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Audit of middle-ear surgery outcomes in a tertiary referral Australian teaching hospital

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Main Article

Dr M da Cruz takes responsibility for the integrity of the content of the paper

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Abstract

Objective. This study aimed to audit middle-ear surgical procedures, provide a record of Australian experiences and allow comparisons with other published audits.

Method. A retrospective continuous series audit was conducted on 274 patients who underwent tympanoplasty, mastoidectomy and stapedotomy surgery at Westmead Hospital, Sydney. All consecutive surgical procedures, performed by multiple operators at various stages of training but under the care of a single surgeon, were included.

Results. Graft uptake was 86.9 per cent in tympanoplasty. Well healed cavities were seen in 72 per cent of mastoidectomies. Although 42 per cent of the patients had one or more co-morbidities, this did not influence the outcome. Hearing improvement was dramatic in stapedotomy and minimally changed in mastoidectomy. Post-operative complications were minimal.

Conclusion. All forms of middle-ear surgery were effective in achieving their surgical goals. Aural discharge and inflammatory diseases were well controlled with tympanoplasty and mastoid surgery.

Introduction

Middle-ear surgical procedures for chronic suppurative middle-ear disease and otosclerosis are performed in all countries, with outcomes of surgical treatment being measurable in terms of symptom and disease control, audiometric improvements and surgical complications. With the high global burden of disease, it is surprising that there are only a few published comprehensive audits of surgical treatment of chronic suppurative otitis media (CSOM).

The Common Otology Database[1] is one such large scale audit. It is a joint effort with 150 surgeons participating from 21 countries with the aim of standardising reporting on middle-ear surgery. It includes data for myringoplasty, ossiculoplasty, otosclerosis surgery and cholesteatoma removal. A web-based audit tool (http://www.ear-audit.net) provided a storage system for otological data, creating a prospective database allowing statistical analysis with sufficient power to produce standards for comparative auditing. The only other comprehensive audit on mastoidectomy and middle-ear surgery was published by the Royal College of Surgeons 25 years ago[2]; they also performed a subsequent audit on 'dead ear' after ear surgery.[3]

In Korea, there have been efforts to establish a standardised classification and nomenclature, to propose guidelines for the post-operative result reporting system and to develop a database management programme for middle-ear surgery that is similar to the Common Otology Database; however, the results are yet to be published.[4] Several smaller audits have been published, most of which are collections of case series on middle-ear surgery.[5–7] In Australia, audits of myringoplasty outcomes in the Aboriginal population[8] and performance audits aiming to assess the effectiveness of government-sponsored interventions to reduce the burden of ear disease in Aboriginal children[9] have been conducted.

A more complete characterisation of surgical experiences of middle-ear disease CSOM and its treatments would be useful to characterise practice patterns and treatment outcomes for this common disease.

With this in mind, we aimed to: (1) audit a large continuous series of CSOM and surgical outcomes, (2) provide a record of Australian experiences in a metropolitan teaching hospital, and (3) review local results with other published series thereby contributing to the broader knowledge base concerning surgical treatment for CSOM.

Materials and methods

We retrospectively reviewed patient records of a cohort of patients requiring middle-ear surgery at Westmead Hospital, Sydney, Australia, from January 2017 to December 2019. Patients undergoing surgery on the eardrum (myringoplasty), ossicles (ossiculoplasty and stapedotomy) and mastoid air cell system (open and closed cavity) were included. The simplest forms of middle-ear surgery (myringotomy, grommet insertion, Eustachian tuboplasty)

