or inflammation of the middle ear mucosa/mastoids found during surgery. The audiometric results are presented according to the internationally accepted recommendations.

The lateral and medial techniques were performed in a similar manner as that described by Rizer,[1] and the over-under technique according to Kartush et al.[15] For the trans-perforation technique a fatty graft was placed through the perforation, with 50% of the graft remaining in the middle ear and the rest in the EAM. A temporal fascia graft was used for the rest of the patients. Those patients who had had a mastoidectomy were included, it being either a high wall or modified radical mastoidectomy (MRM) if the surgery had accompanied the repair of the tympanic membrane. For those patients who presented TM atelectasis a myringoplasty was indicated, with or without mastoidectomy, only when a retraction pocket was present that could not be seen and/or cleaned out completely through the EAM.

Sample Size

The calculations of the sample size were done using the statistics calculator of EpiInfo 6.04. A 95% confidence interval (CI) was chosen, a power of 0.8 and a case/control ratio of 1:3. The odds ratio (OR) and the prevalence of exposure in the cases were taken from the bibliography. The sample size obtained (case/control) and the studies from which the information was obtained were: 18/54 for inflammation at the time of surgery,[9] 44/132 for the location of the perforation (assuming that subtotal perforations presented the worst results),[6] 64/192 for the perforation size (assuming that a size larger than 50% is a risk factor),[11] 68/204 for surgical technique (assuming that the lateral technique has the best results),[12] 62/186 for tympanosclerosis,[2] and 69/207 for cholesteatomy.[2] Therefore a sample size of 70 cases and 210 controls is adequate for trying to find significant links between myringoplasty failure and the variables mentioned. The skew control was done by means of a random selection of the controls and a stratified analysis for the variables considered to be risk/protection factors in the bivariable analysis.

Statistical Analysis

The OR and its corresponding 95% CI is the main association measure used. The level of statistical significance was set as $P<.05$. In order to discard possible factors that lead to confusion a stratified analysis was done using those variables that were statistically significant in the bivariable test. The statistical analyses were done with the SPSS 10.0 program.

RESULTS

The case group included 70 patients and the control group, 210. The case group (surgical failures) was made up of 60 re-perforations and 10 post-operative atelectases. Table 1 shows the general characteristics of the study subjects.

Table 1. Baseline of the Study Subjects[a]

	Cases	*Controls*	*Total*	*P*
Patients, n	70	210	280	
Age, mean (SD) (range), y	26.2 (13.5) (5-62)	28.7 (15.1) (6-69)	28.1 (14.7) (5-69)	.204[b]
Males/females, n	42/28	123/87	165/115	.83[c]
Right ear/left ear, n	30/40	85/125	115/165	.73[c]
HUCSR/HMC, n	35/65	107/103	142/138	.89[c]
Primary/revision surgery, n	61/9	194/16	255/25	.18[c]
Duration of the symptoms, mean (SD) (range), mo	107.5 (110.1) (6-390)	99.3 (142.2) (4-720)	101.4 (134.8) (4-720)	.66[b]
Surgery indicated: perforation of TM/atelectasia TM, n	60/10	163/57	213/67	.029[c]

[a]HMC indicates Central Military Hospital; HUCSR, "San Rafael" University Hospital; SD standard deviation; TM, tympanic membrane.
[b]Student *t* test.
[c]χ^2 test

Table 2. Localization of the Tympanic Membrane Perforation in 213 Study Subjects[a]

Location of the Perforation	*Cases (% of Surgical Failure)*	*Controls*	*Totals*
Anterior	0	14	14
Anterior-superior	0	4	4
Anterior-inferior	15 (31.9%)	32	47
Posterior	2 (10%)	18	20
Posterior-superior	6 (54.5%)	5	11
Posterior-inferior	0	17	17
Inferior	6 (35.2%)	11	17
Subtotal	25 (36.2%)	44	69
Total	6 (42.8%)	8	14
	60	13	213

[a]Surgery was indicated for tympanic membrane perforation in only 213 of the 280 study subjects.

