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Review Article

Hearing Rehabilitation of Patients with Chronic Otitis Media: A Discussion of Current State of Knowledge and Research Priorities

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Although chronic otitis media is a major cause of conductive and mixed hearing loss, auditory rehabilitation is currently not optimal for this patient group. Planning for hearing rehabilitation must accompany strategies for infection control when surgically managing patients with chronic otitis media. Several barriers prevent adequate hearing restoration in such a heterogeneous patient population. A lack of standardized reporting of surgical interventions, hearing, and quality of life outcomes impedes meta-analyses of existing data and the generation of high-quality evidence, including cost-effectiveness data, through prospective studies. This, in turn, prevents the ability of clinicians to stratify patients based on prognostic indicators, which could guide the decision-making pathway. Strategies to improve reporting standards and methods have the potential to classify patients with chronic otitis media preoperatively, which could guide decision-making for hearing restoration with ossiculoplasty versus prosthetic hearing devices. Appropriately selected clinical guidelines would not only foster directed research but could enhance patient-centered and evidence-based decision-making regarding hearing rehabilitation in the surgical planning process.

KEYWORDS: Chronic otitis media, hearing loss, quality of life, hearing rehabilitation

INTRODUCTION

Chronic otitis media (COM), one of the most common infectious and inflammatory diseases worldwide, is a heterogeneous condition defined by persistent inflammation of the middle ear and/or mastoid cavity. Environmental, microbial, host, and genetic risk factors have been identified in this often-multifactorial condition.^{1,2} Besides chronic or recurrent infection, COM can lead to conductive hearing loss, as well as sensorineural hearing loss (SNHL).^{3,4} Several million people with COM suffer from significant hearing impairment, meaning that COM may contribute more than 50% to the global burden of hearing impairment.⁵ Although abundant reports can be found in the existing medical literature, there is little consensus regarding the optimum treatment planning to ensure the best possible hearing result.

Clinical management is focused on eradicating chronic mastoid and middle ear disease to achieve a safe and dry middle ear space. Once this has been achieved, any resultant hearing loss can be treated. Patients in this scenario are usually offered surgical

reconstruction and/or hearing aids depending on the type and severity of the hearing loss.

A recently performed systematic literature review of tympanoplasty outcomes confirmed that the air-bone gap is only closed to within 20 dB HL in 70% of patients at long-term (≥ 12 months) follow-up.⁶ The review presented an overview of expected hearing outcomes for all tympanoplasty subtypes (I-V), but it is also known that higher degrees of ossicular chain discontinuity negatively impact hearing outcomes following tympanoplasty.⁷ Not all patients with COM can tolerate a hearing aid and they are contraindicated in patients with chronic aural discharge. Additionally, patients with more significant conductive hearing loss and mixed hearing losses may require an osseointegrated solution or even cochlear implantation and this calls into question where these technologies fit into the treatment pathway for patients surgically managed for COM.

However, lack of clinical evidence and non-standardized reporting of outcome measures in the literature hinders the otologic surgeons from stratifying patients to appropriate, evidence-based treatment practice aimed at optimally treating COM-related hearing loss, that is global consensus is missing. In an attempt to rectify these issues, The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) published standardized reporting guidelines in 1995, which were updated in 2012,⁸ and these guidelines are still not routinely implemented in the majority of tympanoplasty studies, mainly due to the quality and difficulty of the guidelines themselves, author neglect, and a failure of peer review.⁹

CLINICAL AND RESEARCH CONSEQUENCES OF COM-RELATED HEARING LOSS

Physical, Social, and Mental Health

Untreated hearing loss can negatively impact the quality of life, cognitive abilities, physical health, mental well-being, and educational status.^{10,11} Hearing loss also has a negative impact on social interaction, overall communication, and mental well-being,¹²⁻¹⁴ and the stigma associated with hearing loss can result in social isolation and increased prevalence of psychological conditions.¹⁵ The social stigma of otorrhea in patients with COM can exacerbate these issues.¹⁶ A systematic review demonstrated that parents of children with COM feel guilty due to their inability to recognize their child's symptoms¹⁷ and a growing body of evidence links hearing loss to a decline in overall physical health¹⁸⁻²⁰ and to an increased risk of falls and cognitive decline.^{11,21}

Economic Impact of COM-Related Hearing Loss

The World Health Organization (WHO) estimates that COM is responsible for more than half of the global hearing burden and has compiled extensive data on the incidence of hearing loss due to COM and the huge associated economic burden.²² In the UK alone, a report from The Ear Foundation conservatively estimates a £30 billion per year cost related to hearing impairment to the UK economy,²³ of which half could be attributed to COM based on the WHO data. The foundation specifies the need to separate the societal costs of those with and without hearing technologies. A report commissioned for HEAR-IT, using quality of life (QoL) metrics, estimates that hearing impairment costs the European economy 284 billion euros per year.²⁴ These data support the need to address hearing loss as a public

health concern and for specific data on the cost of untreated hearing loss and the effect of hearing interventions on these expenditures. Hearing aids and cochlear implants are reported to be a cost-effective method of treating patients with sensorineural hearing loss,^{25,26} but limited availability of QoL/cost-benefit data for osseointegrated solutions prevents a comparison between interventions.²⁷ Robust, evidence-driven management strategies could promote more efficient use of healthcare resources to provide maximum patient benefit, which is of particular importance in regions where healthcare resources are limited.