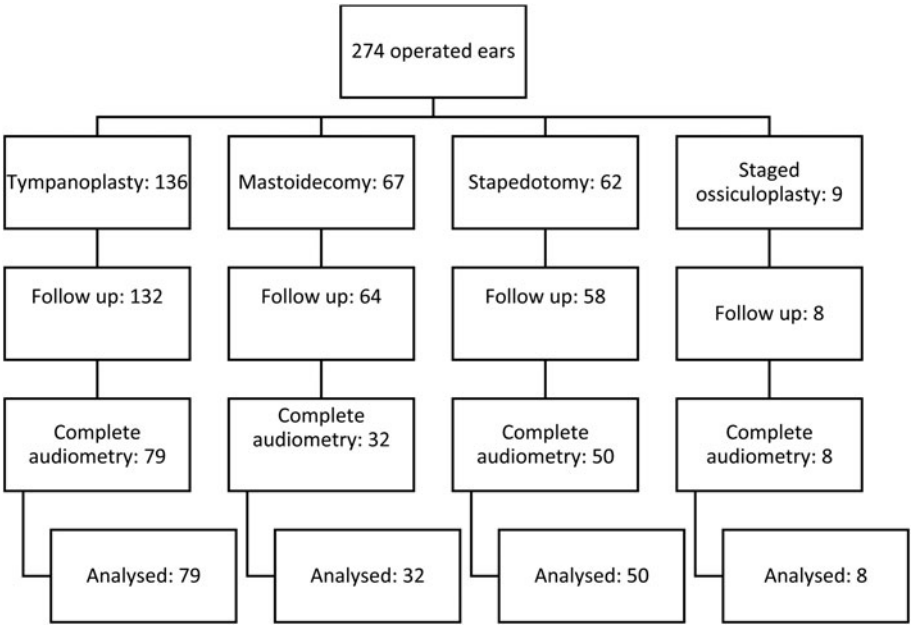

Fig. 1. Flow chart showing ears with complete follow up and analysis.

and those undergoing middle-ear surgery as part of a more complex access procedure (cochlear implantation and translabyrinthine approaches to the cerebellopontine angle) were excluded. Surgery performed by consultants, residents and fellows (under supervision) were all included in the audit. Standard operative steps for mastoidectomy,[10] stapedotomy[11] and tympanoplasty,[12] as outlined in previous publications, were followed. In order to reduce selection bias, all eligible consecutive cases operated on during the above period were included. Data entry and analysis were completed by an independent specialist who was not involved in the care and management of the above patients.

De-identified patient demographic data and medical co-morbidities were recorded. The surgical intervention and outcomes were extracted in detail including: graft survival, persisting otorrhoea and disease control, audiometric outcomes and surgical complications.

Approval for the study was obtained from the human research ethics committee of Westmead Hospital (approval number: 2019/STE16453).

Statistical analysis

Data were analysed using SPSS® (version 22.0) statistical analysis software. For distribution and normality, data were assessed using the Kolmogorov–Smirnov test with Lilliefors significance correction. Descriptive statistics were used to characterise the overall study population and between middle-ear surgery groups. Continuous data were presented as median and interquartile range (range from the 25th to the 75th percentile). The Mann–Whitney U test or, if appropriate, the Kruskal–Wallis test was used to compare groups of continuous data. The chi-squared or, as appropriate, the Fisher's exact test was used to compare proportions. All tests were two tailed, and statistical significance was considered to be at the $p < 0.05$ level.

Results

Age and gender distribution

A total of 274 patients (147 females and 127 males) underwent middle-ear surgery during the audited period. The follow up and outcome analysis are shown as the flow diagram in Figure 1. The median age was 48 years (interquartile range: 36–60). A total of 248 (91 per cent) patients were 18 years or older, with the remainder (26) below 18 years of age. Tympanoplasty ($n = 136$) was the most common surgery performed, followed by mastoidectomy ($n = 67$) and then stapedotomy ($n = 62$). Ossicular reconstruction as a staged operation was the least common among the surgical procedures performed ($n = 9$). A total of 117 patients who underwent surgery had one or more co-morbidities (43 per cent). Hypertension ($n = 29$), diabetes mellitus ($n = 18$), dyslipidaemia ($n = 15$) and cardiac conditions were the most commonly seen. A lower prevalence of other co-morbidities was also seen in the sample, ranging from chronic respiratory disease (bronchiectasis), malignancy (acute myeloid leukaemia), systematic autoimmune disease (rheumatoid disease, systemic lupus erythematosus, psoriatic arthritis, Churg-Strauss syndrome, Sjögren's syndrome), endocrine disease (Hashimoto's disease) and vascular disease (cardiac and cerebral). There was no significant difference ($p > 0.05$) detected in the age, gender and co-morbidities by procedure type (Table 1).