Surgery being indicated due to a TM perforation is associated with surgical failure by the χ^2 test (P=.029).

Chronic otomastoiditis was the most frequent cause of TM perforation, with 77.1% (261/280), followed by explosive wave trauma, with 19.9% (50/280), contuse trauma with 3.2% (9/280), and penetrating trauma with 1.8% (5/280). Surgical failures were 28.7% (62/216), 12% (6/50), 22% (2/9), and 0%, respectively. These differences were statistically significant for Fisher's exact test (P=.045).

The results according to location of the perforation are shown in Table 2. The posterosuperior and total localizations presented the worst results, with a statistically significant difference (χ^2, P<.001).

The size of the tympanic perforation in the entire group was (mean [standard deviation] [interval]) 56.3% (28.1%) (5%-100%); in the case group it was 60% (29.5%), and in the control group it was 54.8% (27.7%), with a non-statistically significant difference according to Student *t* test (P=.23).

The surgery that was performed most frequently was the isolated myringoplasty, for 44.6% (125/280), followed by myringoplasty plus MRM for 25% (70/280), myringoplasty plus simple mastoidectomy (upper-wall mastoidectomy) for 22.5% (63/280), and myringoplasty plus revision MRM for 7.9% (22/280). The surgical failures were 32% (40/125), 11.4% (8/70), 25% 916/63), and 27.3% (6/22) respectively, with statistically significant differences (χ^2, P=.017).

The lateral technique was used the most (50.7%; 142/280) followed by the medial technique (30%; 84/280), the over-under technique (14.6%, 41/280), and the trans-perforation technique (4.6%; 13/280). The failures were 18.3% (26/142), 26.2% (22/84), 34.1% (14/41), and 61.5% (8/13), respectively. These differences were statistically significant (Fisher's exact test, P=.003).

The surgical results are shown in Table 3. Inflammation at the time of surgery was associated with a better surgical outcome. The audiometric results are shown in Table 4. The difference in the closing between the aerial and bone auditory thresholds of the cases (5 [9] dB) and the controls (7 [10] dB) was statistically significant (Student *t* test, P=.043).

There were complications in 51 (18.2%) of the patients: 20 had recurring cholesteatoma; 14 (5%) had a decrease in hearing; 9 (3.2%) had anterior angle loss; and 8 (2.9%) had post-operative infection. Regarding all the complications, the over-under technique presented a lower percentage than the others, with a statistically significant difference (χ^2, P=.002).

Risk Factors Analysis

Table 5 shows the risk factor analysis and there was no significant association (the 95% CI of the OR included 1) between surgical failure and the following variables: age, contuse trauma aetiology, size or location of the tympanic perforation, medial technique, over-under technique and presence of tympanosclerosis, myringosclerosis, or cholesteatoma. Among the possible risk factors (OR>1) were: chronic otomastoiditis aetiology, surgery being indicated for tympanic perforation, isolated myringoplasty as the type of surgery, and trans-perforation technique.

Table 3. Surgical Findings in the Total, Case, and Control Groups

Surgical Findings	*Cases (n=70), No. (%)*	*Controls (n=210), No. (%)*	*Total (n=280), No. (%)*	*P*[a]
Inflammation at the time of surgery				
Yes	31 (44.3)	139 (66.2)	170 (60.7)	.001
No	39 (55.7)	71 (33.8)	110 (39.3)	
Status of the ossicular chain				
Entire and mobile	33 (47.1)	85 (40.5)	118 (40.1)	.13
Discontinuous/fixed	31 (44.3)	122 (58.1)	153 (54.6)	
Undetermined[b]	6 (8.6)	3 (1.4)	9 (3.2)	
Tympanosclerosis				
Yes	10 (14.3)	21 (10)	31 (11.1)	.32
No	60 (85.7)	189 (90)	249 (88.9)	
Myringosclerosis				
Yes	12 (17.1)	33 (15.7)	45 (16.1)	.78
No	58 (82.8)	177 (84.3)	235 (83.9)	
Cholesteatoma				
Yes	20 (28.6)	74 (35.2)	94 (33.6)	.31
No	50 (71.4)	136 (64.8)	186 (66.4)	

[a]χ^2 test.
[b]This row was not included in the statistical analysis.

