Graft take-rates after tympanoplasty. Results from a prospective ear surgery database.

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ABSTRACT

Objective: To present a prospective ear surgery database and investigate the graft take-rate and prognostic factors for graft take-rate in tympanoplasty using the database.

Study Design: Prospective database study.

Setting: Tertiary referral center.

Patients: 1606 cases undergoing tympanoplasty type I-IV were registered in the database in the period from February 2004 to November 2013.

Intervention: 837 cases underwent myringoplasty/tympanoplasty type I.

Main Outcome Measure: Graft take-rate and prognostic factors (age, discharge at time of surgery, tuba function, technique, graft material and revision surgery) for tympanoplasty type I were studied. A comparison with the graft take-rates for tympanoplasty type II-IV and/or cholesteatoma were made.

Results: A user-friendly ear surgery database with fast data entry and direct import of audiometric data was developed. The graft take-rate was found to be 93.0 % at 2-6 months and 86.6 % at >12 months. Except for a discharging ear at the time of the surgery no significant differences using chi-square test of association were found when comparing graft take-rates for different prognostic factors or more advanced tympanoplasty with or without cholesteatoma. A long-term graft take-rate overestimation of 6 % was found if cases with defaulted follow-up due to early re-perforation were not included.

Conclusion: A prospective database can be used to study prognostic factors and reduce bias in reporting the graft take-rate. Prospective databases are needed for high-quality longitudinal studies but require a continuous and daily effort of involved surgeons and therefore need to be convenient and fast to use.

Key-words: tympanoplasty, graft take-rate, database, prognostic factors, bias

INTRODUCTION

Middle ear surgery is often performed on an empiric background with clinical decisions being based on expert opinion and clinical experience. There are two main reasons for this: First and foremost there is a lack of a standardized classification in reporting and evaluating surgical outcome in middle ear surgery which leads to difficulty in translating reported results from individual clinical outcomes in a set population to evidence based clinical practice. Secondly much research in the field has been retrospective and is thereby limited by study design and study size. The retrospective methodology can potentially lead to issues of data quality and bias especially in reporting long-term outcomes. In 2005 Yung called for a systematic review or meta-analysis of tympanoplasty [1], which has yet to appear.

The prospective and consecutive collection of surgeon-registered data on disease, surgical approach and interventions and outcome holds several benefits and can help shed light on the incidence of rare surgical outcomes and association between disease and prognostic factors.

To provide a stronger evidence-base several standardized, prospective ear surgery databases have been suggested and are used at some institutions: The web-based Common Otology Audit Database [1], the standardized Korean ear surgery database [2], The OtoData database [3] and the Otology-Neurotology Database [4]. Several prospective studies from these databases have been reported.

One of the major limiting factors for the use and implementation of such databases is the associated and continuous workload and time spent on data recording, processing and reporting. Yung et al. reported for example that only 57% of 14 invited otologists were able to maintain a continuous data input for more than 6 months to the international Common Otology Audit Database [5]. The feasibility of a prospective database is very dependent on convenience, ease of use and fast data entry. In this paper we introduce a user-friendly database for middle ear surgery, which supports minimal manual data entry due to direct import of audiograms. The graft take-rate and prognostic factors for graft take will be investigated as an example of a surgical outcome measure in tympanoplasty, which without prospective data-entry, rigorous data control and a high quality of the data could be severely biased.

MATERIAL AND METHODS

Database

The OtoKir database was developed by the senior author MSS using Access® 2000 (Microsoft, Redmond, WA/USA) and is currently used at several ENT departments in Denmark and made freely available for download [6]. The database was developed in an iterative process of feedback

and revision by in-house surgeons towards the present format and extent. Participation is voluntary and all but two senior surgeons chose to contribute to the database both during development and later but none have used the database and later withdrawn. From the original middle ear surgery database separate specific databases have been developed for the registration of stapes surgery and implantation of bone-anchored hearing aids.

When the database is opened the main menu is displayed which provides access to the four data entry points as well as cumulative lists and results which includes for example take-rates (for a detailed overview see figures, Supplemental Digital Content 1).

