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Success rates in restoring hearing loss in patients with chronic otitis media

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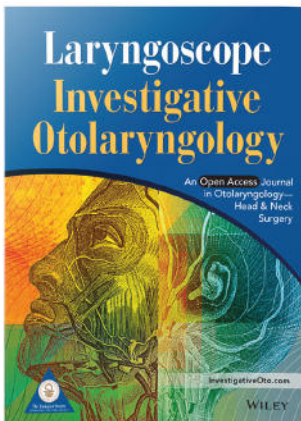


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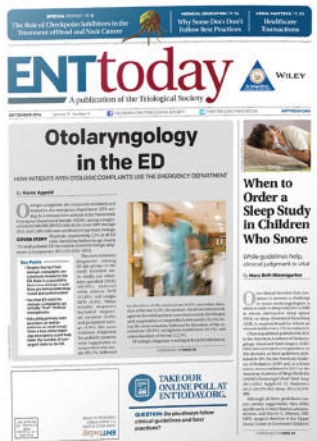


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REVIEW

Success rates in restoring hearing loss in patients with chronic otitis media: A systematic review

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Abstract

Objective: To assess the effectiveness of tympanoplasty in treating chronic otitis media-related hearing loss, published literature was systematically reviewed to determine the clinical success rate of tympanoplasty at restoring hearing in chronic otitis media patients at a minimum follow-up period of 12-months.

Data Sources: PubMed, Embase and the Cochrane Library.

Methods: Two independent reviewers performed literature searches. Publications reporting long-term (≥ 12 -month) hearing outcomes and complications data on adult and pediatric patients with chronic otitis media were included and assessed for risk of bias and strength of evidence. To assess how tympanoplasty influences long-term hearing outcomes, data on pure tone audiometry (air-bone gap) and complications were extracted and synthesized.

Results: Thirty-nine studies met the inclusion criteria. Data from 3162 patients indicated that 14.0% of patients encountered postoperative complications. In adult patients, mean weighted air-bone gap data show closure from 26.5 dB hearing level (HL) (preoperatively) to 16.1 dB HL (postoperatively). In studies that presented combined adult and pediatric data, the mean preoperative air-bone gap of 26.7 dB HL was closed to 15.4 dB HL. In 1370 patients with synthesizable data, 70.7% of patients had a postoperative air-bone gap < 20 dB HL at long-term follow-up. Finally, subgroup analysis identified that mean improvement in ABG closure for patients with and without cholesteatoma was 10.0 dB HL and 12.4 dB HL, respectively.

Conclusion: In patients with chronic otitis media, tympanoplasty successfully closed the air-bone gap to within 20 dB HL in 7/10 cases and had an overall complication rate of 14.0%.

Level of Evidence: 2a.

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KEYWORDS

cholesteatoma, chronic otitis media, hearing loss, tympanoplasty

1 | INTRODUCTION

This systematic review aims to draw conclusions regarding the effectiveness of tympanoplasties at hearing rehabilitation in patients with chronic otitis media (COM). COM is an enduring inflammation of the middle ear and mastoid cavity that is presented under several terms: chronic suppurative otitis media/chronic active mucosal otitis media, chronic oto-mastoiditis and chronic tympanomastoiditis. Patients may also have non-suppurative otitis media, cholesteatomas and additional suppurative complications. For the purpose of this review, patients primarily diagnosed with any sub-type of COM, with or without cholesteatoma, are included to provide a comprehensive overview of hearing rehabilitation. Country-specific prevalence rates of the disease range from 0.3% to 4.0%.¹ However, COM is more common in certain populations, such as in Australian Aboriginal and Torres Strait Islanders, where prevalence rates as high as 10.2% have been reported.¹ Untreated COM leads to progressive degradation of the middle ear cavity and its components, which causes conductive and mixed hearing losses. COM typically produces conductive hearing loss due to tympanic membrane perforation, reduced tympanic membrane mobility, effusion and/or ossicular discontinuity, but complications of the disease have also been linked to sensorineural hearing loss.² There are 164 million cases of hearing impairment attributed to COM worldwide.¹

Hearing impairment has a significant impact on affected individuals' health and development and is therefore important to treat.¹ For example, hearing impairment at childhood negatively impacts spoken language development and impairs communication.^{3,4} It has also been reported that children with hearing losses have lower academic performance and literacy skills compared to their normal-hearing peers.^{5,6}

