Core outcome set for reporting Results of cholesteatoma surgery

International Otology Outcome Group consensus study

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Background

A wide range of surgical approaches is currently advocated for cholesteatoma treatment ranging from minimally invasive trans-canal endoscopic surgery, through closed and open mastoidectomy procedures to mastoid obliteration and blind sac closure. In addition to meeting the traditional objective of providing a "safe dry ear", all aim to eradicate cholesteatoma while trying to conserve or improve hearing function. Assessment of the relative effectiveness of these interventions is hampered by the lack of consistent reporting measures, as clearly demonstrated by systematic reviews of the quality of outcome reporting in surgery for cholesteatoma and conductive hearing loss [1,2]. These studies and others reveal the need for a standardized core outcome set relevant to cholesteatoma surgery [3].

When reporting on the success of cholesteatoma eradication, international consensus has documented the necessity of distinguishing between residual disease (that which has continued to grow inside the ear following incomplete removal) and recurrent disease (that which forms from a new retraction pocket) [4]. The importance of recognising the relative contribution of different surgical approaches to the different mechanism causing residual and recurrent cholesteatoma recidivism has been recognised since the 1960s [5]. However, a systematic review in 2016 of over 2060 publications comparing canal wall up and canal wall down surgery for cholesteatoma in adults included only three that distinguished residual from recurrence [6], of which only one incorporated Kaplan Meier survival analysis [7]. Because the risk of a retraction pocket developing into cholesteatoma increases with time since surgery, it is necessary to perform a survival analysis to account for those that have not been followed for long enough to develop recurrence [8]. While Kaplan-Meier survival curves provide a well-accepted and expected standard for reporting cancer treatment outcome, they have been used infrequently in cholesteatoma outcome reporting [1].

Reporting of hearing outcomes following cholesteatoma surgery has also been found to be of inconsistent quality, for example with failure to specify timing of hearing testing or to provide comparison of pre- and post-operative thresholds [1]. Applicable guidelines for reporting outcome from surgery for conductive hearing loss have been developed by the Hearing Committee of the American Academy of Otolaryngology – Head and Neck Surgery [9,10]. These include use of standards such as 4-tone average thresholds and calculation of change in air bone gap. Systematic review of 169 tympanoplasty and ossiculoplasty studies published between 2005 to 2015 showed that only a minority complied with these standards [2].

In addition to removal of cholesteatoma and hearing outcome, Patient Reported Outcome Measures (PROM) provide an important determinant of the effectiveness of cholesteatoma surgery [11]. Examples of relevant outcomes include presence of ear discharge and frequency of

otolaryngology clinic visits [11]. Validated PROMs for chronic middle ear surgery have been developed that could be used appropriately in reporting surgical outcome though have not yet been implemented widely [12].

In response to evidence-based recommendations for defined publication standards in outcome reporting after cholesteatoma surgery [1,2], the steering committee of the International Otology Outcome Group worked toward a consensus document providing a core outcome set (COS) using Delphi methodology. This work is complementary to the recent Dutch ENT Society registration consensus document produced from national survey of otolaryngologists and cholesteatoma patients to determine optimal outcome standards [11]. This COS is intended to be used for research reporting outcomes from surgery for cholesteatoma in adults and children. It is anticipated that these guidelines, if used as publication standards, will improve the quality of evidence available to guide selection of optimal surgical approach for management of cholesteatoma.

Summary of methodology

Methodology is under development and is described in line with the recommendations of the Core Outcome Set-STAndards for Development and Reporting (COS-STAD and COS-STAR) group [13,14]. The project has been registered with the COMET initiative (https://www.comet-initiative.org/Studies/Details/2104).

Draft Core Outcome Set for research into outcomes from cholesteatoma surgery

Validated outcome measures are listed as Principle Standards for reporting outcomes from cholesteatoma surgery. Important outcomes and variables for which there is insufficient supporting evidence or consensus to define a reporting standard at this time are listed as Suggested standards.

