Hearing and ossicular chain preservation in cholesteatoma surgery

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Abstract

Objective: To assess the hearing changes associated with sacrificing an intact ossicular chain during cholesteatoma surgery.

Methods: We reviewed the operation notes of surgical procedures performed by the senior author between October 2000 and April 2006. Thirty-three cases were identified in which cholesteatoma surgery had been performed in the presence of a mobile, intact ossicular chain. One set of case notes was missing; therefore, 32 cases were included in the analysis. The ossicular chain was preserved in 17 cases (14 males and three females) and sacrificed in 15 (eight males and seven females).

Results: At the first post-operative assessment, a median air-bone gap deterioration of 3.3 dB was seen in patients in whom the ossicular chain had been sacrificed, while a median air-bone gap improvement of 3.3 dB was seen in those in whom the chain had been preserved. However, multivariable logistic regression analysis suggested that this difference in hearing outcomes was due to pre-operative hearing status, and that preservation of the ossicular chain did not lead to a better outcome.

Conclusions: In cholesteatoma surgery, there is at most a marginal benefit in preserving the ossicular chain. In the current study, the better hearing outcomes associated with preservation of the ossicular chain were accounted for by patients' better pre-operative hearing status. This study did not demonstrate a difference in residual disease rate, but was underpowered to do so.

Key words: Cholesteatoma; Hearing; Tympanoplasty; Otologic Surgical Procedures

Introduction

Middle-ear cholesteatoma is an erosive process which classically arises either in the postero-superior quadrant of the pars tensa or in the attic region. The ossicular chain is usually intimately involved with the disease, and is frequently eroded. The degree of ossicular involvement depends upon the site of the disease and its stage; in the majority of cases, the ossicular chain is no longer intact at the time of surgery. The ideal treatment would remove the disease, restore or preserve hearing, preserve normal anatomy, and facilitate middle-ear ventilation to prevent recurrent retraction. In reality, however, a compromise must be reached, and the primary goal of surgery remains the creation of a dry, safe ear. In those cases in which the ossicular chain remains in continuity, it may be sacrificed at the time of surgery in order to ensure complete clearance of disease. It is generally assumed that preservation of the ossicular chain will lead to better post-operative hearing, but at the expense of a higher risk of residual and recurrent disease.

In the current study, we investigated this assumption by comparing the hearing outcomes of patients in whom the ossicular chain had been preserved during surgery with the outcomes of patients in whom the chain had been sacrificed in order to facilitate complete removal of cholesteatoma.

We then performed a multivariable statistical analysis to determine whether preservation of the ossicular chain was significantly associated with a better hearing outcome.

We did not attempt to address the degree to which preservation of the ossicular chain compromised disease clearance and hence influenced residual disease rates. This was because (1) this study was underpowered to address this, and (2) we felt that any conclusion based on this necessarily subjective decision would be unlikely to be applicable to other surgeons' practice.

Methods

An initial power analysis suggested that, in order to identify a clinically significant, 10 dB difference in

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hearing outcome between the groups, we would need 17 patients in each group. (In order to identify a 5 dB difference, one would need 63 patients in each group, which was well beyond the scope of this or any similar published series.)

The operative notes of all surgical procedures performed by the senior author (MJW) over a six year period were reviewed in order to identify those patients who had undergone surgical treatment of cholesteatoma and who at the time of surgery had an intact, mobile ossicular chain. The operative notes provided details of the extent of disease, the surgical resection and any reconstructive procedure.

Data were collected on an Excel spreadsheet (Microsoft, Redmond, Washington, USA) (see Table I for data collected). Cholesteatoma was classified in accordance with Saleh and Mills' 1999 system, although for the purposes of multivariant analysis cholesteatoma was classified as either epitympanic or mesotympanic, and the procedure as either canal wall up or canal wall down, in order to ensure each category was large enough to be included in the analysis.¹

Patients' medical records were then reviewed in order to obtain pre- and post-operative audiographic data, and details of residual symptoms or disease. The pure tone air-bone gap at 0.5, 1, 2 and 4 kHz was calculated and averaged. For the purposes of analysis, we used the first post-operative audiogram in order to assess the transmission properties of the ossicular arrangement, and the last available audiogram in order to assess longer-term stability.² The results of analysis performed on both sets of data did not differ, and the figures presented relate to the first post-operative audiogram, performed between three and six months after surgery.