Available Treatments for COM-Related Hearing Loss

There are a variety of options available to treat COM-related hearing loss. Each intervention presents a unique opportunity for improved hearing, but each also assumes inherent limitations. No current evidence-based approach to the role of observation, ossicular reconstruction/middle ear reconstructive surgery, air conduction hearing aids, osseointegrated devices, and middle ear or cochlear implants has gained global consensus. Such agreement would, in return, foster appropriate preoperative planning and choice of therapy that most effectively utilize available resources. Furthermore, both healthcare professionals and the public should be made aware of the overarching negative impact hearing loss has on an individual.

Reconstructive Middle Ear Surgery

In the hierarchy of surgery for COM, hearing restoration is second only to the achievement of a safe and dry ear. Eradication of infection and cholesteatoma, when present, reduces the risk of recurrence or complications. In cases where a tympanic membrane is present or reconstructed, ossiculoplasty becomes possible. Middle ear reconstruction and restoration of ossicular continuity often result in (partially) persistent or recurrent conductive hearing losses and do not address the sensorineural component of a mixed loss. Air conduction hearing aids may provide useful rehabilitation in cases with hearing thresholds better than 60 dB and/or less than 25-35 dB residual conductive loss, as long as occlusion of the ear canal does not exacerbate the COM.²⁸⁻³⁰ When appropriate, traditional hearing aids can amplify the reduced frequencies in the sensory component of the mixed loss, provided that the conductive component is not so large as to introduce feedback in the hearing aid system. Evidence supports that hearing aids are effective at improving speech recognition in quiet and noise, hearing-specific Health-Related Quality of Life (HRQoL), general HRQoL, and listening ability in adults with mild to moderate hearing loss.³¹ These data are less clear when treating patients with significant mixed hearing loss.^{28,32,33}

It is not uncommon for patients to have multiple revision surgeries to address their conductive hearing loss while osseointegrated implants are reserved as a last option. Reports in the medical literature document cases where patients wait several years before being able to receive a suitable hearing solution following reconstructive surgery.³⁴ More data are needed to challenge whether particular groups of patients would benefit from the use of hearing devices, including air conduction hearing aids, bone conduction devices, and cochlear implants, earlier in the treatment pathway. Additionally, aiding patients with a non-surgical bone conduction device during surgical management should be considered until the ear is declared safe for tympanoplasty.

Air Conduction Hearing Aids

Air conduction hearing aids are the most widely prescribed hearing device for treating a patient's residual hearing loss following tympanoplasty. These devices are placed inside the ear canal and capture and amplify sounds entering the outer ear to compensate for the hearing loss. Patients with safe, dry ears with mild to moderate conductive hearing losses typically obtain excellent aural rehabilitation using these devices.³⁵ However, hearing thresholds may deteriorate outside of the fitting range of the hearing aid over time and some patients can be difficult to fit due to radical cavities, ongoing infection, surgical management, and fluctuating hearing thresholds. Conventional hearing aids are also contraindicated in patients with otorrhea as they obstruct the ear canal and may lead to a resurgence of infection in a previously safe ear,³⁰ which can damage the cochlea.³⁶ Finally, patients with mixed losses, particularly those with greater degrees of sensorineural hearing loss, may experience greater benefit from a bone conduction hearing aid.²⁸

Bone Conduction Hearing Solutions

Bone conduction hearing aids stimulate the cochlea by transmitting vibrations through the skull. High levels of satisfaction in relation to sound amplification and speech perception when using bone conduction hearing aids have been reported in patients with conductive or mixed hearing loss.³⁷ In patients with COM, a key advantage of these devices is that the ear canal is not occluded, minimizing moisture accumulation and skin irritation.³⁰ Therefore, bone conduction devices are widely considered for patients with persistent otorrhea, otitis externa, and patients who are unable to wear an air conduction hearing aid. Bone conductive devices can amplify both the sensorineural and conductive components of a mixed hearing loss within the limits of the device indications. Clinical studies demonstrate significantly reduced aural discharge and high patient satisfaction with bone conduction devices.^{38,39} Bone conduction devices also offer an alternative treatment option for patients who cannot, or will not, undergo middle ear reconstructive surgeries,⁴⁰ with earlier and more predictable amplification.⁴¹

