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Quality-of-Life Outcomes for Surgical Intervention in Chronic Otitis Media

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In partial fulfillment of the requirements

For the award of the degree of

DIPLOMATE OF NATIONAL BOARD OF EXAMINATIONS IN OTORHINOLARYNGOLOGY

BY

Dr. LAKSHMI VENKITARAMAN

Under The Guidance of

DR V.T.ANAND

DEPARTMENT OF OTO RHINO LARYNGOLOGY

MANIPAL HOSPITAL,

BANGALORE.

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INSPIRED BY LIFE

DECLARATION

I hereby declare that the dissertation:

Quality-of-Life Outcomes For Surgical Intervention In Chronic Otitis Media

was prepared by me under the guidance and supervision of

Dr. V.T. ANAND

Consultant, Dept. Of Otorhinolaryngology

Manipal Hospital, Bangalore

This dissertation is submitted to

National Board of Examination in partial fulfilment of the

Award of DNB in Otorhinolaryngology

Dr. LAKSHMI VENKITARAMAN

Place: Bangalore

Date:

CERTIFICATE

We hereby certify that this dissertation entitled :

Quality-of-Life Outcomes For Surgical Intervention In Chronic Otitis Media

is a bonafide work of Dr. Lakshmi Venkitaraman. during the period of 2016- 2017 in Manipal Hospital, Bangalore, under my guidance and supervision. This dissertation is done in partial fulfilment of the requirement of award of DNB in

Otorhinolaryngology

I have great pleasure in forwarding it to the National Board of Examination.

DR.V.T.ANAND

Consultant, ENT Department, Manipal hospital Bangalore

DR.E V RAMAN

HOD and Consultant, ENT Department, Manipal Hospital, Bangalore

Chief of Clinical Services

Manipal Hospital

Bangalore

Date:

Place:

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My appreciation goes out to “TEAM STATISTICS” for their assistance in data analysis.

Place

Date:

LIST OF ABBREVIATIONS USED

(In Alphabetical Order)

CES:CHRONIC EAR SURVEY

COM:CHRONIC OTITIS MEDIA

COMOT-15:CHRONIC OTITIS MEDIA OUTCOME TEST–15

CT:COMPUTER TOMOGRAPHY

EUM:EXAMINATION UNDER MICROSCOPE

GORD:GASTRO OESOPHAGEAL REFLUX DISEASE

HRQOL:HEALTH RELATED QUALITY OF LIFE

IL:INTER LEUKIN

MRI: MAGNETIC RESONANCE IMAGING

MRM: MODIFIED RADICAL MASOIDECTOMY

PTA: PURE TONE AUDIOMETRY

QOL:QUALITY OF LIFE

TM:TYMPANOPLASTY

TNF:TUMOR NECROSIS FACTOR

TS:TYMPANOSCLEROSIS

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INTRODUCTION

Chronic otitis media (COM) is a common disease, defined as a chronic inflammation in the mucosa of the middle ear and/or mastoid which affects approximately 2% of the population [1]. It is associated with significant functional limitations of hearing. This frequently results in communication problems impeding social interaction and professional life. In patients with severe hearing loss even a withdrawal from social activities can be observed frequently. In addition, further symptoms of COM such as persistent discharge from the ear, pain or frequent doctor visits may result in impairment of quality of life of the patients. In cases of cholesteatoma, which represents the most dangerous type of COM, complications like facial nerve paralysis, meningitis, or encephalitis may develop and potentially threaten the patient's life.

Because the main purposes of surgical intervention in COM are to remove the intractable pathologic tissue and restore the normal functions of the middle ear as a sound conductor and the mastoid cavity as an air reservoir, the clinical outcome measurements of ear surgery have been based on disease control rate and audiologic result. But the assessment of treatment results on the basis of functional diagnostics, survival rates, or similar parameters alone does not mirror subjective experiences of the patients. Hence, the importance of measuring subjectively assessed quality of life (QOL) is steadily increasing in clinical medicine.

Various studies has been done where in surgical outcomes as well as quality of life assessment based on frequency of symptoms has been measured but never has the subjective assessment of their severity by the patients been measured. Therefore, it was decided to use disease specific QOL questionnaire which covers subjectively assessed disease-specific QOL: the so-called Chronic Otitis Media Outcome Test 15 (COMOT-15)[2]. This instrument consists of three subscales called ear symptoms (ES, questions 1-6), hearing function (HF, questions 7-9), and mental health (MH, questions 10-13), which form the overall score (OS, questions 1-13). In addition, one question on the general evaluation of the impact of COM on QOL (question 14)

and one question to indicate the frequency of doctor visits in the last six months as a result of COM (question 15) are asked. The total score and the subscores are transformed to a 0-100 scale by dividing the sum of the raw scores of the items by the sum of spans of the items followed by multiplying by 100.

It is important to know the outcome of these routine surgeries for proper counseling of the patient before surgery. As the aim of these surgeries is to improve the quality of life of the patient, a subjective improvement of symptoms is expected .A knowledge about the degree of improvement and the symptoms that are most likely to improve will help us in enlightening regarding outcome.

Tympanoplasty is a surgical technique to repair a defect in the tympanic membrane with the placement of graft along with ossicular reconstruction without mastoid surgery. The goal of this surgical procedure is not only to close the perforation but also to improve hearing. Perforation of the tympanic membrane is nature's way of maintaining middle ear ventilation under the pressure of inflammatory process in the middle ear cleft.[3]

Simple mastoidectomy involves removing the mastoid cortex and varying amounts of the air cell system, depending on the disease process.

Canal wall up mastoidectomy involves a more complete removal of the air cell system than simple mastoidectomy. Because this procedure and simple mastoidectomy maintain the superior and posterior canal walls intact, however, there is some potential overlap. Usually, canal wall up mastoidectomy includes a facial recess approach, and this addition uniquely qualifies the procedure.

The canal wall down mastoidectomy involves a thorough removal of the mastoid air cells, aggressive saucerization of the cortical edges of the mastoid, a complete removal of the superior and posterior canal walls, and a meatoplasty.

Modified radical mastoidectomy refers to the Bondy procedure, in which disease limited to the epitympanum is simply exteriorized by removing portions of the adjacent superior or posterior

canal wall. The uninvolved middle ear is not entered, and the ossicular heads is maintained in place as a lining for the created cavity.

Revision surgeries were performed in those patients who have undergone either tympanoplasty and or mastoidectomy in the past, whose surgery had failed. These paients underwent either revision tympanoplasty or revision tympanomastoidectomy.