TABLE I DATA COLLECTED

Gender
Age at operation
Procedure
Cholesteatoma classification
Previous surgery?
Ossicular chain preserved?
Mucosa status?
Pre-op AC thresholds*
Pre-op BC thresholds [†]
Post-op months to 1st audiogram
1st post-op AC thresholds [*]
1st post-op BC thresholds [†]
Post-op months to last audiogram
Last post-op AC thresholds*
Last post-op BC thresholds [†]
Months of follow up
Status at last follow up
Residual disease?
Recurrent disease?
Operative complications
Disease complications

*At 0.25, 0.5, 1, 2, 4 and 8 kHz. [†]At 0.5, 1, 2 and 4 kHz. Preop=pre-operative; AC=air conduction; BC=bone conduction; post-op=post-operative Statistical analysis was performed using the Statistical Package for the Social Sciences software program (SPSS Inc, Chicago, Illinois, USA).

Ethics

This study represented an audit of our work, and ethical approval was therefore not deemed necessary. All patient data were anonymised in order to maintain patient confidentiality.

Results

Patients

Thirty-two patients were identified, representing 33 operated ears with an initially intact, mobile ossicular chain. The medical notes (and hence audiograms) of one patient could not be located, and this individual was therefore excluded from the study. (At the time of writing, this patient remained well and under follow up.)

The ossicular chain was preserved in 17 cases and sacrificed in the other 15. There was a male predominance in both groups, more marked in the preserved than the sacrificed chain cohort (14 versus eight males, respectively). The mean patient age was 20 years (range eight to 45) in patients with a preserved ossicular chain and 31 years (range six to 62) in those with a sacrificed chain. These gender mix and age differences were not statistically significant.

Disease classification

Attic disease predominated in both groups (occurring in 12 and nine cases in the preserved and sacrificed groups, respectively). One patient whose chain was preserved had an intact tympanic membrane (i.e. pars tensa type two) while the remainder were pars tensa marginal (i.e. pars tensa type one).

The mobility and integrity of the ossicular chain was confirmed. A degree of erosion of the ossicular chain was found in four patients, limited in all to the body of the incus or the head of the malleus. This was equally distributed between the two groups.

With reference to the surgical–prosthetic–infection–tissue–eustachian prognostic classification, the selection of patients for the study largely negated the influence of surgical and prosthetic factors (all patients had undergone complex surgery and had had initially intact ossicular chains.³ Three patients had granulation tissue arising from the middle-ear mucosa, in two of whom the ossicular chain was sacrificed. The presence of pre-operative, unremitting otorrhoea and middle-ear effusion was not reliably documented.

Surgery

Surgery was performed using a combined approach incorporating a tympanoplasty and intact canal wall technique, or an 'inside-out' atticotomy with or without antrostomy and using conchal cartilage to reconstruct the cavity. In three cases, both techniques HEARING AND OSSICULAR CHAIN PRESERVATION IN CHOLESTEATOMA SURGERY

Pt group	Time point	Hearing level (dB)					
		0-10	11-20	21-30	31-40	41-50	>50
ABG^{\dagger}							
OC preserved	Pre-op	6	5	2	4		
	Post-op	7	5	4	1		
OC sacrificed	Pre-op	1	6	4	2	2	
	Post-op	1	4	4	2	3	1
AC	1						
OC preserved	Pre-op	1	5	6	1	3	1
1	Post-op	1	10	2	2		2
OC sacrificed	Pre-op		2	3	4	2	4
	Post-op		1	4	3	1	6

Data represent patient numbers. *At 0.5, 1, 2 and 4 kHz. [†]Pure tone audiometry. Pt = patient; ABG = air-bone gap; OC = ossicular chain; pre-op = pre-operative; post-op = post-operative; AC = air conduction threshold

were utilised, and in one case adequate access was afforded by tympanotomy alone.

Ossicular chain sacrifice comprised removal of the incus and sometimes the head of the malleus, with reconstruction using either a cartilage cap on the stapes superstructure or a direct superstructure to tympanic membrane approximation.