Principle standards:

1. *Residual vs. Recurrent Disease:*
    a. Authors must distinguish between residual and recurrent disease using accepted definitions [4,11].
    b. When the difference cannot be distinguished, subsequent growth of cholesteatoma must be categorized as of "uncertain" origin and referred to as "recidivism" or "regrowth" rather than recurrent or residual.
2. *Survival analysis:*
    a. When reporting rates of recurrent cholesteatoma, it is imperative to include data regarding length of follow-up.
    b. It is imperative to account for censored data (i.e. patients who will develop recurrence, but have not been followed for long enough) [8].
    c. Kaplan Meier survival analysis should usually be used for this purpose (with log rank analysis to compare groups).
    d. The rate of recurrence at 5 years is the recommended reporting standard [11].
    e. Survival analysis can also be used to report rate of residual cholesteatoma (see below).
3. *Detection of residual cholesteatoma:*
    a. A minimum follow-up period of at least one year is required to allow time for detection of residual disease.
    b. When reporting the overall rate of residual disease, authors must describe the method used to detect residual disease (e.g. clinical follow up of a specified minimum duration, MRI, CT, second look surgery).
    c. The proportion of cases with disease must be reported for each method.
    d. When using imaging to screen for residual disease, the proportion of cases with uncertain results must be reported and counted as "censored" in survival analysis.
    e. Patients awaiting assessment (e.g. waiting for surgery or MRI) should be excluded or counted as "censored" in survival analysis.
4. *Audiometric Outcomes:*
    a. Reports should comply with established guidelines for reporting on surgery for conductive hearing loss [9].
    b. Report the proportion of ears with normal hearing pre and post operatively [15].
5. *Complications:* Erosive and suppurative complications of cholesteatoma and complications of surgery should be distinguished and reported separately [1,3].

Suggested standards:

1. *Cholesteatoma severity:*

Current understanding of outcomes from cholesteatoma surgery is severely hampered by the lack of an accepted standard for staging disease severity. The extent and type of cholesteatoma, and factors that influence hearing outcome should be documented.

   a. Data from children and adults should be reported separately as children appear to have a higher rate of recidivism (Figure 1) [16-19]. A validated age cut off has not been defined.
   b. Type of cholesteatoma should be recorded (congenital; acquired from pars flaccida retraction, pars tensa retraction, or both; secondary to perforation or trauma; uncertain [4]).

The collection of data which are compatible with the following classifications is to be encouraged in order to facilitate future collaborative research and development of validated internationally accepted standards [20] (e.g. www.ioog.net/otologydataset).

   a. Classification systems for cholesteatoma extent including:
      i. the EAONO-JOS staging system [4], developed from the JOS staging system [21]
      ii. the STAMCO modification of the EAONO-JOS classification [22],
      iii. the ChOLE staging system [23],
      iv. the Mills staging system [24]
      v. the Potsic staging system for congenital cholesteatoma [25].
   b. Classification systems relevant to hearing outcome [2] including:
      vi. Wullstein's classification [26]
      vii. Belucci classification [27]
      viii. Austin-Kartush classification [28]
      ix. Middle Ear Risk Index [29]
      x. Ossiculoplasty Outcome Parameter Staging Index [30]
      xi. SPITE [31]

2. *Surgical nomenclature:* Authors should use commonly accepted surgical nomenclature to overcome the misleading interpretation that can arise from use of different, overlapping, and conflicting traditional surgical terminologies that are used around the world (e.g. SAMEO-ATO nomenclature from IOOG [32]).
3. *Patient Reported Outcome Measures (PROMs):* The use of PROMs and quality of life assessments is strongly recommended [12]. Examples of disease-specific PROMS that have been validated in several different languages include:
      i. CES [33] ,
      ii. COMQ-12 [34],
      iii. ZCMEI-21 [35].