The first data entry is the "New patient - pre-/per-operative data", which is completed at the end of the surgery. The patient is selected using the patient ID as identifier and the local AuditBase4® (AuditData, Taastrup/Denmark) server is then automatically called by an SQL routine. The preoperative audiogram can be selected from a dropdown list and the audiometric data is then automatically imported upon selection. The surgeon enters the preoperative diagnosis (figure 1), specifies the indications for surgery, the Eustachian tube function, and selected operative findings and procedures (white fields). The data entry only takes 1-2 minutes to complete.

At post-operative follow-ups (at 2-6 months and at >12 months) the patient ID is entered and most data is automatically retrieved. The post-operative audiogram is chosen and imported. The measured and calculated audiometric data reflect the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) guidelines for the evaluation of treatment results for conductive hearing loss [7]. The surgeon then fills out data concerning postoperative infection, deafness caused by surgery and status of the tympanic membrane (figure 2). A change of the function of the chorda tympani and facial nerve and the presence of dizziness and tinnitus compared to the pre-operative condition is also stated. The entry of follow-up data can be done in seconds.

If the follow-up is not completed or is interrupted prematurely this is registered in the "Follow-up interrupted between 2-6 months and 12 months" entry form. Patient specific surgical data are automatically imported after entering the patient ID and only the date for interruption of follow-up/new operation and the reason for the premature interruption need to be entered. If the reason is "state of drum" then the "drum status" box appears and the recorded reason for interruption e.g. perforation is saved with the >12 month results as "follow-up interrupted by perforation".

Case selection

Data from the OtoKir Database from the period February 2004 to November 2013 were extracted. Six ear surgeons of different levels of experience at our department contributed to the database.

For the primary analyses on prognostic factors of graft take-rate only myringoplasty/tympanoplasty type I cases were included and cases of cholesteatoma either suspected pre-operatively or found per-operatively were excluded. In order to study prognostic factors for these cases data on date of surgery, pre-operative tuba function, age at time of surgery, discharge at time of surgery, grafting technique (underlay/interlay) grafting material (fascia or perichondrium ±cartilage) and surgery number (to identify revision surgery) was retrieved. The graft take-rate was also investigated for the excluded cases with cholesteatoma and cases of tympanoplasty type II-IV for comparison. Data on drum status at follow-up at 2-6 months and >12 months as well as data on interruption of follow-up were retrieved for all cases in order to calculate the graft take-rate.

The collected data were analyzed using chi-square test of association with Fishers exact probability test to calculate significance using the two-tailed p-value. 95 % confidence intervals (CI) for the graft take-rate were calculated using the Newcombe method for CI of proportions with correction for continuity [8]. $p<0.05$ was considered statistically significant.

RESULTS

A total of 1606 cases were found in the database including cholesteatoma and revision cases. 49 % of all cases were female and the mean age was 33 years. There were 837 cases of myringoplasty/tympanoplasty type I without cholesteatoma which were included in the study of prognostic factors. The remaining cases were 532 cases of tympanoplasty type II-IV with and without cholesteatoma and 416 cases with cholesteatoma and any type of tympanoplasty (179 cases were thereby represented in both groups).

The patient flow matrix for myringoplasty/tympanoplasty type I is presented in table I. There was missing data due to no show for 210 cases (25.1 %) at the 2-6 months follow-up and 418 cases (49.9 %) at the >12 month follow-up. Loss to follow-up was corrected by excluding cases that had not yet reached the time for follow-up: 43 cases at the 3-6 month follow-up and 125 cases at the >12 month follow-up (cut-off set at 15 months) and the true loss to follow-up was found to be 20.0 % and 35.0 %, respectively.

The graft take-rates at 2-6 months and >12 months are shown in table II. For many of the prognostic factors a significant difference in graft take-rates were found between the graft take-rate at 2-6 months and at >12 months, with a decline in the average long-term graft take-rate of about 6 % compared to the short-term result.