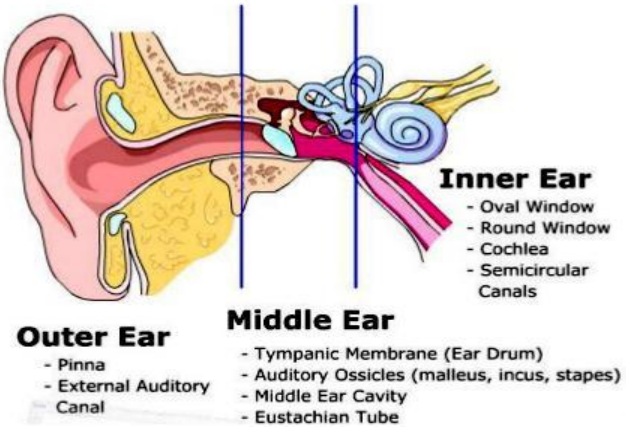


Fig1: Ear

HISTORY

The diagnosis of chronic otitis media (COM) implies a permanent abnormality of the pars tensa or flaccida, most likely a result of earlier acute otitis media, negative middle ear pressure or otitis media with effusion. COM equates with the classic term chronic 'suppurative' otitis media that is no longer advocated as COM is not necessarily a result of 'the gathering of pus'. However, the distinction remains between active COM, where there is inflammation and the production of pus, and inactive COM, where this is not the case though there is the potential for the ear to become active at some time. A third clinical entity is healed COM where there are permanent abnormalities of the pars tensa, but the ear does not have the propensity to become active because the pars tensa is intact and there are no significant retractions of the pars tensa or flaccida. 'Healed COM' can also be the end result of successful surgery. The differences are

summarized in Table 1. Our current ability to accurately assess an individual's ear, particularly with magnification, has made redundant the earlier, mainly anatomical, distinction between 'tubotympanic' and 'attico antral' disease. The terms 'safe' and 'unsafe' are incorrect and misleading as complications can occur from any ear with active COM irrespective of its pathology.

PATHOLOGY AND PATHOGENESIS

A number of histopathological changes can develop in the middle ear and mastoid in COM. Some changes are the direct result of infection and inflammation, while others represent the host response to the disease process. Taken together, these changes lead to the symptoms and signs of COM and also play an important role in determining success or failure of tympanomastoid surgery for COM. Therefore, insight into the histologic changes in COM can improve a clinician's diagnostic and therapeutic capabilities by enabling more rational decisions regarding selection of cases and surgical techniques to optimize control of disease and restoration of hearing.

Chronic otomastoiditis without cholesteatoma is marked by the presence of irreversible inflammatory changes within the middle ear and mastoid. The factors that allow acute infections within the middle ear and mastoid to develop into chronic infections are unclear. Aeration of the middle ear, antrum, and mastoid depends on the free movement of gases from the eustachian tube into the mastoid air cells. In the human temporal bone, gases must travel around the ossicles in the epitympanic space to get into the antrum. Proctor [4] showed that the middle ear is separated from the antrum not only by the ossicles, but also by mucosal folds. Edema and inflammation with granulation tissue may block the communicating openings between mucosal folds, preventing drainage of the antrum and mastoid. Chronic obstruction of the attic and antrum with infection leads to “irreversible” changes in the mucosa and bone of the antrum and mastoid. Granulation tissue within the temporal bone can lead to bone erosion. The bacteria that are found in cases of chronic otitis media generally are P. aeruginosa , S. aureus and Klebsiella pneumoniae .

TABLE 1: PATHOLOGY OF SUBTYPES OF COM

CLASSIFICATION

COM CLASSIFICATION	SYNONYMS	OTOSCOPIC FINDINGS
HEALED COM	TYMPANOSCLEROSIS, HEALED PERFORATION	Thinning and/or local or generalized opacification of the pars tensa without perforation or retraction
INACTIVE MUCOSAL COM		Permanent perforation of the pars tensa but the middle ear mucosa is not inflamed
INACTIVE SQUAMOUS COM		Retraction of the pars flaccida or pars tensa (usually posterio-superior) which has the potential to become active with retained debris
ACTIVE MUCOSAL COM		Permanent defect of the pars tensa with an inflamed middle ear mucosa which produces mucopus that may discharge
ACTIVE SQUAMOUS COM		Retraction of the pars flaccida or tensa that has retained squamous epithelial debris and is associated with inflammation and the production of pus, often from the adjacent mucosa

PATHOLOGY OF SUBTYPES OF COM

Inactive mucosal COM (dry perforation) :

There is a permanent perforation of the pars tensa, but the middle ear and mastoid mucosa is not inflamed. A perforation may be completely surrounded by a remnant of the pars tensa, (figure2) or a part of the perforation may extend to the fibrous annulus. The lamina propria around a perforation is sometimes thickened due to proliferation of fibrous tissue The mucocutaneous junction is usually located at the margin of the perforation.

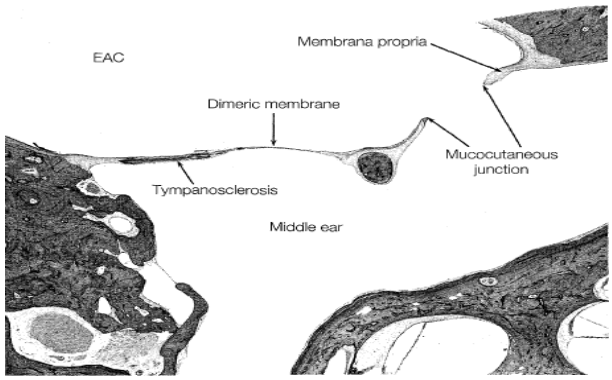


Figure 2: Axial temporal bone section showing dry perforation of the anterior part of the pars tensa. The mucocutaneous junction is located at the margins of the perforation. The drum remnant anterior to the perforation shows fibrous thickening affecting its middle layer, the membrana propria. There is also a dimeric membrane and tympanosclerosis in the posterior part of the tympanic membrane.
EAC = external auditory canal.

Active mucosal COM (perforation with otorrhoea):

There is chronic inflammation within the mucosa of the middle ear and mastoid, with varying degrees of oedema, sub mucosal fibrosis, hypervascularity and infiltration with lymphocytes, plasma cells and histiocytes. Areas of the mucosa may ulcerate with proliferation of blood vessels, fibroblasts and inflammatory cells, leading to the formation of granulation tissue. There is production of mucopurulent discharge which drains via a tympanic membrane perforation. The mucosal changes may progress and coalesce to form 'aural polyps' that can protrude through defects of the tympanic membrane. It is important to realize that the inflammatory changes described above occur not only in the tympanic cavity, but in the entire middle ear cleft including the mastoid antrum and various air cell tracts of the temporal bone[5, 6.] Active mucosal COM is often associated with resorption of parts or all of the ossicular chain ('resorptive osteitis,)[6.] The long process of the incus, stapes crurae, body of incus and manubrium are involved in that order of frequency[6] .

Inactive squamous epithelial COM (retraction. atelectasis and epidermization):

Negative static middle ear pressure can result in retraction (atelectasis) of the tympanic membrane. A 'retraction pocket' consists of an invagination into the middle ear space of a part of the eardrum, and may be fixed when it is adherent to structures in the middle ear or free when it can move medially or laterally depending on the state of inflation of the middle ear.