Surgical variables

A total of 217 patients underwent primary surgery (79 per cent), whereas 57 patients underwent revision surgery (Table 2). Extended post-aural approach was used in 63 patients (mastoidectomy), whereas a limited end-aural approach was used in the remaining 211 cases (tympanoplasty, stapedotomy and staged ossiculoplasty). Composite gelfoam or temporalis fascia was the most common graft material used in tympanoplasty. Temporalis fascia was used in mastoidectomy, whereas small perforations were commonly repaired with fat grafts. No tympanic membrane grafts were used for most of the stapedotomy and staged ossiculoplasty cases with intact tympanic membranes.

Surgical outcomes

Tympanoplasty

The median follow-up duration for tympanoplasty was 2.5 (interquartile range: 2–7) months. Four cases were lost to

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Table 1. Baseline characteristics

Parameter	Overall	Tympanoplasty	Mastoidectomy	Stapedotomy	Staged ossiculoplasty	*P*-value
Patients (*n*)	274	136	67	62	9	
Age (median (IQR); years)	46	49 (36–59)	46 (30–55)	47 (41–63)	45 (14.5–60)	0.407
Gender (male:female)	0.86:1	0.67:1	1:1	1:1.13	2:1	0.523
Co-morbidities (*n*)						
– Yes	117	58	30	27	2	
– Diabetes		9	6	3	0	0.709
– Hypertension		18	6	7	0	0.516
– Cardiac		7	3	4	0	0.938
– Dyslipidaemia		7	5	3	1	0.871
– Others		17	10	10	1	0.583
– No co-morbidity	157	79	36	35	7	

IQR = interquartile range

Table 2. Surgical variables and outcomes

Parameter	Overall	Tympanoplasty	Mastoidectomy	Stapedotomy	Staged ossiculoplasty	*P*-value
Primary (*n*)	217	111	46	54	6	0.042
Revision (*n*)	57	25	21	8	3	
Approach (*n*)						
– Limited end aural		136	3	62	9	<0.0001
– Extended post-aural		0	64	0	0	
Graft material		Composite gelfoam fascia, fat	Temporalis fascia	NA	NA	
Follow-up duration (median (IQR); months)		2.5 (2–7)	11.75 (5.25–17)	2 (1.5–5)	2 (1.5–11)	<0.0001
Graft uptake (%)		86.9	71.7	NA	NA	
Facial nerve paresis (*n*)		0	2	1	0	0.264
Numbness (*n*)		1	0	0	0	0.907
Disequilibrium (*n*)		0	1	3	0	0.113
Bleeding (*n*)		3	0	0	0	0.545

IQR = interquartile range; NA = not applicable

follow up, and the longest duration of follow up was 29 months. Complete graft uptake was seen in 86.9 per cent of cases with some degree of graft failure in the remaining 13.1 per cent of cases. The failure ranged from partial graft failure with residual pinpoint micro-perforations to complete graft failure that left a subtotal perforation. Transient bleeding from the wound was seen in 3 cases (2 per cent). This was treated with simple measures, with no cases taken back to the operating theatre. Andersen *et al.*,[13] in their prospective ear surgery database, mention an 88 per cent graft uptake rate in primary surgery and an 80 per cent graft uptake rate in revision cases. Similar graft uptake rates using temporalis fascia are reported in the literature by Dangol *et al.*,[14] Singh *et al.*[15] and Sandhu *et al.*[16] (83.1 per cent, 85 per cent and 88 per cent, respectively).

Mastoidectomy

The median follow-up period for mastoidectomy was 11.75 (interquartile range: 5.25–17) months. Three patients were lost to follow up. A dry well-healed mastoid cavity was seen in 52 (77 per cent) cases. Persistent discharge was seen in eight of the cases, three of which were associated with persisting perforation, one with granulation, four with discharge alone and four with either residual cholesteatoma or recurrence of cholesteatoma. Transient disequilibrium was reported in one case, whereas two cases experienced temporary partial facial paresis that resolved completely within a few weeks.

As a subgroup analysis, we also examined the effect of co-morbidities on outcomes in tympanoplasty and mastoidectomy. Graft uptake was 59.1 per cent in those without and 40.9 per cent in those with co-morbidities, and failure was similar (50.0 per cent each) in those with and without co-morbidities. There was no significant difference in graft uptake between these two groups ($p = 0.518$), indicating that co-morbidities do not have a bearing on graft uptake. Similarly, co-morbidities did not seem to have a large bearing on the graft uptake and cavity healing in mastoidectomy ($p = 0.608$).