Significant improvements in audiological thresholds and speech recognition can be obtained with non-surgical bone conduction solutions, which offer a potential for reduced time intervals of conductive hearing loss between reconstructive surgeries.^{42,43} These devices can be worn using either headbands, softbands, or by deploying adhesive solutions on the post-auricular skin. Each option is easily removable and can provide significant hearing gain. These solutions can be offered to patients regardless of age⁴⁴ as a bridge between surgeries and subsequent surgical device placement. Both non-surgical and implanted solutions can be used in cases of ongoing, chronic otorrhea, although softband, headband, and adhesive solutions are audiological inferior to implanted solutions. Finally, acoustic and cochlear implants (CIs) should be considered in patients with moderate to profound SNHL, where the fitting range of both non-surgical and implanted solutions is too limited.

Middle Ear and Cochlear Implants

Moderate to profound hearing losses can develop in some patients with COM.⁴⁶ In these cases, hearing aids and bone conduction implants may be unable to compensate for the high degree of sensorineural hearing loss or may be unsuitable due to the underlying

pathology. The middle ear and CI should be considered in these cases, depending on the type and severity of the hearing loss. Middle ear implants couple directly to middle ear structures and convert sounds into mechanical vibrations that are passed along the conductive hearing pathway to the cochlea. They have been successfully implanted in patients with severe, mixed hearing losses due to COM and cholesteatoma and can provide excellent functional gain.⁴⁶ Cochlear implants are indicated for patients with severe to profound hearing loss who fall outside of the indication range for middle ear implants.^{47,48} They convert sound waves into electrical signals and involve the placement of a small electrode inside the cochlea, which directly stimulates the auditory nerve. Long-term outcomes following CI implantation in patients with COM demonstrate that the procedure is safe and capable of providing satisfactory aural rehabilitation.⁴⁹

Evidence Requirements to Improve the Treatment of COM-Related Hearing Loss

Objectively measuring and recording specific data in patients with COM to accurately assess how the selected method of hearing rehabilitation will impact these areas of a patient's life may better reflect the overall impact of hearing rehabilitation methods. Capturing patient satisfaction and patient-reported HRQoL can quantify the subjective changes on overall health. Comprehensive assessment of patient-reported outcomes are therefore necessary to accurately determine intervention success in an era of growing emphasis on value-driven healthcare. Additionally, establishing cost-effectiveness thresholds across the range of available hearing interventions will enable consensus development for optimum hearing management in patients with COM. Treatment cost-effectiveness is a complex calculation based on multiple variables and has been explored for conventional hearing aids and cochlear implants.^{26,50} Even though these studies are not specific for COM, they provide an overview of the general cost-effectiveness of different modes of hearing rehabilitation. Regarding air conduction hearing aids, cost-effectiveness of these devices in first-time hearing aid users has been confirmed⁵⁰ and these devices have also been shown to be cost effective in older recipients.⁵⁰ In contrast, it has recently been reported that hearing aids may not be cost-effective compared to stapedectomy in patients with otosclerosis.⁵¹ Cochlear implants implantation is most likely to be cost-effective for adults and children with profound hearing loss based on a willingness-to-pay threshold below 30 000 GBP²⁶ and implantation may also be cost-effective in cases of profound hearing loss in some low and middle income countries.⁵² Cost-effectiveness calculations for bone conduction solutions is hampered by limited data resulting in a lack of clarity when comparing this mode of hearing intervention.⁵³ As these calculations are performed using utility scores, instrument-dependent utility outcomes can lead to stark differences in cost per quality-adjusted life year gained. This skewed data has the potential to affect policy decision and reimbursement.⁵⁴ Generic QoL instruments are also not sensitive enough to capture hearing-related problems.⁵⁵ Eliminating the need for repeat surgeries to improve hearing would reduce treatment costs and the outcome of ossiculoplasty is also expected to improve with the experience of the operative surgeon.⁵⁶⁻⁵⁸ The current discussion has been formulated to create awareness and stress the need for more widespread and rigorous disease classification and outcome reporting in order to accurately measure cost-effectiveness in patients with COM.

Need for Classification of Surgical Interventions

Attempts to appropriately classify mastoidectomy and tympanoplasty surgeries have been ongoing since the 1950s,⁵⁹ with very diverse systems proposed.⁶⁰ However, there is no existing classification capable of serving as an international standard, mainly because current classifications do not correspond to ICD-10 nomenclature or because they overlook key procedures.⁶⁰ International categorization would allow clinicians to pool their surgical data for important learnings to be made. To harness this opportunity, a recently assembled international otology group has proposed a classification that incorporates surgery, surgical approach, mastoid bone extirpation, external bony wall repair, obliteration of the mastoid cavity, access to the middle ear, tympanic membrane reconstruction, and ossicular reconstruction, known as the SAMEO-ATO classification system.⁶¹ The classification has recently been developed as a freely available web-based platform and mobile application, the SAMEO-ATO app that can be used to easily categorize tympanomastoid surgeries. We believe this newly developed system encompasses all the necessary items to adequately classify tympano-mastoid surgeries in patients with COM.