Active squamous epithelial COM (cholesteatoma):

The hallmark of a cholesteatoma is its retention of keratinous debris, figure 3. Thus, a 'keratoma' would be histologically a more correct term[3.] A cholesteatoma can be filled with keratin and be quite dry, or be associated with active bacterial infection leading to profuse malodorous otorrhoea. Cholesteatomas are potentially dangerous because of their potential to incite resorption of bone, leading to intratemporal or intracranial complications (figure 3)

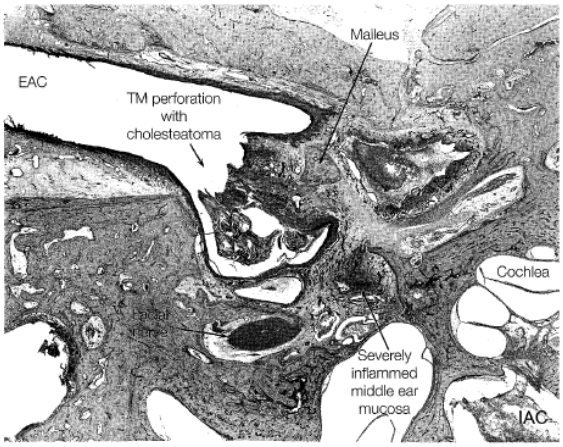


Figure 3: Axial temporal bone section showing active squamous epithelial COM (cholesteatoma). There is a posterior perforation of the pars tensa extending to the annulus with ingrowth of squamous epithelium into the middle ear forming a cholesteatoma. Note the retained keratin within the cholesteatoma sac. There is granulation tissue within the middle ear that surrounds the cholesteatoma sac. EAC = external auditory canal. lAC = internal auditory canal.

Healed perforation (dimeric membrane)

Loss of the lamina propria of the tympanic membrane due to atrophy or failure to reform during healing of a perforation leads to a 'dimeric' membrane that consists of epidermis and mucosa. Such a thin membrane is prone to retraction if there is negative static middle ear pressure.

SURGICAL PATHOLOGY

Tympanic membrane grafts

Tympanic membrane perforations can be successfully repaired using a variety of graft materials. Commonly used grafts include autologous temporalis fascia, perichondrium, cartilage and adipose tissue. Histologically, tympanic membrane grafts become lined by squamous epithelium on the ear canal side and middle ear mucosa on the tympanic cavity side . The graft itself becomes the middle or connective tissue portion of the reconstructed drum[6.] Nevertheless, grafted tympanic membranes can function well, similar to the native drum.

Mastoidectomy cavities

A canal wall-down mastoidectomy cavity that is dry and well healed is characterized histologically by a lining of keratinized squamous epithelium on a layer of subepithelial fibrous tissue and underlying sclerotic mastoid bone[7] (figure 4). A chronically draining or infected mastoid cavity can arise as a result of a number of factors:

(1) recurrent or residual cholesteatoma;

(2) mechanical factors promoting retention of debris such as a high facial ridge, meatal or canal stenosis; and

(3) suppuration in unexenterated cells of the mastoid and middle ear, especially the tegmental cells, and cells of the sinodural angle, mastoid tip and facial recess[8] figure 5.

On occasion, a cavity remains active because of superficial granulation tissue, rather than disease in underlying unexenterated cells.

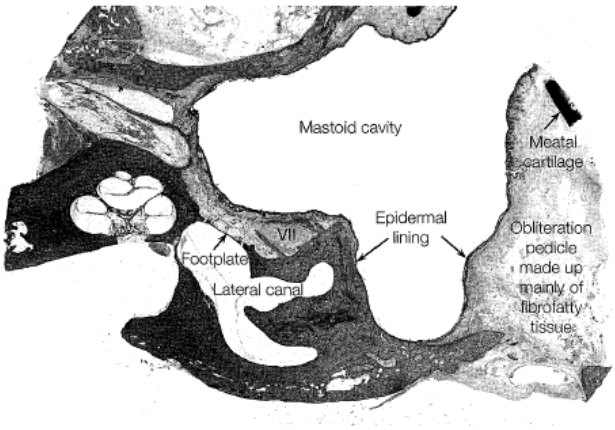


Figure 4: Axial temporal bone section showing post tympanomastoidectomy status for cholesteatoma. The cavity is dry, well healed, and lined by a layer of keratinized squamous epithelium. The mastoid was obliterated by an inferiorly based, pedicled tissue flap that is seen histologically to consist mainly of fibrofatty tissue.

Objectives of surgery

The primary objective of surgery for COM is to eradicate infection and disease and make the ear safe and dry. Success in achieving this primary objective of surgery for COM appears to depend on strict adherence to surgical principles.

A second objective of surgery for COM is to restore hearing to serviceable levels by means of tympanoplasty.

Other factors also play a significant role including biological and pathological factors[9] and factors that influence the mechanics and acoustics of middle ear reconstruction[10.]

A number of pathological mucosal changes can occur within the middle ear as a healing response to COM or as a sequel to surgical trauma. The changes include deposition of fibrous tissue, formation of adhesions and neo-osteogenesis. These tissue responses can compromise middle ear sound transmission in a variety of ways: fixation of the stapes footplate, ankylosis or displacement of an ossicle strut, immobilization of the round window, immobilization of the tympanic membrane, as well as more subtle interference with the mechanics of the tympanic membrane orossicles. Another factor leading to failure of tympanoplasty is total or partial non-aeration of the middle ear and development of negative static middle ear pressure. Total non - aeration of the middle ear is believed to be due to Eustachian tube dysfunction and can lead to severe tympanic membrane atelectasis, middle ear effusion, fibrocystic sclerosis of the middle ear or a combination of these changes.

PREVALENCE OF COM

The prevalence of adult middle ear disease in the British population was obtained from the UK National Study of Hearing (both active and inactive) was 4.1 percent (with 3.1 percent of individuals having unilateral and 1.0 percent of individuals having bilateral disease). The prevalence of healed, inactive and active COM was 12, 2.6 and 1.5 percent, respectively. There was no sex difference in the prevalence of COM. Individuals in the 41-80-year-old age group were twice as likely to have COM as those in the 18-40-year age group. COM has a higher prevalence in lower socioeconomic groups, with manual workers having twice the prevalence than non manual workers.[11.]

AETIOLOGY OF COM IN GENERAL

1) Acute otitis media and otitis media with effusion

Childhood acute otitis media and otitis media with effusion can both cause long-term changes of the tympanic membrane. Histological degeneration of the tympanic membrane occurs in the outer and inner fibrous layers of the lamina propria and in the sub mucosal layer[12] . These changes may reduce the elastic properties of the tympanic membrane, making it more susceptible to chronic perforation or retraction.

2) Genetics and race

The incidence of COM varies in different populations and, in the developed world, is highest in Eskimos, native Americans, New Zealand Maoris and Australian aborigines.[13]

3) Environment

As has already been stated, the prevalence of COM is higher in lower socioeconomic groups. The reason for this is multifactorial, such as
maternal smoking and day care attendance.

4) Eustachian tube dysfunction

Eustachian tube dysfunction is more common in patientscwith COM than in normal individuals [14.] It is not known however, if the Eustachian tube dysfunction is the initiating factor in COM or whether it is a result of COM.