Except for a discharging ear at the time of the surgery, which resulted in a significantly lower short-term graft take-rate, no significance was found when comparing graft take-rates for different

prognostic factors. More complicated cases with cholesteatoma and/or tympanoplasty II-IV had a similar graft take-rate to that of myringoplasty/tympanoplasty type I.

A lower long-term graft take-rate for revision cases (80.8 %) was found compared to primary surgery (87.9 %). Likewise a lower graft take-rate was found for patients with Eustachian tube problems i.e. negative Valsalva (81.7 %) compared to patients with positive Valsalva (88.2 %). Neither of these lower graft take-rates were found to be statistically significant.

Table III presents different graft take-rate calculations. A graft take-rate overestimation of 6.0 % is found when only including cases attending the >12 month follow-up (92.6 %). The long-term graft take-rate should include the cases where follow-up is defaulted due to perforation/graft non-take leading to a true graft take-rate of 86.6 %. Dual sensitivity analysis with patients lost to follow-up counted as all having either an intact drum or all having a perforation gives a best estimate graft take-rate of 92.7 % and a worst estimate graft take-rate of 47.2 % respectively.

DISCUSSION

With this study we introduce a user-friendly ear surgery database with fast data entry and direct import of audiometric data. The participating surgeons all express great satisfaction with the database and its ease of use, which is also reflected in the extent and the quality of the data they contribute. They find the database feasible even with busy clinical schedules, as the user-interface is straightforward with few data entry points and ease of automated import of audiograms.

While the single entry procedure for pre-operative as well as post-operative surgical data offers both convenience and data entered directly by the surgeon it introduces a potential bias, where some cases might never be entered into the database first place. A two-step procedure with data on all scheduled patients entered prior to surgery (by for example non-surgical staff) could minimize such a selection bias but at the likely cost of some loss of data quality.

The graft take-rate in tympanoplasty varies considerably in the reported literature ranging from 60-99 % in adults and 35-94 % in children [9]. Most reports on myringoplasty take-rates have a retrospective study design and selection bias could lead to overestimation of the graft take-rate. A small number of included cases compared to the expected caseload at the reporting institutions could be a sign of other unrecognized bias and only studies with a consecutive, prospective study design can provide the needed reliable results on outcome in ear surgery. Several prospective studies on graft take-rate have been published and most report long-term (>12 months) follow-up. The graft take-rates vary from 82 % to 94 % [10-13] and is thereby comparable to the graft take-rate found in this study.

Several prognostic factors have been suggested in the literature [14] but are mostly based on retrospective studies with a small study size. In this study the graft take-rates for some of the potential prognostic factors were studied and no significant difference between the graft take-rates at 2-6 or >12 months was found for any of the potential prognostic factors except discharge at the time of surgery. A discharging ear (purulent/serous/mucous) significantly lowered the short-term graft take-rate but the long-term result was equal to the long-term result for non-discharging ears. A retrospective study by Mills et al [15] on 268 cases found equal graft-take rates of 83 % and 82 % respectively at 6 months when comparing active and inactive ears in line with our long-term finding.

Albera et al have studied a prospective cohort of 212 patients undergoing myringoplasty [12]. In line with our findings they also report that age and presence of otorrhea and status of the contralateral ear did not affect long-term outcome while time from surgery did. However they found that surgical technique as well as graft material had a significant impact on graft take-rate, which we do not.

The long-term graft take-rate was for several prognostic factors and in general for myringoplasty/tympanoplasty type I found to be significantly lower than short-term results. On average a 6 % lower long-term graft take-rate was found. Kotecha et al also report a 6.7 % long-term decline in graft take in their large prospective study [10].

In the present study the loss to follow-up at 2-6 months (20.0 %) and >12 months (35.0 %) is much higher than found in the other prospective studies. The missing data and loss to follow-up in our database can in large part be explained by patients not scheduling follow-ups, not showing up or having follow-ups scheduled with local ENT-specialists (for example patients from Greenland or the Faroe Islands). A sample of more than 200 chart reviews were performed and showed only minimal missing data due to lack of data entry by the contributing surgeons. A possible explanation for patients not showing up for follow-up could be that they are satisfied with the results and find that the follow-up is unnecessary also considering the distance for many patients to our center. We have no reason to believe that the outcome of the “no show” patients is largely different from patients attending follow-up.