Need for Patient Stratification

The ability to preoperatively stratify patients based on the likelihood of a successful treatment outcome would significantly improve the standard of care. Several indexes have been trialed with the aim of determining whether certain pre-operative factors can influence the level of success of hearing rehabilitation in patients with COM or whether individual factors are affecting the outcomes. For example, studies have shown that presence of cholesteatoma is associated with less successful graft outcomes in tympanic membrane repair.⁶² Attempts have been made to develop indexes capturing a wide range of variables and several have been proposed and tested for their prognostic potential,⁶³ with the Middle Ear Risk Index (MERI) being the most widely adopted.⁶⁴ The MERI is a questionnaire completed by the professional to capture and score the status of the middle ear. The final score ranges from 0 to 15 and is used to categorize disease severity as normal (0), mild (1-3), moderate (4-7), and severe (8-15). Pre-operative classifications of moderate and severe disease have been correlated to increased risk of tympanoplasty failure in adults,⁶⁵⁻⁶⁷ but not in pediatric patients.⁶⁸ Large prospective studies, however, are still required to assess its utility in clinical practice. This should be extremely useful in clinical practice and could be administered pre-operatively to determine the best option for hearing restoration. Appropriate candidates could be offered alternative hearing solutions earlier in the treatment pathway with the additional benefit of not having to undergo revision surgeries.

Need for Standardization of Health-Related Quality of Life Instruments

Currently available questionnaires each have their unique strengths and limitations. The Health Utilities Index Mark 3 is the most frequently used scale to measure generic HRQoL and calculate quality-adjusted life years for cost-utility evaluations in hearing impaired individuals.⁶⁹ The index can identify 972 000 unique health states and is administered as a questionnaire that covers either 5 or 6 levels of health state for 8 different attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain). In patients with chronic ear disease the 13-item chronic ear survey (CES) is most frequently used, which measures frequency, duration, and severity of

the disease, but fails to capture the functional deficits and psychological impairment and more specific instruments are essential to accurately capture HRQoL.⁷⁰ A recent systematic appraisal of the current literature identified 4 patient-reported outcome measure questionnaires for use in patients with chronic suppurative otitis media.⁷¹ In addition to CES, the review assessed the COM-5, COMQ-12, and COMOT-15 questionnaires. The review concluded that COMOT-15 beneficially dedicates a large proportion of questions to hearing but that it does not measure outcomes in the social domain. The COMQ-12 is designed for patients with suppurative COM and measures across somatic, psychological, and social domains, but it was determined to be less focused on hearing compared to the COMOT-15.⁷¹ COM-5 is a short-form questionnaire completed by caregivers and is valid and responsive in pediatric patients.⁷² Recently, an intervention-linked HRQoL questionnaire applicable to adult patients with COM has been developed, known as the Chronic Otitis Media Benefit Inventory.⁷³ However, since the questionnaire is based on the COMQ-12, it is most applicable to patients with active aural discharge. Unfortunately, the review does not identify an instrument capable of collecting patient information across all domains in patients without active aural discharge and clinicians must therefore select the most appropriate instrument for their research needs. Future studies, especially on COM-related hearing loss, should strive to capture both generic and disease specific HRQoL data. Ideally, this data should be collected in conjunction with detailed pre- and post-intervention audiological outcomes, as specified by the AAO-HNS.⁸

CONCLUSION

A review of the literature indicates the apparent shortcomings in current clinical evidence and the lack of high-quality studies comparing the efficacy of different types of hearing rehabilitation available to the clinician in the treatment of COM-related hearing loss. Development of a method capable of generating an evidence-based classification of patients based on pre-operative risk factors should be an important goal of future research. This would drive more awareness for collecting hearing outcomes and patient reported outcomes following hearing interventions in patients leading to higher quality comparative research for overall hearing outcome. Furthermore, high-quality evidence on the full range of available hearing interventions will assist health care professionals and patients in making a well-informed decision. Another important goal of future research is to use the most appropriate instruments to accurately capture hearing outcomes, patient satisfaction, and cost-effectiveness of each intervention, in a standardized way that supports meta-analyses. The resultant cost-effectiveness data would then drive better information for policy makers managing healthcare spending for patients with COM, foster meaningful international registry formulation, and allow the creation of standardized, evidence-based care pathways.

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