These disadvantages follow the child through to adulthood, and adults with hearing loss are more likely to be unemployed and have lower earning potential.^{6,7} Hearing loss also limits cultural immersion and reduces overall quality of life.⁸ Additionally, from an economic perspective, hearing loss costs billions of dollars in direct healthcare costs and economic down-time. In the US, the economic cost due to lost productivity has been estimated to be in the range of \$1.8 to \$19.4 billion and direct medical costs at \$3.3 to \$12.8 billion.⁹ In the EU, disabling hearing losses have been calculated to cost around €185 billion each year.¹⁰

There is now a golden opportunity to undertake this systematic review, as there is a large repository of clinical follow-up data on hearing outcomes following tympanoplasties in patients with COM-related hearing loss. Furthermore, technological advances mean that hearing solutions capable of addressing residual hearing losses are more widely accessible. Review outcomes will provide a global overview of hearing outcomes and complications following tympanoplasties. The information will allow healthcare professionals to plan the most

appropriate treatment strategies for optimal hearing rehabilitation. Our key aim is to assess the clinical success rate of tympanoplasties in restoring COM-related hearing loss at a minimum follow-up time of 12 months in both adult and pediatric patients. The synthesis of data will overcome the current gap in the literature and provide evidence capable of improving current clinical practice.

2 | METHODS

Data from papers published in peer-reviewed journals were extracted by AL and BV. Articles were obtained by searching PubMed, Embase and the Cochrane library for suitable literature. Articles published from September 4 2008 through to September 4 2018 were included to assess current clinical practice and post-intervention outcomes. All references were managed using EndNote X7.8, Thomson Reuters.

Two reviewers (AL and BV) independently compiled a comprehensive library containing all published studies where the primary condition investigated was COM, or a subtype of COM, in adult or pediatric patients. A third review author (KJ) acted as an arbiter in cases of disagreement. A comprehensive set of possible search terms were used, including indexing terms and text words used to describe search terms in various truncations. Additional terms from audiologists and published strategies from other groups were also included. The final search strategy was revised, where necessary, and approved by the research team. The finalized PubMed search strategy was applied to Embase and The Cochrane Library. The search string used was: (CSOM OR "chronic suppurative otitis media" OR "chronic otitis media" OR "chronic active mucosal otitis media" OR "chronic oto-mastoiditis" OR "chronic otomastoiditis" OR "chronic tympanomastoiditis" OR "chronic non-suppurative otitis media" OR "chronic serous otitis media" OR "chronic mucoid otitis media" OR "chronic seromucous otitis media" OR "chronic secretory otitis media" OR "chronic otitis media with effusion" OR "chronic tubotympanic suppurative otitis media" OR "chronic atticofacial suppurative otitis media" OR "chronic adhesive otitis media" OR "chronic suppurative aspergillus otitis media" OR "chronic middle ear catarrh" OR "glue ear" OR "otitis media with persistent effusions") AND (hear* or hearing). Dates for inclusion: 04/09/2008-04/09/2018.

Non-English language studies were excluded, along with non-research letters and editorials, seminar reviews, case studies, in vitro and animal studies. These types of studies were excluded as they do not typically contain extensive evidence, representative cases or human data. For example, case studies commonly present unusual cases that are not representative of general practice. Review articles were not included in the final analysis if they reported data that was collected outside of the study inclusion dates. The study has been deposited in PROSPERO; study number CRD42019122813.

Studies reporting tympanoplasty (types I-V)¹¹ outcomes were included and appraisal of the selected literature was performed to assess the weight, suitability and contribution of each article based on the inclusion criteria. Study authors were contacted in cases where there was unclear or missing information. The primary measure assessed was long-term hearing outcomes following tympanoplasty in patients with COM-related hearing loss. Reporting of complications was a secondary outcome measure. Data concerning number of patients, age, gender, demographic information, COM diagnosis (subtype, relevant disease history information), COM intervention and comparison (if applicable), follow up time, pre- and post-treatment audiological assessment data (speech audiometry, pure tone audiometry: air conduction, bone conduction, air-bone gap data), quality of life data and developmental data (if applicable), side effects and/or complications was extracted to Table S1.

Thirty-nine studies met the inclusion criteria and were assessed for risk of bias against the Cochrane criteria for assessing risk of bias.¹² Quality of evidence was assessed using a modified version of the Oxford Centre for Evidence-based Medicine—Levels of Evidence criteria and extracted to Table S1.¹³

Pre- and post-intervention ABG and post-intervention complications data were used to assess patient hearing outcomes and frequency of complications. Pre- and post-operative ABG data are presented as mean ABG and in bins of greater than 20 dB hearing level (HL) or less than or equal to 20 dB HL. Mean complication rates are also presented for all studies that included complications data. Data were extracted to Microsoft Excel 2016, version 1803. Weighted means and standard deviations were computed and corrected against the number of patients included in each dataset.