In those cases in which the ossicular chain was preserved, the incudostapedial joint was not disarticulated. The proportion of patients in whom the chain was preserved remained constant throughout the study period; therefore, preservation of the chain did not represent improvement in the surgeon's operative skill.

A KTP laser (Laserscope, San Jose, California, USA) was used routinely to 'paint' the surgical cavity and to clear disease in contact with the ossicular chain.

Residual or recurrent disease and follow up

Residual disease was found in two patients in whom the ossicular chain was sacrificed and one in whom it was not. Recurrent disease developed in one patient in whom the chain was sacrificed. One patient in whom the chain was preserved had a wet cavity revised, although there was no residual cholesteatoma.

The mean time to the first post-operative audiogram was four and a half months in the chain-sacrificed group and three and three-quarter months in the chain-preserved group; the mean time to last post-operative audiogram was 25 and 28 months, respectively (range, six to 73 months). The mean duration of follow up for the two groups was slightly longer, at 27 and 34 months, respectively.

Table II presents data for air-bone gaps and air conduction thresholds averaged over 0.5, 1, 2 and 4 kHz from the first post-operative audiogram (approximately four months post-operative), while Table III presents changes in these variables.

Data analysis

Data on patients' ages, mean air-bone gap changes (for 0.5, 1, 2 and 4 KHz) and pre-operative air conduction thresholds were plotted out to check for normality. Data were found to be skewed. The Mann-Whitney test was therefore used to check for significant differences between patients with preserved versus sacrificed ossicular chains. Categorical data were analysed using the chi-square test.

Table IV and V present the results of single variable analyses.

Data on age, air-bone gap, procedure, pre-operative air conduction threshold and cholesteatoma classification then underwent multivariable logistic regression analysis. Only pre-operative air conduction was significant (p = 0.022). This indicates that, after adjusting for

TABLE III PRE- VS POST-OPERATIVE HEARING CHANGES* OF PATIENTS WITH OSSICULAR CHAIN PRESERVED OR SACRIFICED: AIR–BONE GAP AND AIR CONDUCTION THESHOLDS

Pt group		Hearing level change (dB)						
	-30 to -21	-20 to -11	-10 to 0	1-10	11-20	21-30		
ABG OC preserved OC sacrificed AC	1	2	7 8	6 4	3	1		
OC preserved OC sacrificed	3	2 1	7 7	4 2	4 1	1 1		

Data represent patient numbers. *At 0.5, 1, 2 and 4 kHz. Pt = patient; ABG = air-bone gap; OC = ossicular chain; AC = air conduction

TABLE IV PATIENT DATA FOR AGE AND HEARING*					
Variable	OC preserved?	Median	IQR	p^{\dagger}	
Age (y)	No Yes	29 16	12-50 9-32.50	0.142	
ABG (dB)	No Yes	-3.33 3.33	-23.33 to 1.67 -4.17 to 13.33	0.082	
Pre-op AC (dB)	No Yes	39.17 25.83	29.17–55.83 19.58–37.5	0.018	

*At 0.5, 1, 2 and 4 kHz. [†]Mann–Whitney test. OC = ossicular chain; IQR = interquartile range; y = years; ABG = air–bone gap; pre-op AC = pre-operative air conduction

the other variables in the model, there was no significant difference in peri-operative hearing change, age, procedure or cholesteatoma classification, comparing the chain-preserved and chain-sacrificed groups. This analysis was then repeated sequentially, removing least significant variables one at a time, until only significant variables were left (i.e. a backwards stepwise analysis). This process sequentially excluded the other variables in the model, leaving only preoperative air conduction as being significantly associated with preservation of the ossicular chain. This results of the single variable analysis for pre-operative air conduction are therefore valid (Mann–Whitney test; p = 0.018).

In order to address the criticism that pre-operative hearing threshold and chain preservation were co-variables and therefore impossible to differentiate in this analysis, we also analysed the data comparing pre- to post-operative hearing threshold, pre-operative threshold to chain status and post-operative threshold to chain status. A backwards stepwise logistic regression was then repeated but, instead of the preoperative threshold, the difference between the preand post-operative hearing threshold was used. Using this analysis, all other variables were removed from the model (i.e. air-bone gap, age, procedure and cholesteatoma location); the only variable left in the model was the difference between pre- and post-operative hearing. The conclusion of the initial analysis was therefore supported, i.e. the pre-operative hearing threshold appeared to be the only significant predictor of post-operative hearing.