The long-term graft take-rate is dependent on the data used for the calculation and selection bias can easily occur if a prospective approach is not applied including the registration of reason for interruption of follow-up. In many cases a patient presenting at the 2-6 month follow-up with a drum perforation will be offered revision surgery, which will interrupt the primary follow-up schedule. In this study we have included cases with early revisions due to re-perforation and graft non-take at the 2-6 month follow-up. The true graft take-rate needs to take this into account and the

risk of graft take overestimation in retrospective series is easy to understand. Some prospective studies however also report no loss to follow-up [10, 11, 13, 15, 16].

CONCLUSION

We used a prospective database to study prognostic factors for the graft take-rate and find the true graft take-rates, which could be biased without inclusion of cases where follow-up was interrupted due to re-perforation.

Prospective and standardized ear surgery databases and a continuous effort of involved surgeons to enter high-quality data on a daily basis is needed for longitudinal studies that can provide quality control, evidence base and answers to key research questions in otology. These databases need to be feasible in a busy clinical schedule; they need to be user-friendly, convenient and fast to use and the integration of a direct import function of audiometric data reduces the need for manual data-entry by the surgeon.

In Denmark, the Danish Society of Ear Surgeons will use the presented database as a backbone for the implementation of a future national ear surgery database so that data can be exchanged across institutions thereby making it possible to compare local results to a national average and conduct larger prospective studies. The presented database has been made available for download [6].

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Table I: Patient flow matrix for myringoplasty/tympanoplasty type I

		Status at 2-6 months follow-up				
		Perforation	Drum intact	No data on drum	No show/time for follow-up not reached	Total
Status at >12 months follow-up	Follow-up cancelled due to perforation	14	9	2	0	25
	Perforation	8	16	1	2	27
	Drum intact	3	313	8	12	336
	Follow-up cancelled for other reason	1	27	1	2	31
	No show/time for follow-up not reached	17	203	4	194	418
	Total	43	568	16	210	837

Table II: Graft take-rates

	2-6 months follow-up	>12 months follow-up	Significance of difference in graft take-rates between follow-ups
Myringoplasty/type I tympanoplasty	93.0 %	86.6 %	p<0.001
Tympanoplasty type II/III/IV	94.8 %	90.8 %	ns
Cholesteatoma	94.8 %	91.4 %	ns
*Age**			
<16 years	94.2 %	87.9 %	p=0.01
>16 years	92.3 %	85.8 %	p=0.04
Status on time of surgery, †*			
Dry	94.4 %	86.3 %	p<0.001
Discharge (purulent/mucous/serous)	84.8 %	88.1 %	ns
*Tuba function**			
Valsalva positive	94.2 %	88.2 %	p=0.02
Valsalva negative	93.3 %	81.7 %	p=0.02
*Technique**			
Underlay	93.0 %	85.9 %	p=0.001
Interlay	92.9 %	88.9 %	ns
*Material**			
Perichondrium ±cartilage	93.3 %	87.0 %	p=0.002
Fascia	90.7 %	88.2 %	ns
*Revision surgery**			
First surgery	92.6 %	87.9 %	p=0.004
Revision surgery	94.5 %	80.8 %	p=0.03

*Only myringoplasty/tympanoplasty type I data included

† Significant difference between groups at 2-6 months follow-up, p=0.002

Table III: Graft take rates for myringoplasty/tympanoplasty type I

Period of follow-up	**Cases at follow-up**	**Intact drum**	**Perforations**	**Graft take-rate with 95 % CI**
2-6 months	611	568	43	**93.0 %[91.1-94.8]**
>12 months (true)*	388	336	52	**86.6 %[82.7-89.8]**
>12 months (only cases attending follow-up)	363	336	27	92.6 % [89.2-95.0]
>12 months (best estimate)†	712¶	660	52	92.7 % [90.5-94.5]
>12 months (worst estimate)§	712¶	336	376	47.2 % [43.5-50.9]

* Including the 25 cases with follow-up interrupted before 12 months due to re-perforation.