5) Gastro-oesophageal reflux

There are only anecdotal evidence exists that there may be a relationship between GORD and COM.[15]

6) Craniofacial abnormalities

The incidence of COM in cleft palate patients followed up to ten years of age is around 20 percent, with 2 percent of them having a cholesteatoma [16]The tensor veli palatine muscle is hypoplastic in cleft palate children and may predispose to Eustachian tube dysfunction.[17]

7) Autoimmune disease

It is not known if autoimmune disease predisposes to COM. In one study, however, COM was present in 29 percent of consecutive patients with ankylosing spondylitis.[18]

8) Immune deficiency

Although suggested [19], there is no evidence to support the claim that patients with immune deficiencies have higher chances of getting COM, it is found than patients with acquired immune deficiency syndrome (AIDS) have a higher rate of COM.

DIAGNOSIS AND ASSESSMENT

Otoscopy with the aid of a microscope is the 'gold standard' for the diagnosis of COM.

History taking and investigations are an aid to management rather than to diagnosis.

Figure 5: Examination Under Microscope

Otoscopy

Whenever there is a suggestion of COM, otoscopy is aided by having the patient lying on a couch, which allows the head to be positioned variably, and microscopic magnification to be used with an appropriately sized speculum to hold the external auditory meatus open. This also greatly facilitates aural toilet, which is almost always required to some extent to fully visualize all areas. A rigid endoscope (figure 6) gives a good general overall review of anatomy and pathology that is particularly applicable if there is an open mastoid cavity.

Figure 6: Otoendoscopic picture of post MRM cavity

Site Of Pathology

Anatomically the pars tensa can be divided into four quadrants (figure 7) but pathology, such as perforations, tend to be anterior, posterior or inferior. Hence division into thirds rather than quarters is preferred (figure 8). By definition, all perforations of the pars tensa are 'central', indicative of 'tubo-tympanic disease'. The pars flaccida in the attic has always to be cleared of any debris and assessed for pathology which may occur alone or along with pars tensa disease.

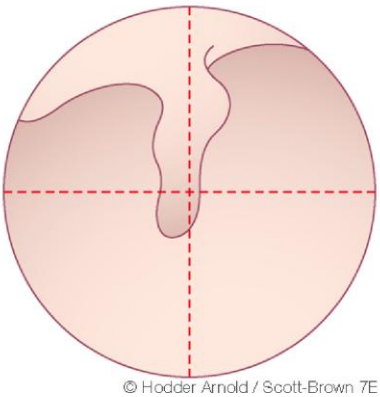


Figure 7: quadrants of TM

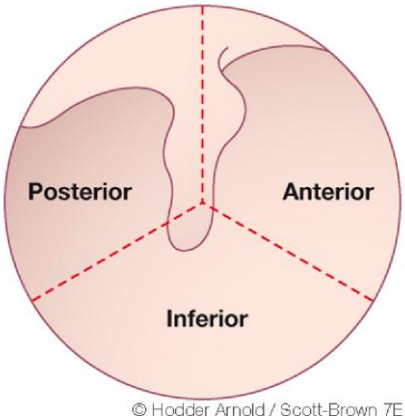


Figure 8: 3- thirds of TM

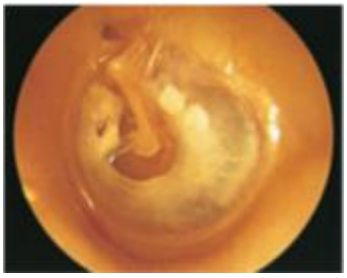
Active or inactive?

A decision as to whether an ear is currently active, i.e. inflamed with the production of inflammatory products including pus, is primarily based on visualization of an inflamed mucosa and secretions.

Otoscopic Diagnostic Categories

Healed Otitis Media

This term is given to an ear where the pars tensa is intact but abnormal. The most common abnormality of the pars tensa are chalk patches / tympanosclerotic plaques (figure 9 and 10). The other abnormality covered by the definition of healed otitis media is thin replacement membranes, usually circular.



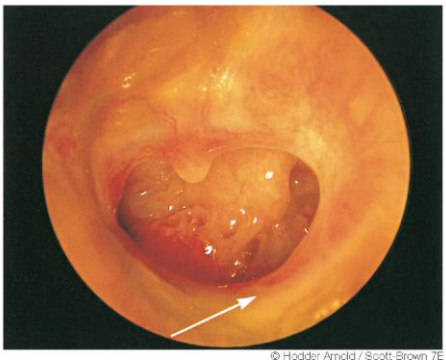
Inactive (Mucosal) COM

This diagnosis implies a permanent perforation of the pars tensa and that the middle ear mucosa, as seen through the perforation is inactive (figure 11).

Figure 11: inactive central perforation of left TM.

Active (Mucosal) COM

Activity is evident, usually with a generally inflamed middle ear mucosa, but sometimes with granulation tissue that is localized and which can become polypoidal (Figure 12, 13). In both active and inactive COM, particularly when the defect involves the posterior third, the intactness or otherwise of the ossicular chain should be assessed.



Inactive (Squamous) Retractions

These can occur in the pars tens a or the pars flaccida. Pars tensa retractions are primarily of the posterior tympanic membrane, the classification most used to document their degree being that of Sade and Berco[20] (figure 14)

Figure 14: Retraction of pars flaccida, TM adherent to neck of malleus (right ear).

Cholesteatoma (Active Squamous Disease)

Cholesteatomas are the end stage of (squamous epithelial) retractions of the pars tensa or flaccid that are not self-cleansing, retain epithelial debris and elicit a secondary, inflammatory mucosal reaction. (Figure 15 and 16)

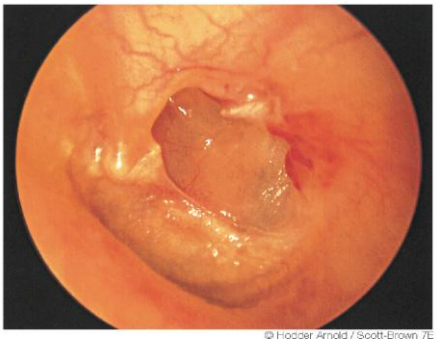


Figure Figure 15: Retraction of pars flaccid, right TM

Audiology

Pure-tone audiometry, air and bone-conduction with appropriate masking will provide numerical values to the degree of hearing impairment, the magnitude of the airbone gap and whether there is an associated sensorineural impairment for each of the two ears. Such information is important to inform decisions regarding management.

Radiology

Computed tomography (CT) scanning with 1.5-mm sections in both the coronal and axial planes of the temporal bone is preferred for most purposes rather than conventional radiology or magnetic resonance imaging (MRI). The latter particularly delineates intracranial pathology that can complicate COM. CT scans have a clear role in the diagnosis of COM when the tympanic membrane cannot be visualized, for example by narrowing or stenosis of the external auditory canal. Equally, if congenital anatomical abnormalities or complications of COM are suspected, radiology has a role in that it gains additional information that may guide management.