Preservation of the ossicular chain was not significantly and independently associated with better postoperative hearing. This analysis was repeated using the post-operative air conduction threshold in place of the air-bone gap (also assessed at 0.5, 1, 2 and 4 kHz); the same conclusion was reached.

Discussion

The information on which this study was based was derived from a case note review, and was therefore limited to what was documented in the original notes. The primary source of information in the operative notes was diagrammatic, and there was therefore the danger of trying retrospectively to glean too much from these diagrams. We would ideally have liked to know whether the attic disease was lateral or medial to the heads of the ossicles, but this could not consistently be deduced. The power of the study was also limited – the number of patients represented those available, and would (as ever) ideally have been larger.

Two previously published series have specifically addressed the assumption that preserving an intact ossicular chain will improve hearing outcomes following cholesteatoma surgery.

Bruzzo *et al.* compared 20 patients in whom the ossicular chain was preserved with four in whom it was sacrificed, and concluded that there was benefit in preserving the chain, although the group in whom the chain was disarticulated had worse pre-operative hearing.⁴

In contrast, Sakagami and colleagues' study of 31 patients concluded that hearing outcomes were better in those patients in whom the ossicular chain was sacrificed and a Wullstein type three tympanoplasty performed, in that their peri-operative reduction in air–bone gap was greater.^{5,6} However, again, this study did not specify the pre-operative hearing levels

TABLE V PATIENT DATA FOR SURGICAL PROCEDURE AND CHOLESTEATOMA CLASSIFICATION*					
Variable	Category	OC not preserved	OC preserved	p^{\dagger}	
Procedure	CWU CWD	6 9	8	0.69	
Cholesteatoma	Epitymp Mesotymp	9 6	12 5	0.53	

Data represent patient numbers unless otherwise specified. *Categorical data. † Chi-square test. OC = ossicular chain; CWU = canal wall up; CWD = canal wall down; epityp = epitympanic; mesotymp = mesotympanic

of the two groups, and it is therefore unclear whether they were comparable.

Authors assessing hearing outcomes following middle-ear surgery have delineated some general principles which are also relevant to the current findings. In particular, Blakley *et al.* concluded that the major predictor of post-operative hearing following tympanoplasty was pre-operative hearing, irrespective of the surgical procedure or the final hearing mechanism.⁷ In addition, Black proposed a classification of factors associated with ossiculoplasty success, which comprised 12 features grouped together as surgical, prosthetic, infection, tissue or eustachian.³

Recent papers more directly relevant to our study topic have reinforced the correlation between hearing outcome and ossicular chain status. In a series of 26 patients with cholesteatoma treated via a post-aural atticotomy, Pennings and Cremers included 13 cases with an initially intact and post-operatively preserved ossicular chain.⁸ This group of patients had a better hearing outcome than those in whom the chain was not intact before surgery; however, this is likely to reflect differences in the extent and severity of disease. These authors also noted the difficulty of ensuring complete disease clearance while preserving the ossicular chain, and documented a residual disease rate of 46 per cent, although the majority of these were small keratin pearls easily removed at 'second look' surgery.

An association between an intact ossicular chain and a better hearing outcome has also been documented by Roth and Haeusler.⁹ They reported a series of 604 ears operated upon using an inside-out small cavity approach. The series contained 21 patients described as undergoing type one tympanoplasty, who therefore had intact ossicular chains post-operatively. All of these patients had a post-operative air-bone gap of less than 30 dB; this outcome was achieved by only 82 per cent of patients undergoing incus interposition. However, it is again unclear whether any patients had an intact ossicular chain sacrificed at surgery, and to what extent this affected their hearing.

A similar conclusion can be drawn from Stankovic's series of 758 ears operated upon to remove cholesteatoma, in which hearing outcomes correlated with the pre-operative presence of ossicles.¹⁰ It is again not specified to what extent intact ossicular chains were dismantled to facilitate surgery. Again, the likely conclusion is that hearing outcomes mirrored pre-operative hearing thresholds and the extent of disease.