Table 4. Audiometric Findings in the Total, Case, and Control Groups[a]

	Audiometry, Mean (SD), dB								
	Pre-surgical			*Post-surgical*			*Difference*[b]		
	Cases (n=70)	*Controls (n=210)*	*Total (n=280)*	*Cases (n=70)*	*Controls (n=210)*	*Total (n=280)*	*Cases (n=70)*	*Controls (n=210)*	*Total (n=280)*
Air PTA	51 (23)	47 (20)	48 (20)	50 (26)	39 (21)	42 (23)	1 (14)	7 (11)	6 (12)
P							.62	<.001	<.001
Bone PTA	19 (15)	18 (11)	18 (12)	23 (18)	18 (12)	19 (14)	–4 (10)	0.2 (6)	–1 (7)
P							.001	.72	.047
Difference between auditory thresholds air – bone	32 (14)	29 (13)	30 (13)	27 (14)	22 (14)	23 (14)	5 (9)[c]	7 (10)[c]	7 (9)[c]
P							<.001	<.001	<.001
SRT	49 (23)	45 (19)	46 (20)	49 (26)	38 (22)	40 (24)	0.2 (14)	8 (13)	6 (14)
P							.9	<.001	<.001

[a]PTA indicates pure-tone average; SD, standard deviation; SRT, speech reception threshold.
[b]The statistical differences before and after surgery were analyzed by the Paired Student *t* test.
[c]Corresponds to the closing of the difference between air and bone auditory thresholds in each group.

Among the possible protection factors (OR<1) were: explosive trauma aetiology, myringoplasty plus MRM as the type of surgery, lateral technique, and inflammation at the time of surgery.

Stratified Analysis

The stratified analysis results are shown in Table 4. For the myringoplasty plus MRM and isolated myringoplasty variables no confusion factors were found, so they are considered to be protection factors and risk factors, respectively. These 2 variables are used as stratification variables.

The results show that associations between surgical success and surgery being indicated for TM perforation, the presence of inflammation at the time of surgery and the lateral technique are not real and are present due to the confusion effect caused by the type of surgery performed. Regarding the possible protection factor of explosive trauma aetiology this effect was constant when the surgery did not include a MRM. The association between chronic otomastoiditis aetiology and surgical failure was constant when the surgery performed was an isolated myringoplasty.

For the trans-perforation technique no confusion factors were found, so they are considered to be a risk of failure of myringoplasty.

DISCUSSION

The results of the studies on failure of myringoplasty are not unanimous and have lead to recommendations being

Table 5. Bivariable Analysis of Myringoplasty Risk Factors[a]

Variable	*Cases, No.*	*Controls, No.*	*OR*	*95% CI*	*P*[b]
Age ≥14 y	15	38	1.23	0.63-2.53	.54
Aetiology					
Chronic otomastoiditis	62	154	2.82	1.21-6.81	.009
Explosive wave trauma	6	44	0.35	0.13-0.92	.02
Contuse trauma	2	7	0.82	0.12-4.62	.84
Size of the tympanic perforation ≤50%	37	85	1.29	0.67-2.48	.41
Location of the tympanic perforation					
Posterior-superior	6	5	3.29	0.84-13.6	.08[c]
Total	6	8	2.01	0.59-6.78	.20
Subtotal	25	44	1.77	0.91-3.45	.07
Surgery indicated for tympanic membrane perforation	60	153	2.24	1.07-4.66	.03
Surgery type					
Isolated myringoplasty	40	85	1.96	1.09-3.52	.02
Myringoplasty + MRM	8	62	0.31	0.13-0.72	.002
Surgical technique					
Trans-perforation	8	5	5.29	1.5-19.42	.005[c]
Lateral	26	116	0.48	0.26-0.86	.009
Medial	22	62	1.04	0.58-2.04	.76
Over-under	14	27	1.69	0.78-3.64	.14
Surgical findings					
Inflammation at the time of surgery	31	139	0.41	0.23-0.73	.001
Tympanosclerosis	10	21	1.5	0.62-3.58	.32
Myringosclerosis	12	33	1.1	0.5-2.41	.78
holesteatoma	20	74	0.74	0.39-1.38	.31