SURGICAL HISTORY

The history of otology followed the history of medicine. Otologists have sought to restore hearing loss due to infections of the eardrum since the seventeenth century. And at that time otology was mainly considering foreign body removals and management of trauma. The use of magnification at the end of eighteenth century added so much and evolved the modern otology. This historical review describes the history of otology and the development of modern techniques of ear surgery.[21]

Historical Background

The early Egyptian healers on 1000 B.C. had a large number of prescriptive available for the treatment of ear problems. Many types of otologic problems were treated with herbs and other extracts. It is of note that ear disease was often attributed to brain disease, and efforts directed accordingly. One of the earliest physicians, Hippocrates, who is on 400 B.C. recognized that a painful, discharging ear with fever was a life-threatening condition and described classic symptoms of otitis media.

Surgery for a mastoid infection was first proposed five centuries ago by Ambriose Paré (1510-1590) on the young King Charles II of France, who was dying with a high fever and discharging ear. Thus another 100 years passed, before the next recorded attempt at otologic intervention. In 1640, Banzer published an account of a case of tympanic membrane repair. A pig's bladder was stretched across an ivory tube and placed in the ear. This marks a trend in repair of the drum, that of placing artificial membranes in the ear temporarily. Around that time 2 textbooks were published 20 years apart discussing ear problems, the first one was "The treatise of Guichard Joseph Duverney (1648-1730)". The first documented successful surgery for a mastoid infection was performed by Jean Petit of Paris in 1774.[22] Shortly thereafter, in 1776, a Prussian surgeon named Jasser successfully performed a mastoid operation on a soldier with a draining ear. No significant descriptions of further ear surgery exist in the literature until 1853. Then, a procedure was published by Sir William Wilde for sepsis and suppuration of the ear. He described the post auricular incision and removal of the mastoid cortex for purulent infections. This was the beginning of the modern era of otologic surgery. Nearly every operation that followed until the present built upon this basic technique and expanded the indications and techniques. Twenty years later, in 1873, Herman Schwartze published both the indications and the procedure for

removing the mastoid. The simple mastoidectomy became a mainstay in the treatment of acute mastoiditis and saved many lives. Whiting described the state of the art: "As a life saving measure, few surgical procedures equal and none surpass in efficiency the modern mastoid operation (Rizer, 1997). Also in 1873, von Troltsch and, later, von Bergmann expanded the simple mastoidectomy of Schwartze to include the attic and antrum. This increased the success of mastiod surgery.[23, 24] No significant changes in the therapy of otologic disease occurred until the advent of the operating microscope and antibiotics in the 1950.[25, 26]

Parallel to these developments were efforts to improve hearing. In 1853, Toynbee placed a rubber disk attached to silver wire over a perforation with hearing improvement .[27]In 1877, Blake introduced the idea of placing a paper patch over the perforation.[28] Then, with the operating microscope, they became able to examine the ear and developed instruments for manipulating the drum and ossicles. House, Sheehy and Glasscock developed techniques for creating a satisfactory onlay graft.[29, 30] Storrs switched to fascia, and Patterson determined the reasons for the success of fascia as a grafting material.[31, 32]

Control of Ear Infections

It was critical that infection be controlled before hearing could be reconstructed. Although the radical mastoidectomy resulted in surgical control of infection, much was to be desired in the way of improving the patient's hearing. In 1906, the first conservative surgical procedures were described by Health and Bryant. Both described modifications of the radical mastoid operation that preserved the tympanic membrane and ossicles. Their procedures did not gain wide acceptance, presumably because of complications.[33, 34]

In 1910, Bondy described the classic modified radical.[35] Opinions of the day were against conservation surgery, and the procedure was neglected until the 1940s, when it was reintroduced and popularized by Day and Baron.

Antibiotics and Instrumentation

By the early 1930s, acute and chronic ear infections were adequately managed surgically. Medical therapy of the ear was becoming useful with the availability of sulfonamide antibiotics. Instrumentation facilitated further development of mastoid and middle ear surgery. The dental drill was used for mastoid exenteration. Cautery helped control hemorrhage. The improvement of

techniques in general anesthesia, as well as the availability of blood replacement and intravenous fluid therapy, spurred and sustained further advances in surgical techniques.[36]

Magnification

The operating microscope and the intraoperative use of ocular magnification were revolutionary advances, essential to the fledgling art of microsurgery and otology. Holmgren, a pioneer in fenestration surgery of the horizontal canal for otosclerosis, was the first otologist to use the binocular operating microscope.[37] Delays in bringing this device to the United States led Julius Lempert to implement the alternative technique of optic loop. Shambaugh, who tutored under Lempert, was finally able to bring the operating microscope to the United States and became the first American to use the instrument routinely in surgery.

Tympanoplasty

Many of the dramatic advances in medicine and surgery in the 19th century occurred in Germany. In 1863, a landmark discovery of the workings of the middle ear was made by Herman von Helmholtz. His description of the middle ear transformer mechanism was essentially ignored. It was not understood until 90 years later. This work formed the foundation for all reconstructive middle ear surgery. The concept of a tympanoplasty is credited to Berthold, who in 1878 was thought to have performed the first true tympanoplasty. He deepithelialized the tympanic membrane by applying a court plaster against the membrane for 3 days, then removing it with the epithelium. A skin graft was then applied.[38] Nothing more was done with the technique until 1944, when tympanoplasty was reintroduced by Schulhof and Valdez. In 1952 the procedure was publicized and popularized by Wullstein using split-thickness skin grafts**.** Zollner began his work in 1952 and finished it a year later. They recognized that unless the ossicles were extensively involved by disease, a radical mastoidectomy would lead to an unnecessary sacrifice of middle ear structures. Furthermore, they recognized and expounded on the principles introduced by von Helmholtz almost a century before: a new tympanic membrane and an adequate tympanic cavity with intact ossicles are necessary for the transformation of sound pressure upon the oval window as well as sound protection of the round window .[39]The work of these two surgeons integrated the previous works and formed the basis of modern otologic practice. The broad availability of the Zeiss operating microscope and micro instrumentation spurred further advances in middle ear surgery.[40]

Evolvement of Grafting Techniques

The full-thickness and split-thickness skin grafts of Wullstein and Zollner laid over the denuded drum remnant were prone to infection, graft failure, and iatrogenic cholesteatomas.[41, 39]They became boggy, edematous, and desquamative as a result of the presence of sweat and sebaceous glands. Histologic studies revealed that years after grafting onto the drum, sweat glands, hair follicles, and sebaceous glands were still present. The graft "take" rate, even in ideal cases, was only 71%.[42]

Canal skin grafts

In 1956 it occurred to Sooy that the most readily available skin was the skin

of the ear canal. A canal skin pedicle flap was rotated onto the drum remnant for closure of marginal perforations.[43]House and Sheehy advanced the technique by using the canal skin as free grafts laid over the drum remnant. As ear canal skin was devoid of glands, it was thought that the problems associated with full thickness and split-thickness skin grafts could be avoided. The take rate was initially excellent in tympanoplasty cases (97%), but the problems of desquamation and frequent cleaning persisted. On further follow-up, reperforation occurred, so after 5 years, only 77% of cases were successful. The major problem was that the canal skin did not hold up well in the presence of infection. The grafts were not robust and thus reperforated.[44]

Vein grafts

This technique of placing a vein graft medial to the damaged tympanic membrane was accidentally discovered when the drum was torn during fenestration of the oval window (stapedectomy). Shea placed a small piece of vein underneath the perforation and the drum healed completely in 3 days.[40] Tabb subsequently replicated the results of Shea's technique. As mesothelium, vein was an excellent graft material, but vein grafts tended to atrophy after a few months and occasionally reperforated. They did not form durable repairs of the drum.[45]

Temporalis fascia

Seeking to avoid these complications, Hermann described the use of temporalis fascia as a graft in 1960, performed the first fascia graft in the United States in 1960. The superior qualities of fascia, its ready availability in the operative field, and its ideal handling qualities made it the standard for drum grafting, as it is today.

