Challenges in managing complex chronic middle ear disease: MERF experience

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INTRODUCTION

Chronic middle ear disease is a major public health problem in developing countries such as India. Chronic otitis media accounts for approximately 80% of the burden of hearing impairment worldwide and 90% of these cases are from developing countries. Poverty, ignorance, problems with access to ENT healthcare are reasons for late presentation of patients and advanced disease presentation in such developing countries. Cholesteatoma may remain undetected for many years before potentially dangerous manifestations occur. A canal wall down mastoidectomy is the norm in the presence of cholesteatoma. The goal of surgery is the complete removal of disease to minimize the risk of recurrence. Pre-operative radiology is essential for diagnosis and appropriate management. Pediatric cholesteatoma is usually characterized by aggressive growth and increased risk of residual and recurrent disease compared with adults. In patients with extensive granulations, severe hearing loss and presence of complications, the diagnosis of tuberculous otitis media...
The aim of this study was to retrospectively analyze patients with complex, advanced chronic otitis media, with respect to their clinical presentation, extension of disease and associated complications such as hearing loss, labyrinthine fistula, facial paralysis, dural involvement, etc. Their surgical challenges and the eventual outcomes were analyzed, to reflect upon the long-term results of our institutional protocol.

METHODS

This retrospective study consisted of 47 patients who presented with complex chronic otitis media to Madras ENT research foundation, a tertiary referral ENT care centre in South India from January 2016 to December 2020. The inclusion criteria were all patients with extensive middle ear disease and the presence of complications with challenges encountered intraoperatively. The exclusion criteria were early middle ear disease and lack of any complications.

All patients underwent a thorough ENT evaluation, otomicroscopy, audiological evaluation and radiological evaluation. CT scans helped confirm the extent of disease, presence of complications such as labyrinthine fistula, involvement of the fallopian canal, tegmen, cochlea, internal auditory meatus, and internal carotid artery. Magnetic resonance imaging (MRI) was done in patients with suspected dural involvement, sigmoid sinus thrombosis and suspected intracranial involvement. All patients underwent surgical management of the disease and its associated complication, if any along with appropriate peri-operative antibiotic therapy. In all these patients with extensive cholesteatoma, a canal wall down procedure was done to ensure complete disease clearance. Ossicular reconstruction was done in all patients except in four who had profound hearing loss. Facial nerve decompression was done in patients with pre-operative facial palsy. Patients with labyrinthine fistula had complete disease clearance. The location of the fistula was in the lateral semicircular canal in all patients. At the end of the procedure, cholesteatoma covering the fistula was removed under high magnification, and sealed with temporalis fascia. Patients with cholesteatoma found extending into the cochlea underwent complete disease removal. Patients with cholesteatoma involving the internal auditory meatus had profound hearing loss and underwent a trans-labyrinthine approach for disease clearance.

Cerebrospinal fluid (CSF) leak was controlled by sealing with fat, temporalis fascia and fibrin glue. In patients with recurrent cholesteatoma and fungus cerebri, bipolar diathermy was used to coagulate the herniating brain tissue, CSF gusher was controlled by packing with fat, fascia and fibrin glue. In patients with jugular bulb or sigmoid sinus involvement, cholesteatoma was dissected completely. One patient had cholesteatoma involving an aberrant internal carotid artery; matrix was dissected off without any adverse event. Patients with extensive granulations underwent canal wall down mastoidectomy, which was subsequently diagnosed as tuberculous otitis media by HPE and MTB PCR, and had post-operative anti-tuberculous therapy.

Patients with extensive tympanosclerosis underwent cortical mastoidectomy, and removal of the tympanosclerotic plaques to ensure adequate drainage at the aditus. Ossicular reconstruction was done in all patients with tympanosclerosis except in two patients who had extensive fixation of the stapes footplate. All patients underwent surveillance with otomicroscopy at follow-up visits.

For statistical analysis, SPSS software v21.0, Vermont USA was used. Paired t test was applied to derive the results. Follow-up after surgery ranged from 4 months to 4 years and the mean follow-up period was 30 months.

RESULTS

Forty-seven patients (4.9%) presented with complex, advanced chronic otitis media in our Institute from January 2016 to December 2020. Their age ranged from 5 years to 73 years (mean 46 years). There were 24 males and 23 females in the study. Eight patients were in the pediatric age group (17%). Figure 1 depicts the number of patients with cholesteatoma, tuberculous otitis media and tympanosclerosis.

![Figure 1: Distribution of advanced/complicated otitis media.](image-url)
Hearing loss was the commonest symptom seen in thirty-nine patients (83%); four patients had profound sensorineural hearing loss (9%). Six patients (13%) presented with facial palsy-grade IV in 3 patients and grade VI in 3 patients. Three of these patients with pre-op facial palsy had cholesteatoma and 3 patients had TBOM. The challenges encountered in management of chronic otitis media with cholesteatoma and TBOM are mentioned in Figure 2 and 3.