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Table 3. Hearing success: post-operative ABG by the type of surgery

	Tympanoplasty		Mastoidectomy		Stapedotomy	
ABG	Pre-operative ABG (%)	Post-operative ABG (%)	Pre-operative ABG (%)	Post-operative ABG (%)	Pre-operative ABG (%)	Post-operative ABG (%)
<10 db	24.1	46.6	9.9	8.5	7	60.3
11–20 db	30.0	26.7	23.0	15.8	24.4	22.4
21–30 db	22.4	14.8	23.0	27.9	25.8	7.9
>30 db	23.4	11.9	44.1	47.9	42.7	9.3

ABG = air–bone gap

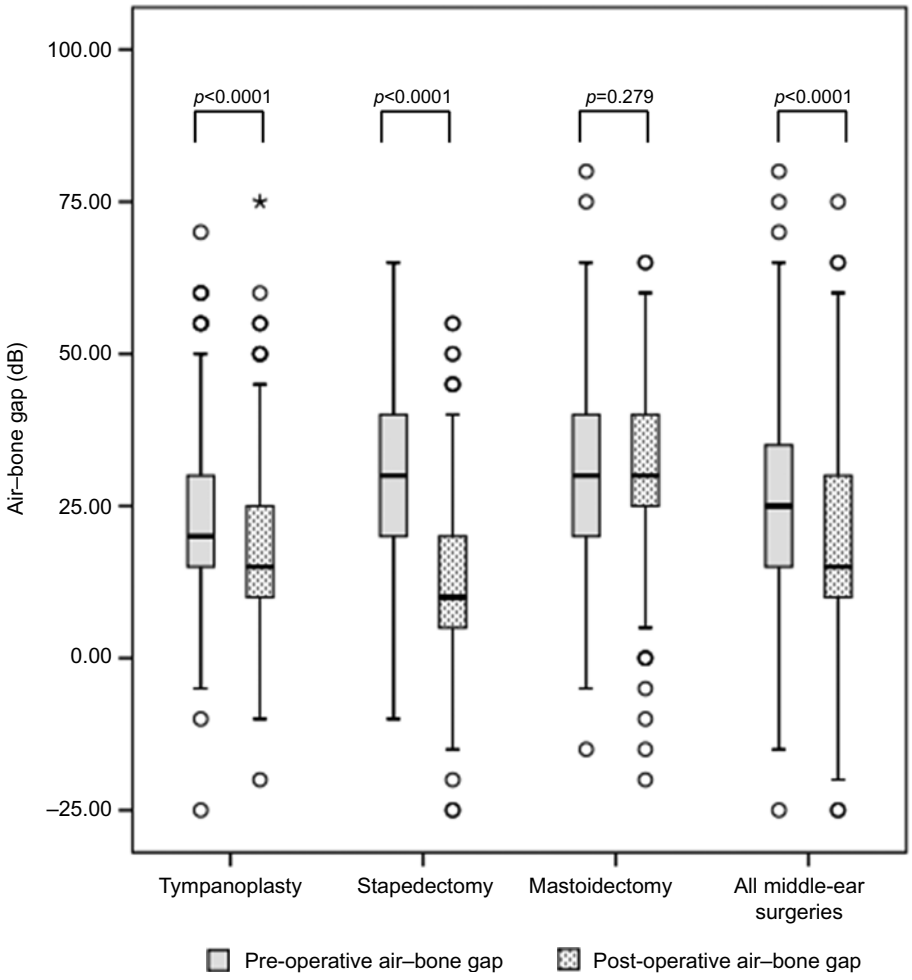

Fig. 2. Clustered box plot comparing the pre-operative air–bone gap and post-operative air–bone gap for all surgery.

Stapedotomy

The median follow-up for stapes surgery was 2 (interquartile range: 1.5–5) months. Four patients did not attend follow up. Transient dysequilibrium was seen in three cases. One patient developed dead ear at four months, and one patient developed partial facial paresis at two weeks following stapedotomy; this later resolved completely. No significant differences were noted between facial paresis, disequilibrium, dysgeusia and bleeding among the four types of middle-ear surgery, implying that no surgery is a greater risk for these complications (Table 3).