3 | RESULTS

In total, 1222 records were identified through a combined search of Pubmed, Embase and the Cochrane Library. Duplicates were removed and the remaining 1175 records were screened against the inclusion and exclusion criteria. During the initial screening phase, 1043 records did not meet the criteria and were excluded, leaving 131 articles suitable for full text interrogation (Figure 1). On examining the full texts, 92 articles were assessed as unsuitable where COM was not the primary disease (7), tympanoplasty subtypes were not the primary

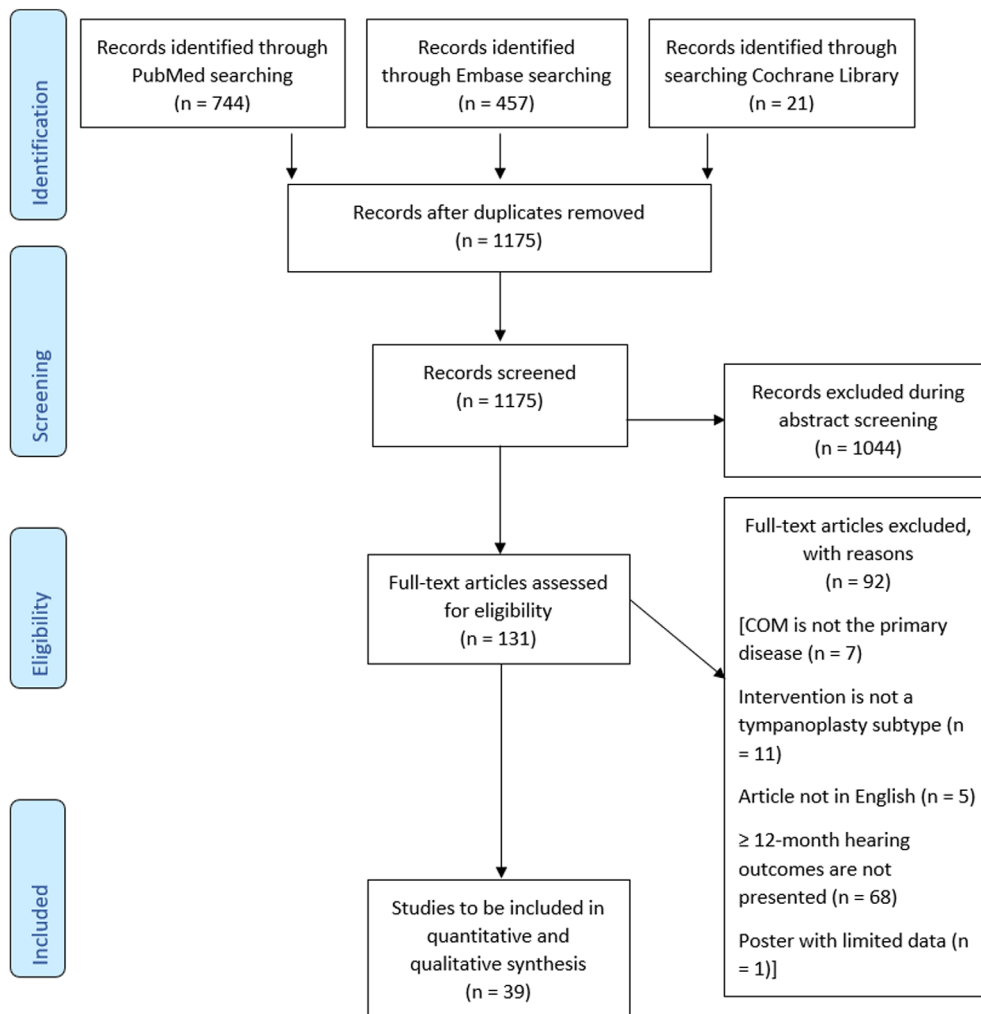


FIGURE 1 Study selection protocol. A total of 1175 unique articles from PubMed, Embase and the Cochrane Library were screened against the inclusion/exclusion criteria and 39 articles were found to meet the criteria for inclusion

intervention (11), the article was not published in English (5), the article did not contain long-term hearing outcomes (68) or the presented data were too limited (1). Thirty-nine studies¹⁴⁻⁵² reporting long-term hearing outcomes and/or complications following middle ear interventions were included for synthesis.