   Use of ear-domain specific PROMS (e.g. OQUA[36] or COQOL[37]) and more generic quality of life measures (e.g. Glasgow Benefit Inventory [38]) can also be considered.
4. *Audiometric Outcomes:* Consideration should be given to:
   a. Using the Amsterdam plot of postoperative gain in air conduction plotted against preoperative air bone gap [39]

b. Providing additional data on post-operative air conduction thresholds, for example by
    i. plotting pre- versus post-operative air conduction threshold
    ii. providing a histogram in bins of 0-10 dB, 11-20 dB, 21-30 dB, and >30dB.
c. Reporting between 0.5 and 4kHz.
d. Reporting of other frequencies:
    i. 0.25kHz: as low frequencies are commonly improved by surgery for conductive hearing loss and a five tone average including 0.25kHz has been shown to correlate better with hearing disability than other averages [40].
    ii. 8kHz: as uncertainty exists as to whether worse post-operative thresholds are secondary to conductive or sensory impairment [41].
e. Investigation of scattergram plot (clustered frequency distribution of patient numbers by audiometric threshold and word recognition score [10]) may help assess its utility in conductive hearing loss.

Discussion

A core outcome set (COS) designed for use in research investigating the results of surgery for cholesteatoma in adults and children is presented. The requirement for a standardised set of outcome measures for cholesteatoma reporting has been emphasised in systematic reviews, which emphasise a lack of consistency in published literature on this topic [1,2]. The lack of a standardized COS hinders meaningful comparison of outcomes from evaluation of different techniques between publications and completion of meta-analysis. Development and reporting of this COS follows the thoroughly researched methodology recommended by the COS-STAR group [13,14]. The views of patients and otolaryngologists regarding clinically important outcomes are incorporated by reference to previous publication [11]. Formulation of the COS was completed by otologists in academic practice and approved by consensus of the IOOG membership and wider otological community through consultation with society boards. Previously published definitions and guidelines were incorporated where available, giving emphasis to those that were developed with consensus protocols [4,9-11]. Consistent with clinically important outcomes, the COS focuses on measures that describe the success of eradication of cholesteatoma and hearing status [11].

Eradication of cholesteatoma

A distinction must be made between residual and recurrent cholesteatoma using established definitions [4,5]. Residual cholesteatoma is disease that continues to grow in the middle ear or mastoid after incomplete surgical removal. The matrix of this disease is not in continuity with the squamous layer of the tympanic membrane or ear canal. It is typically cystic though may grow *en plaque* as a sheet of skin within the middle ear or mastoid. In contrast, recurrent disease is acquired from a new in growth or retraction from the surface of the tympanic membrane or ear canal so the matrix is in continuity with the skin lining the ear canal. When there is uncertainty as to which is which, either at the time of surgery or during retrospective chart review (when an accurate distinction may not have been made contemporaneously) authors should emphasize this uncertainty and describe the cholesteatoma as regrowth or recidivism. As residual disease may be hidden, methods used to detect residual disease should be described clearly [11]. The risk of recurrent cholesteatoma increases with time so, as is standard for reporting cancer treatment outcome, survival analysis (eg Kaplan-Meier) must be used. Recommendations for presentation of Kaplan-Meier plots have recently been published and include the suggestions that (1) confidence intervals should be plotted around each curve and (2) a table below the plot should show the numbers at risk, censored and having experienced an event at different timepoints [42]. An example is shown in Figure 1 which plots rate of recurrent cholesteatoma with time for adults and children. Other appropriate methods for survival analysis include Cox's proportional hazards (to evaluate the effect of continuous variables such as age), and competing risks analysis (when other events may prevent development of recurrence, e.g. as would occur when a patient dies from other causes) [43]. Adequate follow up is required to allow detection of recidivism which should be a minimum of one year for residual and ideally five years for recurrent cholesteatoma.