Audiometry outcomes

Audiometric data were analysed according to the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) guidelines,[17] with minor modifications for Australian practice conditions. Four-frequency average was calculated using 0.5, 1, 2 and 4 kHz (it is not routine to measure 3 kHz in Australia). The pre-operative air–bone gap (ABG) was calculated by subtracting the pre-operative bone conduction from pre-operative air conduction thresholds. The post-operative ABG was calculated by subtracting the post-operative bone conduction from post-operative air conduction thresholds. The pre- and post-operative ABG were then placed in 10 dB bins for comparison. Audiometric analysis was completed for 169 (62 per cent) patients because complete audiometric data could only be retrieved for these cases.

The median pre-operative ABG for all middle-ear surgery was 25 dB (interquartile range: 15–35) compared with 15 dB (interquartile range: 10–30) for post-operative ABG ($p < 0.001$). The median pre-operative ABG for tympanoplasty

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Table 4. Comparison with audits on middle-ear surgery

Parameter	Westmead Hospitals, Australia (this study)	Mastoidectomy: NHS, UK[2] (1995)	Stapedotomy: Common Otology Database[23] (2009)	Tympanoplasty: Western Australia audit[8] (2018)
Primary surgery (*n*)	45/67	466/611		
Revision surgery (*n*)	21/67	101/611		
Follow up (months)	Median (IQR): 11.75 (5.25–17)	3–15		
Dry ear (%)	77	60.4 (open cavity); 67.3 (closed cavity)		
Recurrence (%)	6	Not mentioned		
Facial paralysis	None (transient paresis in 2 cases)	0.8% (3, open cavity)		
Dead ear	None	1.9% (7, open cavity)		
Comparison of outcome following stapedotomy				
– Total ears (*n*)	62		660	
– Follow up (IQR; months)	2 (1.5–5)		3 months	
– Post-operative ABG <10 dB (%)	60.30		63.60	
– Post-operative ABG <20 dB (%)	82.70		92.60	
– Vertigo	Transient		1.40	
– Facial palsy	None		0.20	
– Tinnitus	None		2	
– Wound infection	None		0.20	
– Dead ear	1.61%		None	
Comparison of outcome following tympanoplasty				
– Total ears (*n*)	136			419
– Approach	100% endaural			51% transcanal; 25% endaural
– Graft material	– Composite gelfoam fascia			47% temporalis fascia
	– Fat plug			20% cartilage
– Follow up (%)	58			21.50
– Tympanic membrane closure (%)	86.90			39

was 25 dB (interquartile range: 15–35) compared with 15 dB (interquartile range: 10–30) for post-operative ABG ($p < 0.001$). The median pre-operative ABG for stapedotomy was 30 dB (interquartile range: 20–40) compared with 10 dB (interquartile range: 5–20) for post-operative ABG ($p < 0.001$). The median pre-operative ABG for mastoidectomy was 30 dB (interquartile range: 20–40) compared with 30 dB (interquartile range: 25–40) for post-operative ABG ($p = 0.279$). Hearing was significantly improved following tympanoplasty and stapedotomy. In contrast, there was no significant change (improvement or worsening) in hearing following mastoidectomy (Figure 2). Variable outcomes in hearing improvement following mastoidectomy are mentioned in the current literature. Some authors (e.g. Goyal *et al.*[18] and Lavana *et al.*[19]) report improvement in hearing, whereas others (Lucidi *et al.*,[20] Azevedo *et al.*[21] and Islam *et al.*[22]) mention no improvement following mastoidectomy. Many centres, especially in the developing world where follow up is an issue, tend to perform disease removal and hearing reconstruction in a single-stage procedure, whereas in our centre ossiculoplasty is performed as a staged procedure after the mastoid cavity has become stable, usually after 12 months. This practice preference helps explain the variation between those centres reporting hearing improvement following mastoidectomy and ours where the hearing was unchanged.

Air–bone gap was calculated and placed in bins of 10 dB as per the guidelines of the AAO-HNS. Post-operative ABG closure to less than 10 dB occurred in 46.6 per cent of tympanoplasty cases and 60 per cent of stapedotomy cases. Closure of the ABG to less than 20 dB occurred in 73.3 per cent and 82.7 per cent of tympanoplasty and stapedotomy cases, respectively. However, ABG closure to less than 20 dB was seen only in 24.3 per cent of mastoidectomy cases (Table 3). Lack of compliance with the guidelines set forth by the AAO-HNS for reporting hearing makes comparison difficult.