† All cases lost counted as *intact drum*.

§ All cases lost counted as *perforations*.

¶ Expected cases at >12 months: 418 cases of no show/time for follow-up not reached - 125 cases where time for follow-up was not yet reached + 31 cases with follow-up interrupted for other reasons.

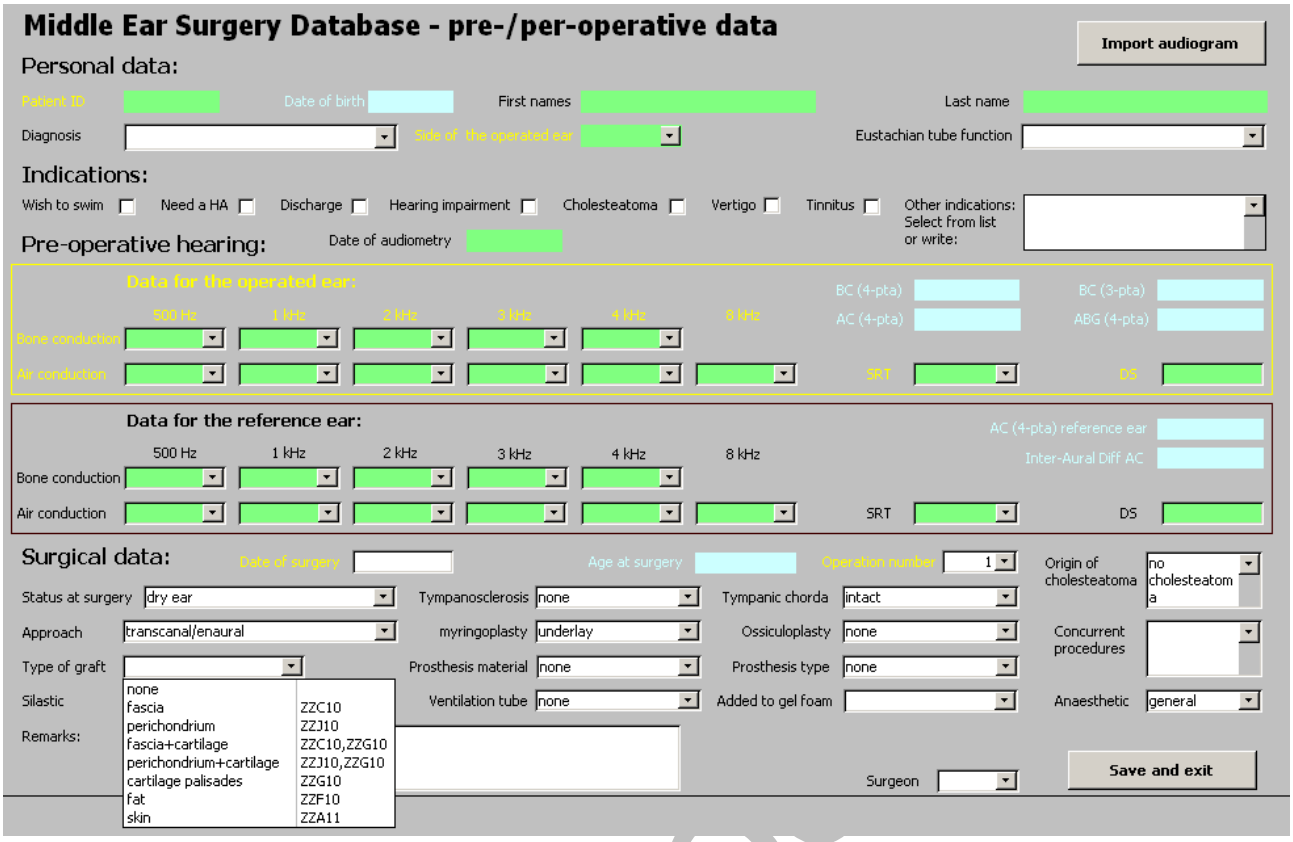

Figure 1: The "New patient - pre-/per-operative data" screen. The green fields are automatically imported, the blue fields are calculated by the database and the surgeon enters data in the white fields.