Perichondrium grafts

Goodhill used perichondrium for grafting the tympanic membrane in the 1960s. Although acceptable, it has not been widely used.[46]

Mastoidectomy

The first scholarly treatise "mastoid surgery for suppurative disease" was by Schwartze in 1873.[47, 48]The procedure he described was a cortical mastoidectomy with limited exenteration of mastoid air cells. For acute and coalescent mastoiditis, which were prevalent in the preantibiotic era, this procedure proved remarkably efficacious. As one might expect, however, the simple mastoidectomy rarely cured chronic otitis media or cholesteatoma. During the next 20 years, it became evident that creating an open cavity was necessary for these diseases, and in 1890, Zaufal described removing the superior and posterior canal wall, tympanic membrane, and lateral ossicular chain, a procedure now known as the radical mastoidectomy.[49]This procedure was modified by Bondy, who recognized that disease limited to the pars flaccida could simply be exteriorized, leaving the uninvolved middle ear alone. His description of the "modified radical mastoidectomy" or "Bondy procedure" in 1910 represented one of the first reports addressing hearing function.

Interest in hearing preservation and restoration gained further attention after Lempert introduced the fenestration operation in 1938, and Zollner and Wullstein described tympanoplasty techniques in the early 1950s.[50, 51, and 52]During the next decade, Jansen, Sheehy, and others extended these principles of restoring function and maintaining normal anatomy with the introduction of the intact canal wall mastoidectomy with facial recess approach.

SURGICAL TECHNIQUE

Tympanoplasty

Tympanoplasty is a surgical procedure performed to eradicate infection and restore the function of the middle ear.[53]Wullstein introduced a classification for tympanoplasty that is based on two things: (1) the remaining structures of the middle ear after all pathology has been eradicated, and (2) how sound is transferred to the oval window while the round window is being protected.[54,55]Restoration of the middle ear transformer mechanism requires a secure connection

between an intact tympanic membrane and inner ear fluids. The tympanic membrane should close an air-filled, mucosa-lined middle ear cavity. Traditional teaching attributes most of the middle ear gain to the hydraulic effect, which is the ratio of the effective vibrating area of the tympanic membrane to the area of the mobile stapes footplate.[56]Round window protection to avoid phase cancellation (i.e., when sound impacts the oval and round windows at the same time) was also thought to be an important contributor to effective sound transmission to the inner ear. A perforation of the tympanic membrane causes hearing loss by reducing the difference in sound pressure across the two sides of the tympanic membrane, causing decreased ossicular coupling.[57]

Pre operative evaluation

A detailed history and careful physical examination are essential to the planning of the surgical approach and the counseling of patients regarding the expected outcome. The extent of tympanic membrane perforation and the condition of the ossicular chain are evaluated. The health of the remaining membrane is assessed, paying particular attention to atrophic areas and the degree of myringosclerosis. The size of the external canal is evaluated, and canalplasty is planned if a prominent anterior canal wall prevents complete visualization of the perforation. Comprehensive audiometric evaluation is performed, and tuning fork tests are used to confirm the audiogram. Radiographic evaluation is usually not needed if clinical examination reveals a dry central perforation. As mentioned previously, postoperative aeration of the middle ear is key to the success of tympanic membrane repair and the restoration of hearing. The otologic surgeon has no direct control over this factor, however, which depends mostly on eustachian tube function. There is currently no test that accurately predicts postoperative eustachian tube function. Some indicators—the aeration of the opposite ear, increased age in children, fewer episodes of otorrhea, and normal middle ear mucosa—may suggest reasonable eustachian tube function.

Graft material used

Temporalis fascia is the most commonly used material for the repair of tympanic membrane perforations; it was introduced for this use in the early 1960s.[58]

Formal tympanoplasty

Anesthesia

Tympanoplasty can be performed under local or general anesthesia. In children and anxious adults, general anesthesia is preferred. In either case, the ear canal skin is injected with lidocaine (usually 1%) with epinephrine (1: 100,000) for vasoconstriction.

Approaches

Three main approaches are used in tympanoplasty are transcanal, endaural, and postauricular. The approach used depends on the perforation size, the anatomy of the external auditory canal, and the surgeon's preference. Most importantly, the approach used should provide complete visualization of the perforation.

Wullstein and Zollner classified Tympanoplasty according to the type of ossicular reconstruction needed. Six types of Tympanoplasty have been classified (figure 17)

Type I Tympanoplasty: This is indicated in patients with presence of all the middle ear ossicles with normal mobility. Ossicular chain reconstruction is not needed in these patients. Efforts are made to close the perforated ear drum using temporalis fascia graft. This procedure is also known as myringoplasty.

There are two available techniques for performing myringoplasty / type I Tympanoplasty.

1. Overlay technique

2. Under lay technique

Overlay technique: Here the graft material is inserted under the squamous (skin layer) of the ear drum.

Underlay technique: This is a simpler and commonly used technique. Here the graft is placed under the tympano meatal flap which has been elevated hence the name under lay. The major advantage of this procedure is that it is easy to perform with a good success rate.

Indications of Myringoplasty:

1. Central perforation which has been dry at least for a period of 6 weeks.

2. As a follow up to mastoidectomy procedure to recreate the hearing mechanism

Prerequisites for myringoplasty:

1. Central perforation which has been dry for at least 6 weeks

2. Presence of normal middle ear mucosa

3. Intact ossicular chain

4. Good cochlear reserve

Type II Tympanoplasty: In this procedure the tympanic membrane is grafted to the intact incus and stapes. This procedure is very rarely used, since it is very rare for erosion of the handle of malleus to be present alone without the involvement of other ossicles. The neotympanum created is draped over the existing incus and stapes.

Type III Tympanoplasty: This technique is used only when a mobile suprastructure of stapes alone is present. In this surgical procedure the tympanic membrane graft is draped over the mobile suprastructure of stapes. This is also known as Columella effect. This surgical procedure is useful in patients without malleus and incus.

Type IV Tympanoplasty: This surgical procedure is performed in patients only with mobile foot plate of stapes. The grafted ear drum is draped over the mobile foot plate. In these patients there is virtually no middle ear space at all. The grafted ear drum virtually drapes the promontory.