Of the 39 included studies, 24 were retrospective, 11 prospective and 4 were RCTs. Study participants included 2177 adults, 305 pediatrics and 1945 participants in mixed (adult and pediatric) studies. Interventions were limited to tympanoplasty subtypes I-V.

Mean preoperative and postoperative pure tone audiometry was reported in accordance with the inclusion criteria, and was therefore suitable for quantitative synthesis, in 21 studies.^{14,17,18,20,21,24,25,31,32,36-39,42,45-47,49-52} 10 of these studies^{20,21,24,25,32,38,39,42,45,52} reported air-bone gap (ABG) data in sufficient detail so that it could be categorized in to bins of ≤ 20 dB HL or >20 dB HL. Additionally, 14 publications^{15,18,19,23,24,35,36,38,42,43,46-48,52} reported mean pre- and post-operative ABG for patients with and without cholesteatoma in sufficient detail to permit weighted averages for these subgroups to be calculated. Eight studies^{18,21,24,32,34,42,45,52} also reported these data for patients that underwent ossicular reconstruction, permitting the calculation of weighted averages for this subgroup.

Risk of bias was assessed in five areas (adequate sequence generation, allocation concealment, blinding, incomplete outcome data addressed and free of selective reporting) using the Cochrane risk of Bias tool.¹² The completed assessment table is presented in Table S2. An additional notes section detailing important information related to bias that did not fall under any other category is also included. As most studies were retrospective, blinding, allocation concealment and sequence generation was not controllable, and these studies were deemed high risk in these three categories. The majority of studies were deemed to be low risk in the outstanding categories (incomplete outcome data addressed and free of selective reporting). Only the study by Cabra et al was free of bias across all measures.²⁰ Thirty-eight out of 39 studies reported complete outcome data or explained missing data adequately. Three studies were rated as high risk for selective reporting.^{18,22,23} The exclusion criteria in several studies resulted in exclusion of more complex cases with ossicular discontinuity or revision cases.^{35,36,45} One study noted competing interests⁴² and one study did not present a declaration of competing interests.³⁸

Level of Evidence of included studies were graded using a simplified version of the Oxford Centre for Evidence-based Medicine for ratings of individual studies, which is a widely-published system used to classify the strength of evidence for use in clinical decision making.⁵³ Studies were given a numerical rating from 1 to 5, with 1 being the highest quality and 5 being the lowest. The distribution of grades can be seen in Table 1. A comprehensive list of individual study ratings can be found under "quality grading" in Table S1. No studies were deemed grade 5 since they did not meet the initial inclusion criteria based on poor quality of evidence. Since most of the literature was assessed to be either level 2 or 3 (34/39, 87.2%), the outcomes are supported by fair evidence.

TABLE 1 Grading of included studies based on the Oxford Centre for Evidence-based Medicine rating of individual studies

Oxford Centre for Evidence-based Medicine rating of individual studies	Number of studies (total n = 39)
Grade 1: adequately powered and conducted RCT or systematic review with meta-analysis	4
Grade 2: well-designed controlled trial without randomization or a prospective comparative cohort trial	10
Grade 3: case-control studies and retrospective cohort studies	24
Grade 4: case series and cross-sectional studies	1
Grade 5: case reports	0

Long-term follow-up ABG data were presented for 2501 patients. It was possible to stratify data into an adult patient group ($n = 1464$) and a mixed patient group ($n = 1037$) as studies typically reported adult and pediatric outcomes combined. Individually presented mean data for included studies can be found in the online-only supplement (Figure S1 and Figure S2, respectively). Sub-analysis of weighted mean ABG data showed that tympanoplasty led to a closure of the ABG in adult and mixed patient groups, in patients with COM both with and without cholesteatoma, and in patients that underwent ossiculoplasty specifically (Figure 2). The mean pre-intervention ABG for adults and mixed patients was found to be 26.5 dB HL (SD 2.4 dB) and 26.7 dB HL (SD 2.5 dB), respectively. The mean ABG improvement was 10.3 dB HL in adult patients and 11.0 dB HL in the mixed patient group. ABG closure between groups was found to differ by 0.7 dB HL, which suggests that there is no difference between outcomes in adult and pediatric cohorts. The mean ABG improvement for patients with and without cholesteatoma was 10.0 dB HL and 12.4 dB HL, respectively, indicating that better postoperative hearing outcomes may be achievable in patients without cholesteatoma. Regarding the sub analysis of patients with COM that underwent ossiculoplasty, the mean preoperative ABG was 29.6 dB HL (SD 3.0 dB), which was closed to a mean ABG of 16.8 dB (SD 2.8 dB) following surgery.