[a]CI indicates confidence interval; MRM, modified radical mastoidectomy; OR, odds ratio.
[b]χ^2 test
[c]Fisher's exact test.

supported by some and discouraged by others. For example, in children, a "minimum age" of 7, 8, 10, or 12 years old has been recommended for surgery, while others think that patients as young as 3 can undergo surgery without an increase in the risks.[1,8]

An important point to take into account is that when the results of the different studies are compared the definition of surgical failure is where we find 2 proposals in the literature. The first one considers surgical failure to be the reappearance of a TM perforation or atelectasis.[3,5-7,9,11-16]

The second one also includes audiometric results,[2,4,8,10] considering that surgical failure occurred if the difference between the airway and bone auditory thresholds is not closed.[2,8] Although including the audiometric values makes the definition seem more physiologically precise, a drawback is that some cases of conductive hypoacusia may be considered to be failures but in fact are explained by alterations that differ from the surgical procedure[1] or because some surgeons prefer to postpone the auditory reconstruction for another surgery. For these reasons we use the first definition in order to try to restrict the false positives that may be included when taking into account audiometric results.

It is important to mention that for those variables for which the sample size was not calculated, even though the discussion is pertinent, it cannot be confirmed that the results are representative of the study population.[18]

Patients who underwent myringoplasty plus MRM showed the best surgical results, while those who underwent isolated myringoplasty showed a risk factor 1.96 times higher than when mastoid procedures were used in combination. Regarding isolated tympanic perforation management, McGrew et al[16] found that, even though adding mastoid procedures did not improve the percentage of perforation closing, it did decrease the need for additional procedures (such as ventilation tubes being put in). When we restrict our analysis to patients with isolated tympanic perforations (n=73) we did not find a link between a better surgical outcome and an additional mastoid procedure (OR=80; 95% CI, 0.06-7.44; *P*=.81). These results show that in perforations without additional otomastoid conditions, mastoidectomy did not improve the surgical outcome, and the protective effect observed may be explained through the including of patients for whom surgery was indicated for chronic otomastoid conditions.

The trans-perforation technique presented a strong link with surgical failure (OR=5.29). A statistically significant difference was found in the size of the perforation among the cases (mean, 25% [6.55%]) and the controls (16% [5.48%]) (Student *t* test, *P*=.027). We believe the use of this technique

Table 6. Stratified Analysis of the Possible Risk/Protection Factors Found in the Bivariable Analysis[a]

Variable	*Stratification Variable*	*Levels*	*OR*	*95% CI*	*P*[b]
Inflammation at the time of surgery	Myringoplasty + MRM	Yes	0.36	0.03-10.17	.39[c]
		No	0.54	0.28-1.03	.60
Explosion-related traumatic injury	Myringoplasty + MRM	Yes	NC	NC	1[c]
		No	0.31	0.10-0.80	.009
Lateral technique	Myringoplasty + MRM	Yes	0.2	0.02-1.25	.059[c]
		No	0.58	0.30-1.11	.078
Chronic otomastoiditis	Isolated myringoplasty	Yes	4.46	1.44-19.57	.004
		No	1.79	0.55-7.64	.31
Indication due to perforation of the TM	Isolated myringoplasty	Yes	NC	NC	.18[c]
		No	1.38	0.60-3.19	.45

[a]CI indicates confidence interval; MRM, modified radical mastoidectomy; NC, not-computable; OR, odds ratio; TM, tympanic membrane.
[b]χ^2 test
[c]Fisher's exact test.

for perforations larger than 15% may explain these poor results.