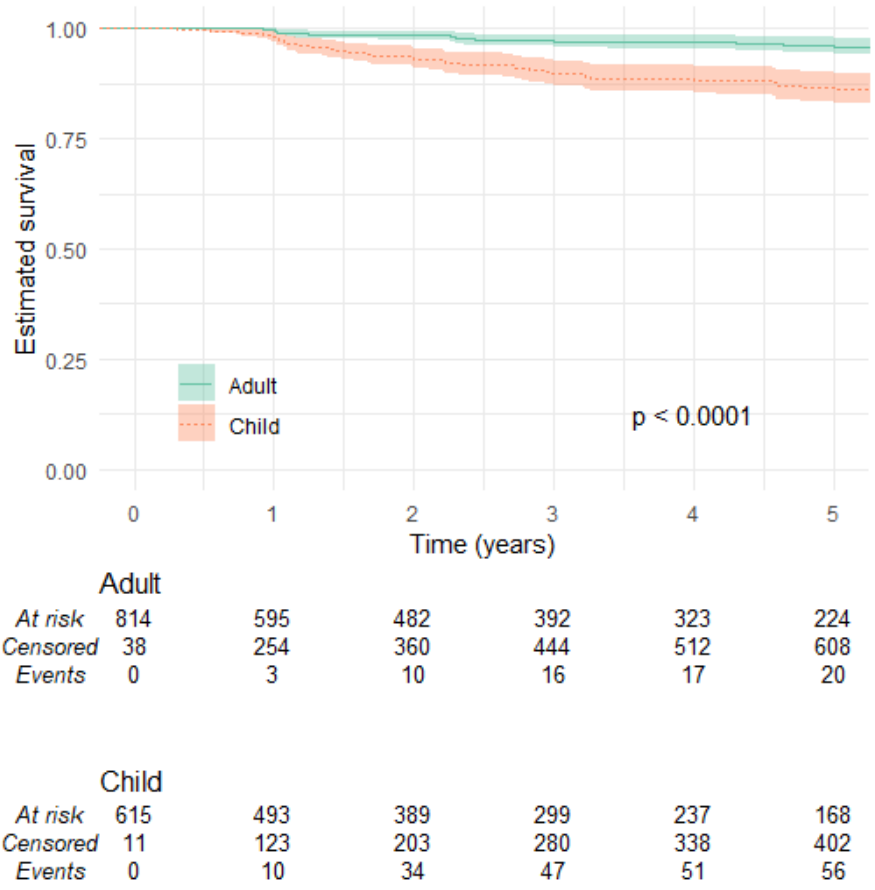

Figure 1: Kaplan-Meier plot showing time to development of recurrent cholesteatoma for children (<18 years age) and adults. Modified from James et al [18] using R code from https://ellessenne.github.io/KMunicate-package/ in accordance with KMunicate recommendations [42]. Rate of recurrence at 5 years appears higher in children, though this analysis does not control for multiple confounding variables such as type of cholesteatoma and surgery for which Cox's proportional hazards could be utilized.

Recognising that the risk of recidivism appears to correlate with severity of disease at presentation, an evidence-based validated staging system is required to categorize cholesteatoma extent in a standardized manner [1,16,18]. Dichotomising patients into paediatric and adult cohorts would also appear to be appropriate as children are commonly found to have greater risks of residual and recurrent disease [16-19]. Many staging systems have been proposed, including several in the past that have not succeeded in gaining widespread acceptance [24] though a staging system by Potsic is commonly used for congenital cholesteatoma [25]. More recently the EAONO-JOS staging system has been developed and supported by international consensus [4]. Modification to include ossicular status has been recommended, as used in the

original JOS staging system [22]. However a clear correlation between stage and residual or recurrent outcome has not been convincingly shown [1,16-18]. Prospective recording of data on cholesteatoma extent and severity that includes items used in published staging systems is recommended in order to develop a reliable dataset for identification of factors that predict outcome and evidence-based development of an improved staging system [1,16,18,20]. An inevitable limitation of published literature on this topic is that different interventions are typically used for cholesteatomas of different severity. To allow comparisons between different interventions that might be used in different centers for similar cholesteatomas, clearly defined criteria for assessment of disease severity and nomenclature of surgery are required in addition to use of a standardized COS. The SAMEO-ATO system provides consensus-approved, validated nomenclature for this purpose [32].