Next, data were synthesized to determine the proportion of patients in which ABG closure to within 20 dB HL was achieved. Studies typically present an intervention as successful if ABG closure to within 20 dB HL is achieved postoperatively and 10 studies presented data suitable for assessment against this measure of success.^{20,21,24,25,32,38,39,42,45,52} At the patient level, it was uncovered that 29.3% ($n = 1370$) of patients have a postoperative ABG of > 20 dB HL, which is considered a failure in restoring hearing (Figure 3).

Regarding complications, 31^{14,15,17,19-27,29-32,34-39,41-44,46,47,49-51} studies presented complications data, however, three of these studies^{30,41,54} presented complications data in terms of ears and could not be included in the data synthesis calculation, which is based on complication per patient. The mean complication rate, calculated for a total of 3162 patients from the remaining studies, was 14.0% (Figure 4). The rate of complications in individual studies ranged from

Subgroup analysis: pre and post-operative ABG

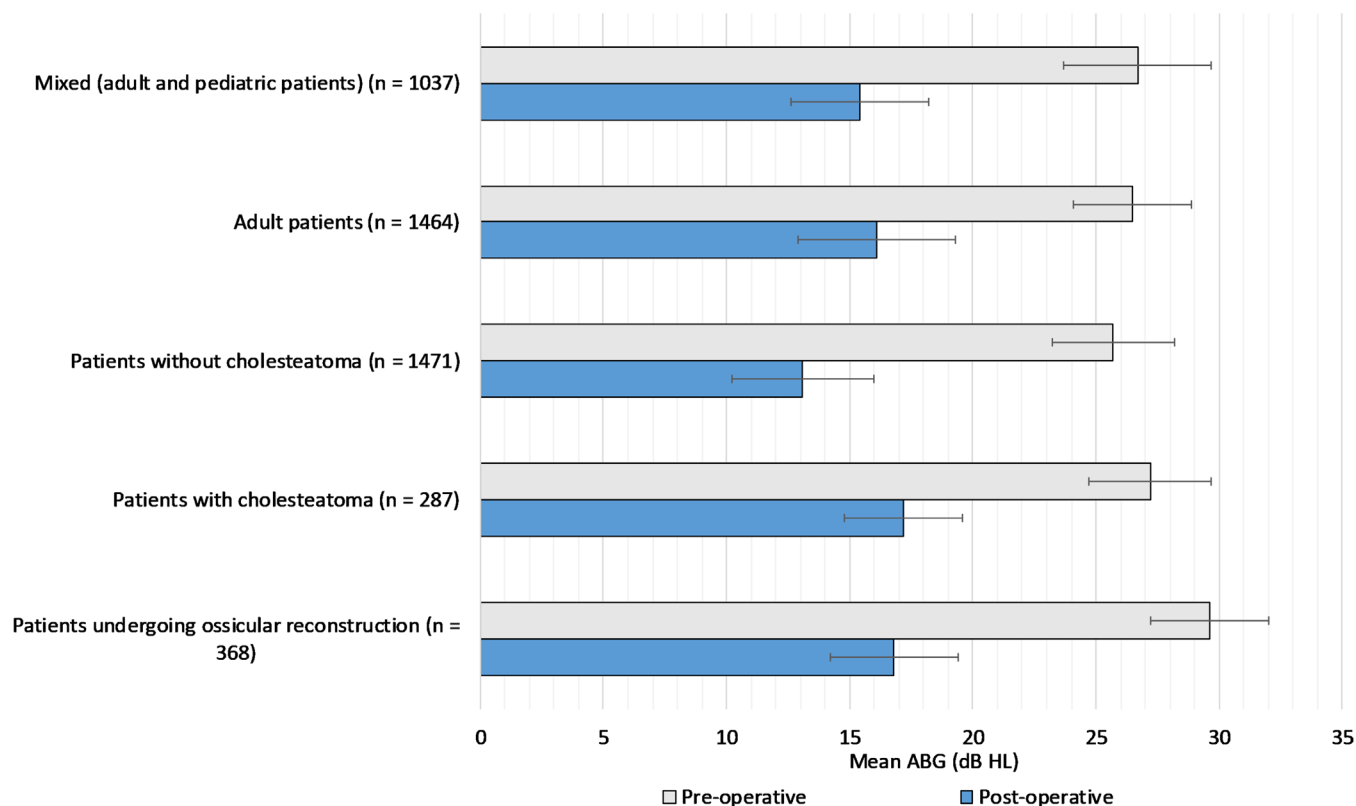


FIGURE 2 Weighted mean and SD ABG for interventions in adult and mixed patient groups, patients with and without cholesteatoma and patients that underwent ossiculoplasty. In studies that presented adult patient data only, the mean pre-intervention ABG was 26.5 dB HL (SD 2.4 dB), which reduced to 16.1 dB HL (SD 2.5 dB) at minimum 12-month follow-up. In studies that presented combined adult and pediatric data, the pre-intervention ABG was 26.7 dB HL (SD 2.5 dB), which reduced to 15.4 dB HL (SD 2.2 dB) at minimum 12-month follow-up. Patients without cholesteatoma had a mean pre-intervention ABG of 25.7 dB HL (SD 2.4 dB), which reduced to 13.1 dB HL (SD 3.2 dB) at minimum 12-month follow-up. In studies that presented data on patients with cholesteatoma, the pre-intervention ABG was 27.2 dB HL (SD 2.5 dB), which reduced to 17.2 dB HL (SD 2.9 dB) at minimum 12-month follow-up. Patients that underwent ossiculoplasty had a mean preoperative ABG of 29.6 (SD 3.0 dB) and a mean postoperative ABG of 16.8 dB HL (SD 2.8 dB)

47.1% to as low as 0.0%. The most common postoperative complication was a persistent perforation of the tympanic membrane, which occurred in 7.3% of patients. Postoperative infection/otorrhea was reported to occur in 1.4% of patients.