Type V Tympanoplasty: In this surgical procedure a third window is created over the lateral semicircular canal. (Fenestra over lateral canal).

Type VI Tympanoplasty: (Sono Inversion) All sound waves enter through the round window keeping the oval window covered (reverse direction)

Ossicular grafts have revolutionized Tympanoplasty procedure these days. These grafts help in the preservation of middle ear space, as well as produces excellent improvement in hearing.

Cartilage harvested from the patient or from donor can also be refashioned and used as prosthesis.

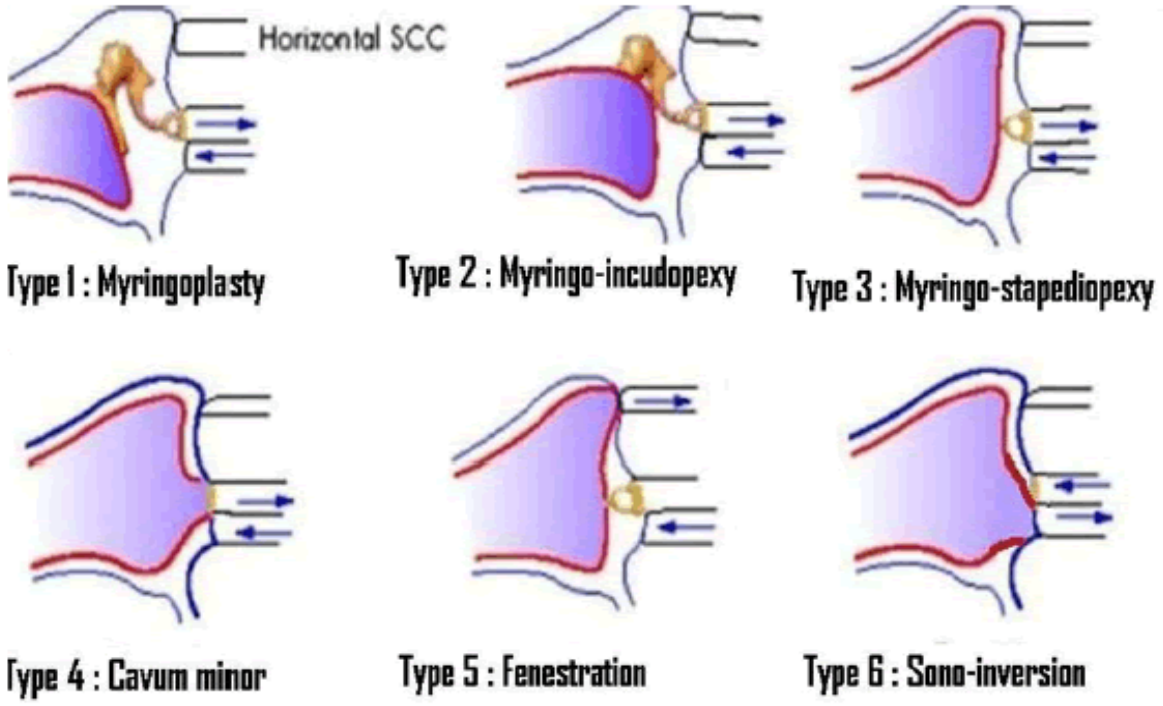


Figure: Types of tympanoplasty by Zollner and Wullstein

Mastoidectomy

The otologic surgeon has various mastoid procedures from which to choose, depending on extent of disease. In addition, variations on these standard approaches are often discussed in the literature.

Nomenclature

Simple mastoidectomy

Simple mastoidectomy involves removing the mastoid cortex and varying amounts of the air cell system, depending on the disease process. Only a limited air cell exenteration may be needed to drain a coalescent mastoiditis with subperiosteal abscess, whereas a more extensive dissection to expose the antrum would be necessary to inspect for cholesteatoma.

Canal wall up mastoidectomy

Canal wall up mastoidectomy involves a more complete removal of the air cell system than simple mastoidectomy. Because this procedure and simple mastoidectomy maintain the superior and posterior canal walls intact, however, there is some potential overlap. Usually, canal wall up mastoidectomy includes a facial recess approach, and this addition uniquely qualifies the procedure. More recent variations on canal wall up mastoidectomy include removing a portion of the canal wall, then reconstructing the defect with bone, cartilage, or an alloplastic material, to maintain the normal anatomic barrier between the external ear canal and mastoid cavity.

Canal wall down mastoidectomy

The canal wall down mastoidectomy involves a thorough removal of the mastoid air cells, aggressive saucerization of the cortical edges of the mastoid, a complete removal of the superior and posterior canal walls, and a meatoplasty.

Radical mastoidectomy

Radical mastoidectomy is a canal wall down procedure with exteriorization of the middle ear. No attempt at restoring middle ear function is made. The eustachian tube is occluded, and the malleus and incus (and possibly the stapes superstructure) are removed. The tympanic membrane remnant is excised, and no graft is placed, leaving the middle ear open. The expectation is for squamous epithelium to grow over the middle ear and mastoid cavity. This procedure is rarely performed today, but may be indicated in situations in which cholesteatoma cannot be completely excised (e.g., cochlear fistula, disease tracking into the petrous apex).

Modified radical mastoidectomy

Most of the confusion over terminology centers on modified radical mastoidectomy. Frequently, the term modified radical mastoidectomy is used interchangeably with canal wall down mastoidectomy. Classically, modified radical mastoidectomy refers to the Bondy procedure, in which disease limited to the epitympanum is simply exteriorized by removing portions of the adjacent superior or posterior canal wall. The uninvolved middle ear is not entered, and the cholesteatoma matrix on the lateral surface of the ossicular heads is maintained in place as a lining for the created cavity. Small cholesteatomas are frequently amenable to the Bondy approach

Mastoid obliteration

The indications for and extent of obliterating mastoid air cells varies considerably from surgeon to surgeon. Various materials are used, including autogenous bone and cartilage, free or vascularized soft tissue, and bioactive or biocompatible alloplastic materials. Mastoid obliteration is typically used when the canal wall has been removed to decrease the size of the mastoid cavity and make it as care-free as possible. In rare cases, the eustachian tube and external ear canal are closed, completely isolating the mastoid from the exterior.

Technique

The surgical site is prepared by shaving 1 to 2 cm of hair around the ear and injecting 5 to 10 mL of local anesthetic with a vasoconstrictor (e.g., 1% lidocaine with 1 : 100,000 epinephrine) postauricularly and within the external ear canal. To facilitate closure, the C-shaped incision is placed about 1 cm behind the postauricular crease, rather than within it. Superiorly, the incision is carried down to the temporalis fascia. Inserting a small Weitlaner retractor and lifting it laterally facilitates this dissection. The subcutaneous tissues are elevated off the fascia and easily incised. Inferiorly, the incision is extended to the anterior lateral surface of the mastoid tip. Making two periosteal incisions—one along the temporal line and the second per-pendicular to this and extending to the mastoid tip—exposes the mastoid bone itself (figure 18). The periosteum is elevated and retracted forward with the auricle. With the mastoid cortex fully exposed, the first bur cut is made along the temporal line, which approximates the level of the middle cranial fossa dural plate. It is important to recognize, however, the variability of the position of the tegmen, depending on the degree of mastoid pneumatization. The second bur cut is made perpendicular to this and tangential to the external bony canal; it should be carried inferiorly to the mastoid tip.