In all patients with cholesteatoma, a canal wall down procedure was done for complete disease clearance (100%). In 41 patients (87%), the surgery was a primary procedure and in 6 patients (13%), the surgery was a revision procedure; primary procedure was done elsewhere in these patients. Figures 4-8, depict a spectrum of advanced cholesteatoma management. No intra-operative surgical complications were noted. The outcomes of surgical management were good and patients were on an average follow-up of 30 months (range-4 months to 4 years).

**Figure 2: Number of patients with challenges encountered in management of otitis media with cholesteatoma.**

**Figure 3: Number of patients with challenges encountered in tuberculous otitis media.**

**Figure 4: Cholesteatoma involving the left internal auditory meatus.**

**Figure 5: Cholesteatoma being removed from the left internal auditory meatus.**

**Figure 6: CT scan with brain herniation and recurrent cholesteatoma.**
In all patients with cholesteatoma, canal wall down mastoidectomy was effective in disease clearance ($p<0.05$). Two patients (5%) had recurrent disease and became disease free after revision surgery. Serviceable hearing improvement was noted in thirty-six patients (77%). None of the patients had worsening of hearing after the procedure. Vertigo was reported by 7 patients (15%) prior to the surgery. Post-surgery, none of the patients experienced vertigo ($p<0.05$). Tinnitus was present in 5 patients (11%) pre-operatively. Post-surgery, there was resolution of tinnitus in all patients ($p<0.05$). Facial palsy was the presenting feature in three patients with cholesteatoma (8%). In one patient the paralysis recovered completely and in two patients, facial function improved to House-Brackmann grade III after facial nerve decompression, over 6 months follow up. The follow-up of all the patients was by clinical evaluation and otomicroscopy.

Five patients (11%) with extensive pale granulations in the middle ear and mastoid were diagnosed to have tuberculous otitis media. All patients had canal wall down mastoidectomy with post-operative antituberculous therapy. (Figures 9 and 10). Three of these patients had pre-operative facial palsy (grade IV) and underwent facial nerve decompression. Lateral semicircular canal fistula was seen in one patient who underwent modified radical mastoidectomy and sealing of the fistula with temporalis fascia. One patient had a defect in the tegmen which was sealed with tragal cartilage. At 6 months follow up all these patients showed completely healed ears, due to successful surgery and ATT regimen.

Five patients (11%) with extensive tympanosclerosis were managed by canal wall up mastoidectomy and removal of tympanosclerotic plaques. Ossicular reconstruction was done in all patients with tympanosclerosis with good hearing outcomes except in two patients who had extensive fixation of the stapes footplate, where no reconstruction was possible.
DISCUSSION

Otitis media constitutes a spectrum of infectious and inflammatory diseases that involve the middle ear and includes acute otitis media (AOM), otitis media with effusion (OME) and chronic suppurative otitis media (CSOM). The clinical features and sequelae of otitis media depend on the duration, severity and progression of the disease. CSOM has an incidence of approximately 4.8% and the complication rates may be as high as 12.5%. The world health organization considers CSOM prevalence of ≥4% indicative of a serious public health problem. Episodes of negative ear pressure and middle ear inflammation can result in middle ear and tympanic sequelae such as tympanosclerosis, atrophy and atelectasis. Hearing loss due to chronic otitis media can significantly impact language and social skills development, school attendance and educational outcomes. Chronic otitis media is associated with intracranial and extracranial complications including mastoiditis, labyrinthitis, facial palsy, meningitis, brain abscess formation, and sigmoid sinus thrombosis and early detection and management is therefore paramount.

There has been a reduction in otogenic complications of CSOM from 2.3% to 0.04% after the introduction of effective antimicrobial agents since 1930s. Otitis media has a multifactorial etiology with anatomical variations, cell biology of the middle ear cleft (middle ear cavity, mastoid, eustachian tube) and nasopharynx, as well as the pathophysiology including the interaction between microbial agents and host immune response playing a part. Inheritance of AOM and CSOM has been reported to be between 40-70%. The prevalence of CSOM tends to be significantly more in patients with gastroesophageal disease (GERD), craniofacial abnormalities (e.g., cleft lip/palate) and autoimmune and immunodeficiency states. Factors such as overcrowding, malnutrition and inadequate immunization may contribute to a higher prevalence of CSOM.

Otitis media is one of the commonest otologic diseases requiring surgery. Challenging situations are faced by the otolaryngologist, especially in the presence of complex, advanced disease. The difficulties during surgery may depend on the pathology viz. extensive granulations, tympanosclerosis, cholesteatoma, tuberculous otitis media, and presence of dual pathology such as otitis media with otosclerosis. In pediatric patients, cholesteatoma is invariably very extensive and surgery must be meticulously done by an experienced otologist. Otitis media in patients with cleft palate or syndromes such as Treacher Collins, down syndrome may pose challenges in surgical management.