4 | DISCUSSION

The purpose of tympanoplasty is to improve hearing through repair of the tympanic membrane and/or middle ear ossicles. Any closure of the ABG following surgery can be considered a clinical improvement in hearing, although an ABG closure to within 10 dB HL is optimal since normal hearing to the sensorineural level is restored (for patients with mixed hearing loss).⁵⁵ Complete closure of the ABG is known to be difficult to achieve and closure to within 20 dB HL is most commonly reported as a successful hearing outcome. In-line with the clinical literature we therefore defined an intervention as successful if an ABG of ≤ 20 dB HL was measured at long-term follow-up. Here, long-term postoperative audiological outcomes show that

29.3% of patients are not successfully rehabilitated. Data also indicate that hearing rehabilitation is more difficult to achieve in patients with cholesteatoma compared to those without. This is likely due to poor aeration, the frequency of ossicular chain lesions in patients with cholesteatoma⁵⁶ and the difficulty in restoring continuity of the ossicular chain.⁵⁷ This is supported by our data, as the postoperative ABG in patients with ossicular discontinuity was larger than those that did not undergo ossicular reconstruction. However, these data should be interpreted with care due to the underlying disease heterogeneity between subgroups.

Effective hearing rehabilitation is a major consideration that cannot be ignored due to the range of detrimental issues associated with hearing loss. It is well-documented that poor hearing has severe implications on patient quality of life and their mental development and wellbeing.⁸ Although, it is beyond the scope of this study to examine the many social determinants of health that play a role in the success of any surgical intervention in relation to hearing rehabilitation. However, the authors acknowledge the importance of health equity, particularly pertaining to vulnerable populations.

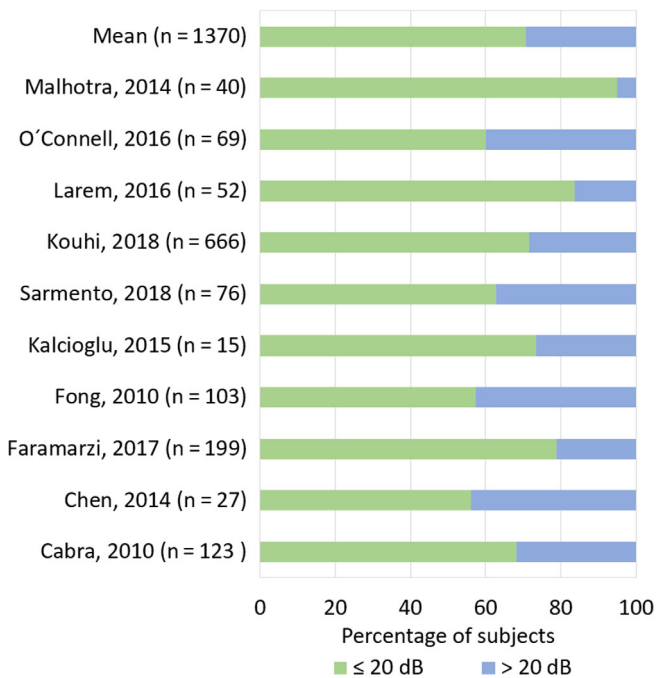


FIGURE 3 Percentage of patients with a residual ABG in individual studies of ≤ 20 dB HL (green bars) or > 20 dB HL (blue bars). Data is presented for 1370 patients from 10 individual studies. The weighted mean shows that 29.3% of subjects have a postoperative ABG of greater than 20 dB HL