Comparison of our single-centre results were made with multicentre surgical audits on middle-ear surgery published

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by the UK National Health Service (NHS),[2] Common Otology Database[23] and the Tympanoplasty Audit in Western Australia[8] (Table 4). Although the rates of non-discharging ears following mastoidectomy are comparable with the NHS audit, the rates of facial paralysis and dead ear were 0.8 per cent and 1.9 per cent, respectively, in the NHS audit, whereas equivalent rates of complications were seen in our audit. Recurrence of cholesteatoma was seen in 6 per cent in our series, whereas the NHS audit did not mention recurrence.

We also compared our stapedotomy data with the Common Otology Database audit. The hearing outcomes in both audits were comparable. Post-operative ABG closure of 10 dB or less was seen in 60.3 per cent of cases in our series versus 63.6 per cent in Common Otology Database, and ABG closure of 20 dB or less was seen in 82.7 per cent of cases in our series versus 92.6 per cent in the Common Otology Database audit. In the Common Otology Database audit, vertigo was reported in 1.4 per cent of cases, persisting facial palsy in 0.2 per cent, persistent tinnitus in 2 per cent and wound infection in 0.2 per cent. There were two cases of disequilibrium and two cases of partial facial paresis, both of which recovered, in our audit. There was one case of dead ear (1.61 per cent) following stapedotomy at 4 months post-operatively. In an expanded analysis of stapedotomy outcomes, the dead ear rate was (0.5 per cent)[11] compared with the Common Otology database,[23] which reported 2.1 per cent. Significant post-operative sensorineural hearing loss occurred after stapedotomy.

Furthermore, we also compared the tympanoplasty outcomes with that of the tympanoplasty audit of Western Australia.[8] There was a variability in the approach, graft material and surgical technique in both the audits. Although the graft uptake in our audit was 86.9 per cent, the graft uptake rate in the Western Australia audit was 39 per cent. Similarly, hearing comparisons could not be made between the two audits because of the difference in reporting the hearing outcomes.

Discussion

Formal audits of surgical activity provide local data, which allows meaningful comparisons of outcomes with other regional series. Together, these monitoring activities provide an important quality improvement tool for individual surgeons, surgical units and hospitals. They also provide surgical teams with robust outcome data that is essential for counselling of prospective surgical candidates, thereby setting reasonable expectations as to the outcomes of surgical treatments.

The data gleaned from our middle-ear surgery audit shows outcomes consistent with benchmark data set by international audits. Complete graft uptake in tympanoplasty was seen in 86.9 per cent of cases in our study, compared with benchmark rates ranging from 83–88 per cent,[5,13–16] using similar temporalis fascia grafting techniques. The dry ear rate following canal wall down mastoidectomy for cholesteatoma is 77 per cent, superior to rates reported from the UK Royal College of Surgeons audit[2] (ranging from 60 per cent (open cavity) to 67 per cent (closed cavity)) and superior to the rates reported for endoscopic cholesteatoma surgery in the study by Diale *et al.*[24] Air–bone gap closure of less than 10 dB occurred in the majority of stapedotomy cases (60 per cent) and almost half of tympanoplasty cases (46.6 per cent). Air–bone gap closure of less than 20 dB occurred in higher proportions: for stapedotomy it was 82.7 per cent and for tympanoplasty it was 73 per cent. These results are generally consistent with those reported in the Common Otology Database.[23]

In contrast, the hearing outcomes following mastoidectomy were inferior to benchmark rates. Our series showed only modest improvements in hearing post-mastoidectomy, with only 24.3 per cent achieving an ABG closure of less than 20 dB (Table 3). This is likely to be because of our preferred practice to not reconstruct the ossicular chain at the time of primary surgery so as to optimise disease control rates and not compromise otoscopic examination of the tympanic membrane to detect early recurrence. This contrasts with other surgical preferences for primary ossiculoplasty, leading to potentially superior audiometric outcomes. Furthermore, as most patients had unilateral disease or disease in the worst hearing ear at 12–18 months (preferred timing for consideration of second look or ossicular chain reconstruction), many patients had habituated to unilateral hearing loss or elected to have hearing aids or bone-anchored hearing aids, and therefore the ossicular chain reconstruction numbers were low (9 of 56 (16 per cent)).