In presence of advanced cholesteatoma, signs and symptoms of complications include sensorineural hearing loss, headache, dizziness, facial nerve paralysis, altered mental status, etc. Cholesteatoma in children is more extensive than in adults due to extensive mastoid pneumatization. High-resolution CT and MRI are the imaging techniques of choice to assess the extent of cholesteatoma, to look for complications and plan management. Labyrinthine fistula is one of the most common complications of cholesteatoma with a frequency varying approximately from 4% to 12% and may cause sensorineural hearing loss. The fistula most commonly involves the lateral semicircular canal. It is managed by canal-wall-down mastoid surgery, removal of the matrix, and sealing of the fistula with temporalis fascia, temporalis fascia and fibrin glue, or temporalis fascia and bone pate. Cochlear fistulae result in a higher incidence of sensorineural hearing loss. Dehiscence of the facial nerve is most frequently observed in the horizontal tympanic portion of the facial nerve near the oval window. The presence of lateral semicircular canal fistula increases the risk of facial nerve dehiscence by about 4.7 times. Tegmen erosion with dural exposure is one of the major reasons for recurrence of disease. Using bipolar cautery to devitalize the epithelium helps ensure complete clearance of cholesteatoma.

Intra-operative CSF leak can be managed by muscle plug and obliteration of the cavity. The subarachnoid space should not get exposed to cholesteatoma or chemical meningitis can ensue. During revision mastoidectomy, particular care should be taken especially in the presence of fungus cerebri (brain herniation). The presence of intracranial complication requires combined neurosurgical and otological clearance. Involvement of the jugular bulb, sigmoid sinus, internal carotid artery involvement should be identified pre-operatively by imaging and managed carefully. Infection of the petrous apex is challenging to manage because of its proximity to the middle and posterior cranial fossae and requires management by an experienced otologist.

Following resurgence of mycobacterium tuberculosis world-wide, the incidence of TBOM may now be on the rise. The classic clinical features of tuberculous otitis media were described in 1953 by Wallner as painless otorrhea, multiple tympanic membrane perforations, pale granulations, ipsilateral facial nerve paralysis, early severe hearing loss and bone necrosis, including sequestrum formation. Complications of TBOM include facial palsy, mastoiditis, labyrinthitis, meningitis, and osteomyelitis of the petrous pyramid. Hearing loss out of proportion to clinical findings, presence of complications, failure to respond to medical therapy, post-mastoidectomy recurrence of granulation tissue, slow wound healing, persistent otorrhea, formation of bony sequestra must arouse suspicion of TBOM. Currently, the major criteria for diagnosis of TBOM are histopathological demonstration of AFB, smear/culture of ear discharge showing acid fast bacilli, and positive polymerase chain reaction. Minor criteria are multiple tympanic membrane perforations, abundant pale granulations, severe hearing loss often with cochlear...
involvement, facial palsy, presence of bony sequestra and constitutional symptoms. The criteria for diagnosis are one major and 2 minor criteria. In the absence of positive major criteria, presence of three or more minor criteria should arouse a high level of suspicion of TBOM.13 A combination of clinical criteria and diagnostic tests, is necessary for diagnosing tuberculous otitis media.

Hearing improvement by ossicular chain reconstruction is possible following canal wall down surgery for cholesteatoma.14 In chronic otitis media, if incus and stapes are involved rather than only the incus, the lever mechanism for conduction of sound is lost during ossicular reconstruction and the hearing outcomes may not be satisfactory.15 Ossicular reconstruction may be challenging in certain situations such as extensive tympanosclerosis with stapes footplate fixation or disease extending into the cochlea. In patients with extensive tympanosclerosis, hearing reconstruction by ossiculoplasty may be challenging. Tympanosclerosis depending on its size, site of involvement and ossicular mobility can impede sound transmission and can interfere with satisfactory hearing outcomes following tympanoplasty.16 In patients with stapes fixation, stapes mobility may sometimes be restored by plaque removal; however severe involvement of the stapes is generally treated by stapedotomy as a staged procedure or a hearing aid. Stapedotomy may be complicated by a floating footplate, where there is an increased risk of sensorineural deafness and the erosion of the long process of the incus due to CSOM may not allow proper attachment of the prosthesis.17 Therefore revision surgery for complex otitis media is fraught with several risks and challenges and is best performed by an experienced surgeon.

In our study, several challenging situations in chronic otitis media surgery were encountered and managed successfully over the years. Pre-operative radiology was found to be invaluable to study the extent of disease and complications. Long-term follow-up is necessary after mastoid surgery, especially in the presence of challenging situations or advanced disease. Diffusion weighted MRI is helpful in identifying recurrence of cholesteatoma. Technological advances in the field of otomicrosurgery with novel research in microbiology, biofilm studies, vaccine developments, oto-genetics, and better drug delivery systems may result in better management of complex chronic otitis media in the near future.18

The limitation of this study was a small sample size. Follow-up after surgery ranged from 4 months to 4 years; the lack of a long-term follow-up was a limitation of this study.

CONCLUSION

In the Indian subcontinent, patients with chronic otitis media may present in advanced stages of disease with facial nerve, skull base, labyrinth involvement, etc. and these pose intra-operative challenges. Pre-operative identification of these challenging situations is crucial to plan appropriate surgical management. Long-term otomicroscopic and occasionally radiological surveillance, is necessary to detect any disease recurrence. Management of such complex cases of otitis media has to be done by a well experienced otologist, based in a fully equipped tertiary care centre.

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