COM-related hearing loss can be addressed through several interventions, including additional middle ear surgeries that aim to repair the tympanic membrane, clear obstructions from the middle ear space and restore ossicular chain continuity. Alternatively, patients can be provided with a hearing device that can either bypass the malfunctioning middle ear or amplify sounds entering the ear canal. Data presented here show that overall complication rates for tympanoplasty are 14.0%, which should be taken into consideration when determining the most appropriate course of hearing rehabilitation.

The inclusion criteria did not impose any country-specific limitations, which is important as healthcare provision can alter dramatically between countries and it is important to gain an overview of the global standard of care. Also, data were recent and represent modern surgical outcomes and hearing solutions. The search was not limited to a particular COM subtype, but interventions were limited to tympanoplasty subtypes to provide a comprehensive overview of the success of these interventions in restoring hearing in patients with COM. Finally, the review analyzed long-term hearing outcomes, which is necessary as patients may not reach a stable state for many months after middle ear surgery⁴² and early follow-up may lead to an incorrect estimation of hearing gain.

A potential limitation of the study is that only English-language articles were included. Even though language restrictions do not introduce systematic bias⁵⁸ they may limit data collection. Heterogeneity in audiological frequencies measured

meant that audiological data from some studies could not be used in the final analysis and only ABG data could be synthesized as the primary measure of hearing outcomes since it was most widely recorded across the 39 included studies. The ABG is an effective measure of conductive hearing losses, but the strength of data would be improved if it were possible to utilize full audiograms since it is known that hearing thresholds can vary substantially at discrete frequencies in a patient-dependent manner. For instance, high frequency hearing losses would not be adequately captured by a pure tone average measured at 500, 1000, 2000, and 4000 Hz. The review does not include grey literature, which may lead to publication bias where neutral and negative results are not included, thereby inflating the positivity of outcomes following the intervention.⁵⁹ 38/39 studies were not free of bias, which must be taken into consideration when evaluating the final outcomes of this review as real-world hearing outcomes may be worse than presented here. Finally, many studies were retrospective and patients were selected based on the author's criteria, which introduces high selection bias in such a heterogeneous disease pathology. The exclusion of difficult and unsuccessful cases from the final analysis in several studies means that the postoperative ABG reported is likely underestimated. Furthermore, the clinical history of many patients was incomplete, particularly regarding mastoidectomy status, which may influence hearing results depending on the type of tympanoplasty procedure.^{60,61}

Evidence presented here shows that there is a group of patients with COM that have a persistent hearing loss following tympanoplasty. These patients are left with a residual ABG of at least 20 dB HL. The ENT surgeon and team must then decide, together with the patient, how to treat the residual hearing loss in the most effective manner where revision surgeries do not necessarily imply a better hearing outcome and are accompanied by additional risk of complications.⁵⁴ This is a difficult decision to make in such a heterogeneous disease, without clear guidelines detailing which patients may benefit from additional reconstructive surgeries or whether an alternative form of hearing rehabilitation should be implemented (either permanent or to bridge between surgeries). Middle-ear imaging techniques, such as diffusion-weighted imaging and magnetic resonance imaging could be used to inform decision-making and guide follow-up in these cases. This is especially beneficial in preventing second look surgeries in cholesteatoma cases.⁶² Several indices have also been trialed for their predictive power in the past, including the middle ear risk index, which provides an overview of the status of the middle ear and has shown some promise in predicting postoperative hearing outcomes.⁶³

Future research should also investigate the efficacy of individual measures to support decision making around treatments for COM-related hearing loss. These focused studies could investigate how outcomes with hearing solutions, such as hearing aids or bone conduction devices, compare with the current standard of care in areas such as infection rates, hearing rehabilitation and healthcare utilization.