Hamilton has compared hearing outcomes in patients undergoing canal wall up cholesteatoma surgery, and has demonstrated superior post-operative results in patients with a continuous ossicular chain, compared with those with a disrupted chain, an intact stapes superstructure and reconstructive ossiculo-plasty.¹¹ This author has demonstrated both a significantly better air–bone gap associated with preservation of an intact chain, and a higher proportion

of patients meeting the Belfast rules for binaural hearing benefit.¹² The assumption is made that sacrifice of an ossicular chain which was intact at the start of surgery will lead to a similar deterioration in outcome; however, the evidence supporting this assumption is by no means clear.

All these series have demonstrated an association between better post-operative hearing outcomes and the presence of more of the ossicular chain. However, none have controlled for the association between the extent of the disease, pre-operative hearing and postoperative hearing outcome; therefore, none of these series have answered the question addressed by the current study.

In our experience, preservation of the ossicular chain is possible both in a canal wall up 'combined approach' and in an extended atticoantrostomy or canal wall down approach. In our series, both approaches were used in both groups of patients. Therefore, the merits of preserving the ossicular chain should not be confused with the merits or otherwise of an intact canal wall combined approach procedure for the eradication of cholesteatoma.

The practice of clearing disease from those ossicles which remain in place is controversial. It has been demonstrated that ossicles in contact with the choles-teatoma sac are likely to be invaded by squamous epithelium, despite appearing clear of disease under the operating microscope, prompting the conclusion that 'if disease is on the ossicles then it is in the ossicles'.¹³ This conclusion often appears to be at odds with surgical experience – a cholesteatoma sac may elevate cleanly from underlying bone, leaving no evidence of residual disease at subsequent surgery.

The use of a KTP laser as an adjunct to surgery has been shown to significantly reduce the incidence of residual cholesteatoma.¹⁴ The assumption is made that the ability to clear disease and partially resect ossicles without physical contact should also reduce the likelihood of sensorineural hearing loss associated with ossicular manipulation, which primarily affects the higher frequencies.^{14–16}

In the current study, we specifically set out to address only one of the variables influencing the decision of whether or not to take down an intact ossicular chain, which is the degree of hearing loss to be expected as a consequence. There would clearly be merit in also knowing the degree to which residual disease rates would be affected. However, we believe that addressing this issue would require a far larger, prospectively randomised study, which we are not currently in a position to perform.

In the current series, the ossicular chain was sacrificed if we felt that its preservation would compromise disease clearance. The two resulting patient groups did not differ significantly in any respect other than their pre-operative hearing. This may be a consequence of an increased reluctance to sacrifice the ossicular chain in patients with better hearing; alternatively, better pre-operative hearing may reflect less intimate involvement of the ossicles in the disease process.

- During cholesteatoma surgery, preservation of an anatomically intact ossicular chain is often feasible, although sometimes technically demanding
- However, reluctance to sacrifice an intact ossicular chain may compromise the surgical view of cholesteatoma, and therefore jeopardise complete eradication of disease
- In this case series, preservation of the ossicular chain had at most a marginal benefit
- The better hearing outcomes generally associated with ossicular chain preservation were in this study accounted for by patients' better pre-operative hearing status

In the current study, multivariable analysis enabled us to isolate out the influence of the pre-operative hearing threshold; we were thus able to determine that this factor explained the difference between our two patient groups' outcomes.

Conclusion

Preservation of an anatomically intact ossicular chain is often feasible, although sometimes technically demanding. However, reluctance to sacrifice an intact ossicular chain may compromise the surgical view of cholesteatoma and therefore the complete eradication of disease. In addition, ossicular chain manipulation carries the risk of sensorineural hearing loss. Whether to retain or sacrifice an intact ossicular chain is a dilemma that all otological surgeons will face.

Our results indicate that there is at most a marginal benefit in preserving the ossicular chain. This may initially appear counter-intuitive. However, we found that the better outcome generally associated with preservation of the ossicular chain was accounted for by patients' better pre-operative hearing status. Whilst preservation of the ossicular chain is a reasonable aim, the associated benefit is not sufficient to justify the compromised disease clearance required.

Individual circumstances, involving both patient and surgeon, will dictate in which patients ossicular chain preservation is worthwhile and acceptable.

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