Surgical complication rates (dysgeusia, bleeding and vertigo) were generally lower than in published series. Major complications were also lower than benchmark rates, with a single post-stapedotomy dead ear (delayed sensorineural hearing loss at four months post-stapedotomy) compared with no reported dead ears in the Common Otology Database[23] and no permanent facial palsy cases following mastoidectomy (two transient delayed partial palsies with full recovery).

Audit limitations

Meaningful comparison of outcomes between different centres can be made using audited data. However, clinically available data is associated with limitations, which is evident in both our study and other published studies:

In terms of use of standardised outcome measures, although recommended reporting guidelines have been set by the AAO-HNS[17] compliance is variable. In a review of stapedotomy reporting, Watson *et al.*[11] found that although the majority of publications complied with the recommendations, a large minority failed to report to the required standards. In some cases, reporting criteria were not included in the publications, making meaningful comparisons impossible.

The nature of the audited cohort is also important. An inclusive series of cases is vital because the omission of cases with incomplete data or those failing to attend follow up are likely to reflect poorer outcomes, leading to upscaled results. This aspect of published audits is often ambiguous. The Common Otology Database, for example, accepts voluntary contributions from its members with no guarantee of case inclusions or exclusions.[1] We aimed to minimise these biases in our report by using a strictly inclusive consecutive series.

In addition, case numbers that are too small are also affected by the surgical learning curve, with generally more variable outcomes seen early in a surgeon's operating experience.[25] This is particularly notable in stapedotomy surgery.[26] Our dead ear rate is calculated on a case volume of 61 cases as 1.6 per cent, lower than reported by Rompaey *et al.*[23] However, when a larger case number (204 cases) was reviewed, inclusive of this audit period, the dead ear rate was lower at 0.5 per cent.[11]

The duration of follow up affects results such as disease recurrence rates (in particular tympanic membrane re-perforations and cholesteatoma recurrences). We had a

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high follow up in our study (95 per cent), with reasonably complete audiometric data (62 per cent); however, the duration of follow up was generally shorter than desired (median, 12 months for mastoidectomy). As a consequence, it is likely that our true recurrence rates for perforation and cholesteatoma are higher than we have detected through our audit protocol. Low follow-up rates affect the usefulness of audit data; for instance, patients with presumably satisfactory and stable outcomes may fail to return. The median follow up for tympanoplasty was 2.5 months. Although this may seem a short duration compared with other studies, it is our practice to follow up tympanoplasty cases until the graft is stable and hearing gains are documented by audiometry, rather than for a defined time. Generally, a stable outcome or early graft failure is found during this period (8–12 weeks). Patients were not formally followed up for longer periods to detect late graft failure that may occur months to years after the initial graft take was achieved and recorded. Audits of remote populations have generally low follow-up rates. Soumya *et al.*,[8] in their myringoplasty audit on indigenous Australians, indicated a low 21.5 per cent complete follow-up rate. Rompaey *et al.*,[23] in a stapedotomy audit, reported a high rate of 92 per cent follow up at 3 months, but only a quarter of patients (25.3 per cent) attended follow-up reviews 1 year later. Tympanic membrane reperforation, incus necrosis in stapes surgery and cholesteatoma recurrence are all likely to be under-reported in most audits.

- There are only a few published comprehensive audits on surgical treatment of middle-ear disease
- This audit showed that current middle-ear surgical procedures are effective in controlling symptoms of chronic ear disease
- Medical co-morbidities do not have a bearing on graft uptake and cavity healing in tympanoplasty and mastoidectomy surgery
- Methodological hurdles in maintaining complete datasets and follow-up durations limit the usefulness of some clinical audits

There is evidence that middle-ear surgery outcomes are operator dependant, making grouping of audit data from multiple surgeons and/or institutions problematic.[25,27] Multiple operators at different stages of their training pathway were involved in our series; however, the cases were managed under a single consultant with a common treatment approach for all cases. Therefore, the similarity in findings in this audit and the larger published audits suggest that outcomes are consistent with broader international experiences and are generalisable to traditionally used surgical techniques for CSOM and stapedotomy by multiple surgeons, institutions and countries.

Competing interests. None declared

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