Hearing status

Standards for reporting outcomes from surgery for conductive hearing loss were published in 1995 including recommendations for use of air and bone conduction thresholds, air bone gap and observation intervals [9]. Although limitations of these guidelines are recognised [44] and their use has been very inconsistent [2], they still provide a basic reporting standard [2]. However, the emphasis on improvement of ABG after surgery under-represents the beneficial outcome of ears with hearing that remains good or normal pre- and post-operatively. Evaluation of the proportion of ears achieving normal hearing (e.g. <20dB HL) provides a more widely applicable, patient focused outcome [15]. Other strategies for reporting hearing outcome are suggested in the COS pending evidence-based evaluation and consensus approval. These should include patient reported measures of their hearing quality of life [12,35,45]. The more recent recommendation to use scattergram plots (of clustered frequency distribution of patient numbers by audiometric threshold and word recognition score) in reporting outcomes from surgery for hearing loss was accepted as a publishing standard by some journals [10,46-49] but it is not used universally [2]. It was not developed with international consensus and does not yet appear to have been validated as being of value in evaluating outcomes from surgery for conductive hearing loss so was not included as a principle standard in this COS.

Many factors have been shown to influence the success of surgery for hearing rehabilitation [26-31]. Just as cholesteatoma extent should be recorded when reporting recidivism as a measure of disease severity, predictive factors such as the status of the ossicular chain and middle ear mucosa should be included in data collection, analysis and reporting [2]. Clarity is required when recording data on whether an ossicle is normal, functionally intact (partial incomplete erosion), not functionally intact, or not inspected.

Patient Reported Outcome Measures

Inclusion of validated PROMs is necessary to provide information about the outcomes most meaningful to patients [50]. The use of disease-specific PROMs such as CES [33], COMQ-12 [34] or ZCMEI-21 [35] ensures that in addition to concerns about clearance of cholesteatoma and hearing [11], patients' experience of outcomes such as otorrhoea, pain, balance, tinnitus, activity restriction, number of

related clinic visits, and mood are reported. Also ear-domain specific PROMS, which can be value to evaluate all otologic diseases and procedures, can be considered. Two domain-specific PROMS are available OQUA[36] or COQOL[37].

Additional outcome measures

Further to the outcomes described above, a variety of other measures can be considered in evaluation of surgery for cholesteatoma, as summarised in Supplementary material 3. While research into these outcomes is to be encouraged, they were not included in the COS because they were not listed as of primary clinical importance in stakeholder review [11], specific guidelines to describe how they should be reported were considered either unnecessary or were unavailable, or because they are not specific to the treatment of cholesteatoma. Examples of these outcomes include dysfunction of taste or periotic sensation, cosmesis (of scars and meatoplasty), duration of surgery or length of stay, and cost effectiveness.

Limitations and future directions

Incorporation of the views of relevant stakeholders is required in COS development. This study builds on the Dutch survey of opinions of patients and otolaryngologists on clinically important outcomes[11]. Based on other literature review, we consider it reasonable to generalise these findings internationally, but further research could evaluate whether these opinions are applicable to patients and practitioners in other health care jurisdictions. Our Delphi process canvassed the views of academic otologists with an interest in outcomes from cholesteatoma surgery and sought input from the boards of national otological societies. We chose not to broaden our survey to the wider otolaryngological community as our intention was to introduce new evidence-based standards for future research rather than to canvas opinion on existing standards which have already been shown to require enhancement [1-3]. The lack of availability of established widely-accepted criteria for staging cholesteatoma and parameters of relevance to hearing outcome also limits the content of this COS. Future versions of this COS are envisaged in which standardized criteria for describing cholesteatoma severity, surgical nomenclature, PROMs and additional measures of hearing outcome are defined based on evidence-based validated criteria. While revision within a 5 – 10 year timeframe would appear desirable, the merits of doing so will be dependent upon development of an evidence base or consensus on current controversies in the interim.

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