When we take into account procedures different than myringoplasty plus MRM the results are improved when the aetiology is from explosive wave trauma. On the contrary, when patients with chronic otomastoiditis aetiology undergo isolated myringoplasty they showed 4.46 times more risk of failure than those with other aetiologies. In the literature consulted we found that the results are comparable, both for traumatic and infectious origins.[2,3,12] Observing our results we believe that perhaps we are more inclined to add mastoid procedures for patients with chronic otomastoiditis, since the cavity ventilation and mucous elimination may help the perforation close up. An indirect observation that supports this affirmation is the strong link that we have found between the inflammation at the time of surgery and an additional MRM (OR=22.76; 95% CI, 6.63-96.7; *P*=.0001), which, in turn, was linked to an improved surgical outcome.

Regarding the size of the perforation, tympanosclerosis, and cholesteatoma, the results found do not show a significant link with surgical failure, which is opposed to the results found by other authors.[2,11] In our opinion these variables by themselves do not make up a myringoplasty risk of failure, so that the surgical procedure be the right one for the condition found (for example, an additional mastoidectomy if the condition extends into that cavity).

The localization of the perforation is not linked with the surgical outcome, contrary to what is found in another study, which found a poorer result in subtotal perforations.[6] We believe that choosing an appropriate technique, such as performing a canalplasty to completely see the perforation, may lead to good results with perforations of any localization.

One aspect that is widely debated is the comparison between medial and lateral techniques. Rizer[12] found that the lateral technique presented a higher failure rate (4.4%) than the medial technique (11.2%), a difference that is just on the edge of being statistically significant (*P*=.05). In this study the lateral technique showed a higher success rate than other techniques. However, this link was lost when it was stratified according to type of surgery performed. Although, for certain perforations, such as the total ones, the lateral technique is the only alternative. Our results show that when there is a fibrous ring the results are similar to those for medial, lateral, or over-under techniques and therefore, choosing one over the other is up to the surgeon.

There was no significant link between the patient being under 14 and surgical failure, which is similarly seen in other studies.[9,15] Even though the meta-analysis data seems to show that the results are poorer in children than in adults, it is impossible to reach this conclusion since the patients included in this study were under 13,[7] meaning that children were not compared with adults. Our feeling is that age is not something that impedes us from offering myringoplasty to a child, but we must be attentive to age-related conditions such as Eustachian tube dysfunctions, technical difficulties during surgery and problems with care following the surgery.

An important variable that was not included in the analysis of this study was the functional state of the Eustachian tube, which some consider that its normal functioning is a requirement for myringoplasty success.[5,6] Even though this variable was included in the research protocol the information gathered was not trustworthy and was eliminated from the final analysis. In Vrabec's et al[7] meta-analysis the functional state of the Eustachian tube was not linked with the surgical outcome. However, we must remember that there are doubts regarding the validity of the methods currently available to evaluate the Eustachian tube.[6]

Regarding audiological results, even though we found that airway auditory thresholds significantly improved after surgery among the control group, but not so with the case group, we must say that it was an unexpected finding and should be looked at carefully. Since there were alterations of the ossicular chain, both in cases as well as controls, an auditory improvement would not be expected following surgery. We believe that this effect is due to the fact that in 85 patients, control group with an intact and mobile chain, the conductive hypoacusia was resolved and the effect was to such a degree that, even comparing the total number of controls (n=210) with cases (n=70) the difference was still significant.