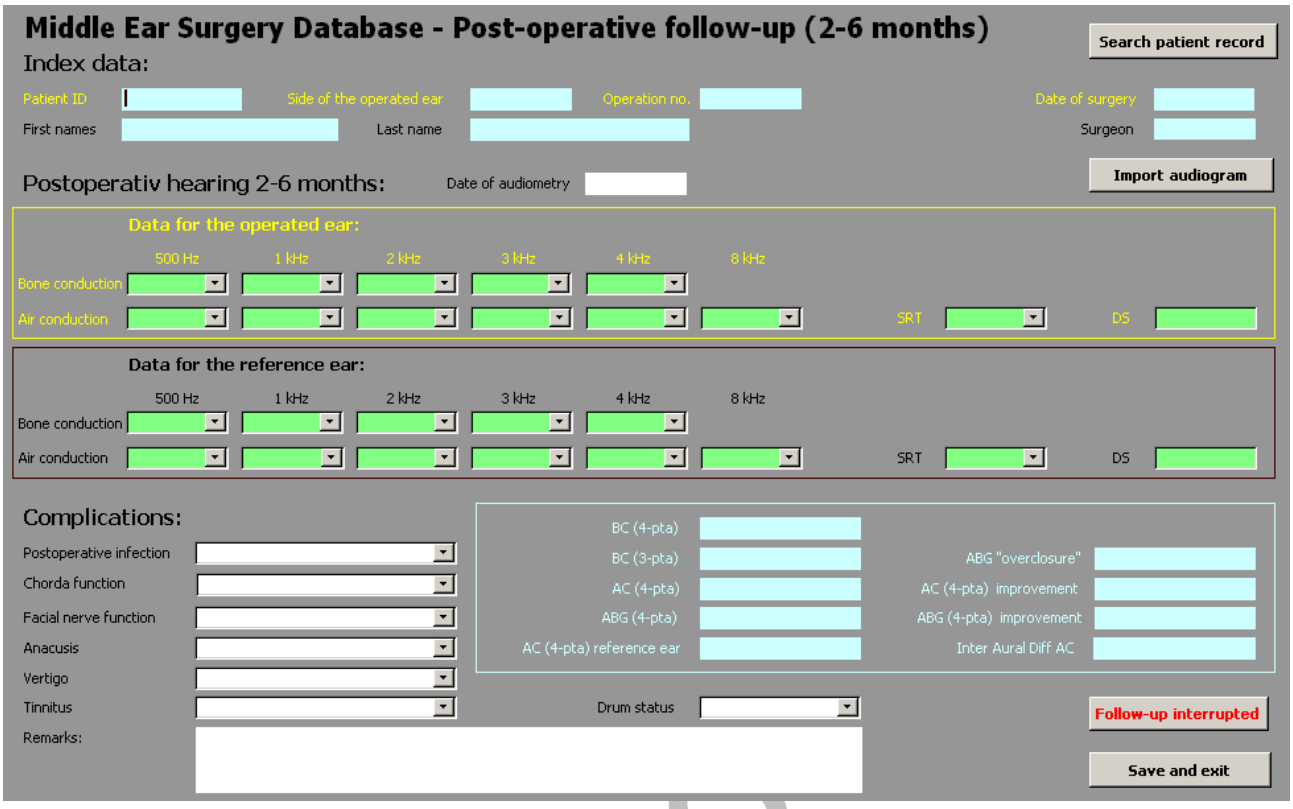

Figure 2: The "Post-operative follow-up results" screen.

LIST OF SUPPLEMENTAL DIGITAL CONTENT

Supplemental Digital Content 1. Additional screenshots from the OpenOtokir database. pdf.