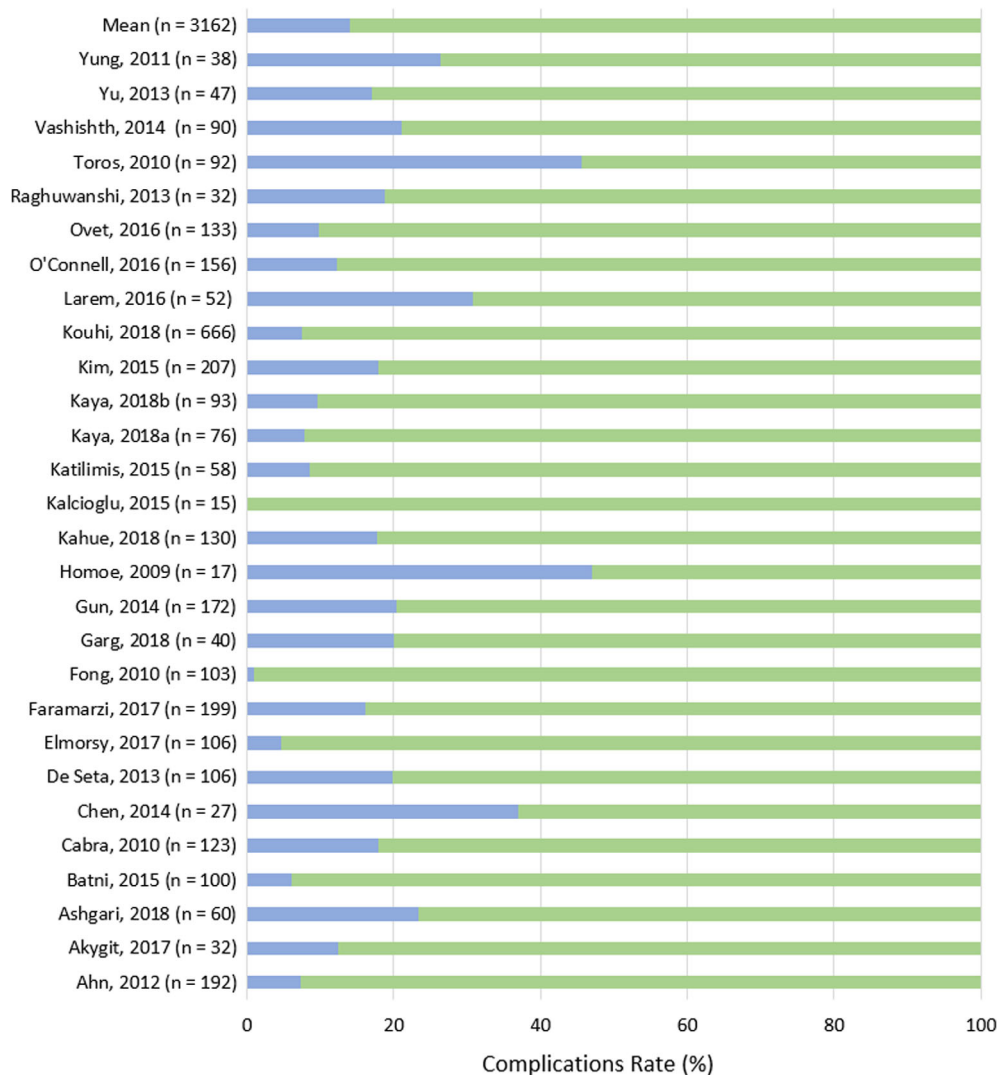


FIGURE 4 Complication rates by study. Percentage of patients that experienced complications in 28 individual studies that presented complications data (N = 3162). The mean complication rate was 14.0%. The lowest reported complication rate was 0.0% and the highest was 47.1%

5 | CONCLUSIONS

Tympanoplasties are reported to successfully restore hearing in 7/10 patients with COM-related hearing loss, however, less successful hearing outcomes should be expected in patients with cholesteatoma. Consistent preoperative evaluation and quantification of care is crucial for effective treatment and best practice guidelines for treating COM are mandatory to achieve a mutual goal: a safe and dry middle ear space with maximum hearing potential.

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CONFLICT OF INTEREST

A. L., B. V., H. H., and K. J. are current employees of Cochlear Bone Anchored Solutions AB. M. K. H. reports financial support to the authors' institution (Radboudumc) for conducting clinical studies from

Oticon Medical AB (Askim, Sweden) and from Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden) outside the submitted work. M. K. H. declares no other conflict of interest.

DATA AVAILABILITY STATEMENT

Any additional data and materials not made available in the supplementary materials can be obtained from the corresponding author upon request.

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