CONCLUSIONS

Our results show that the variables for which the sample size was calculated (inflammation at the time of surgery, perforation localization, size of the perforation, tympanosclerosis presence, cholesteatoma presence, and surgical technique) do not make up risk factors for myringoplasty failure in this population.

To clarify the doubts that still remain regarding the issue more studies with analytical and/or experimental designs should be done, preferably prospective, which take into account additional factors than those used for this study, such as care following surgery and a systematic assessment of the functional state of the Eustachian tube. They should also include sample sizes that are adequate for the variables that were not included in the calculations of this study.

Acknowledgements

We should like to thank Professor Conrado Gómez, epidemiologist at the El Bosque University, Isaac Huertas Forero, statistician at the Nueva Granada Military University and Esperanza Mayorga and Laura Rojas, nursing assistants, for theirco-operation in compiling case histories.

REFERENCES

1. Rizer FM. Overlay versus underlay tympanoplasty. Part I: historical review of the literature. Laryngoscope. 1997;107(12Pt 2):1-25.
2. Kageyama-Escobar AM, Rivera-Moreno MA, Rivera-Mendez A. Risk factors for myringoplasty failure. Gac Med Mex. 2001;137:209-20.
3. Sprem N, Branica S, Dawidowsky K. Tympanoplasty after war blast lesions of the eardrum: retrospective study. Croat Med J. 2001;42:642-5.
4. Albu S, Babighian G, Trabalzini F. Prognostic factors in tympanoplasty. Am J Otol. 1998;19:136-40.
5. Vartiainen E, Nuutinen J. Success and pitfalls in myringoplasty: follow-up study of 404cases. Am J Otol. 1993;14:301-5.
6. Frade Gonz·lez C, Castro Vilas C, Cabanas RodrÌguez E, Elhendi W, Vaamonde Lago P, Labella Caballero T. Factores pronósticos del resultado anatómico y funcional de las miringoplastias. Acta Otorrinolaringol Esp. 2002;53:729-35.
7. Vrabec JT, Deskin RW, Grady JJ. Meta-analysis of pediatric tympanoplasty. Arch Otolaryngol Head Neck Surg. 1999;125:530-4.
8. Bajaj Y, Bais AS, Mukherjee B. Tympanoplasty in children: a prospective study. J Laryngol Otol. 1998;112:1147-9.
9. Tos M, Stangerup SE, Orntoft S. Reasons for reperforation after tympanoplasty in children. Acta Otolaryngol Suppl. 2000;543:143-6.
10. Saito T, Tanaka T, Tokuriki M, et al. Recent outcome of tympanoplasty in the elderly. Otol Neurotol. 2001;22:153-7.
11. Lee P, Kelly G, Mills RP. Myringoplasty: does the size of the perforation matter? Clin Otolaryngol Allied Sci. 2002;27:331-4.
12. Rizer FM. Overlay versus underlay tympanoplasty. Part II: the study. Laryngoscope. 1997;107(12 Pt 2):26-36.
13. Wielinga EW, Derks AM, Cremers CW. Tympanosclerosis in the tympanic membrane: influence on outcome of myringoplasty. Am J Otol. 1995;16: 811-4.
14. Potsic WP, Winawer MR, Marsh RR. Tympanoplasty for the anterior-superior perforation in children. Am J Otol. 1996;17:115-8.
15. Kartush JM, Michaelides EM, Becvarovski Z, LaRouere MJ. Over-under tympanoplasty. Laryngoscope. 2002;112:802-7.
16. McGrew BM, Jackson CG, Glasscock ME 3rd. Impact of mastoidectomy on simple tympanic membrane perforation repair. Laryngoscope. 2004;114: 506-11.
17. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. Otolaryngol Head Neck Surg. 1995;113:186-7.
18. Neely JG, Karni RJ, Engel SH, Fraley PL, Nussenbaum B, Paniello RC. Practical guides to understanding sample size and minimal clinically important difference (MCID). Otolaryngol Head Neck Surg. 2007;136:14-8.