Figure 18: Initial bur cuts are along the temporal line and tangential to the bony canal.

Although various drill systems are available, several common principles relate to bur selection and fluid irrigation. When possible, larger rather than smaller burs are preferable for bone dissection (figure 19) with appropriate irrigation to clear bone dust from the field of dissection, to prevent excessive heat transfer to underlying structures (especially the facial nerve), and to maintain a clean cutting surface on the bur. A key landmark in performing mastoid surgery is the antrum with the dome of the horizontal semicircular canal (HSCC) along its floor. Three key principles assist this part of the dissection: saucerization, identification of the tegmen plate, and thinning the posterior canal wall. Posteriorly, one must consider the sigmoid sinus. The importance of identifying the tegmen plate cannot be overemphasized. All mastoid air cells should be removed superiorly, effectively skeletonizing this structure.

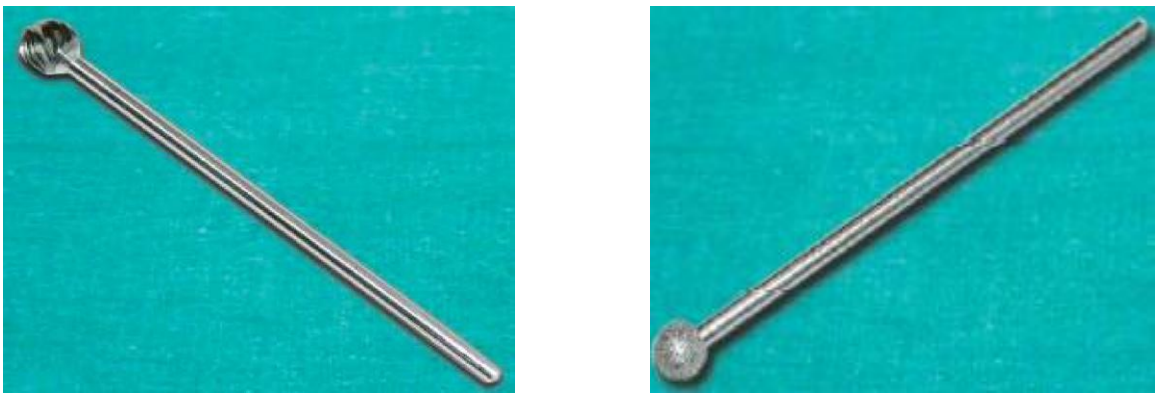


Fig 19: cutting burr tip and diamond burr tip.

QUALITY OF LIFE ASSESSMENT

Quality of life has become a prominent issue in biometry, philosophy, social science, clinical medicine, health services and outcomes research. There has been efforts to reflect the wide application of quality of life assessment and research in the biological and social sciences.
Health-related quality of life (HR-QOL) has an ever-increasing importance as an outcome parameter. For the proof of the success of surgical interventions, the evidence of an improvement of HR-QOL in addition to an improvement in objectively measurable parameters is required. To demonstrate this evidence, the availability of validated disease-specific instruments is an essential prerequisite.

COM is characterized by the clinical symptoms of hearing loss, otorrhoea, fullness of the ears, ear pain, headaches, and often tinnitus. In addition, there is usually a restriction on the ability to communicate because of the hearing loss. This often causes depression, anxiety and social withdrawal. This leads to a reduced health-related QOL in different dimensions (physical, functional, social, psychological, and familial.

Treatment of patients having chronic otitis media generally improves the disease, hearing status and prevents complications. So far, in adults, studies have been carried out with non-validated measurement tools only. Other studies were focused on the influence of reduced hearing on HR-QOL, but did not pay attention to the symptoms. These studies include validated instruments like the Hearing Handicap Inventory for Adults (HHIA) and the (modified) Amsterdam Inventory Auditory Disability and Handicap Score. Measurements of all aspects of HR-QOL in patients with CSOM with validated measurement tools were, however, to date, only rarely carried out systematically.

Until 2009 the Chronic Ear Survey (CES) has been the only validated instrument. Evaluating the CES, we came to the opinion that the clinical symptoms of CSOM are well represented in the CES, whereas functional deficits (e.g. understanding in noisy environment) or psychological impairments (e.g. anxiety, depression) were not represented. This was for us the motivation to develop and validate the Chronic Otitis Media Outcome Test 15 (COMOT-15). In this study, the COMOT-15's suitability for the detection of disease-specific QOL in patients with CSOM has been established. The assessment of treatment results with functional diagnostics test or similar parameters alone does not reflect the subjective experiences of the patients. Hence, the subjectively assessed Health related quality of life (QOL) is steadily increasing in clinical

medicine. Though there are different QOL index to measure the heath related QOL but Baumann et al developed a novel disease specific QOL questionnaire which assesses the severity of subjective symptoms; as Chronic Otitis Media Outcome Test 15 (COMOT 15).

In phase 1 the development of the Chonic Otitis Media Outcome Test (COMOT) was conducted. A group of experts identified 31 HR-QOL concepts as being relative for COM which was reduced to 15 items (COMOT-15) by sequential statistical analysis on the basis of data from 50 consecutive COM patients. In addition to the overall score (GS), three sub-scores (ear symptoms, OS; hearing function, HF; and mental being, MB) were introduced. In phase 2, validation was performed by calculating reliability, validity, and responsiveness with the data of 121 prospectively evaluated patients.

It was found that COMOT-15 showed an excellent reliability with high internal consistency (Cronbach's ά from 0.89 to 0.91) and high retest reliability coefficients (all r>0.8). Content validity was determined by a study of the literature. COMOT-15 can distinguish COM patients from healthy subjects. Global assessment of impairment of HR-QOL by COM correlated very well with the scores of COMOT-15.

REVIEW OF LITERATURE

- Rosenfeld RM, Goldsmith AJ, Tetlus L and Balzano A[59] in 1997 conducted a study- "Quality of life for children with otitis media". It was Cohort study using a 6-item quality-of-life survey (OM-6) representing the domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns. One hundred eighty-six children aged 6 months to 12 years (median age 3.4 years) with chronic otitis media with effusion or recurrent acute otitis media were evaluated. The OM-6 questionnaire was completed at entry by the child's caregiver and again at least 4 weeks after routine clinical care. Otoscopic findings, static admittance, tympanometric width, audiometric thresholds, and ear-related global quality of life (10-point visual scale) were recorded concurrently. The study proved OM-6 to be a valid, reliable, and responsive measure of quality of life for children with otitis media. The

brevity and ease of administration make the OM-6 ideal for use in outcomes studies, clinical trials, and routine clinical care.

- In another study "Outcomes assessment for chronic otitis media: the Chronic Ear Survey" by Nadol JB Jr, Staecker H, Gliklich RE[60] where the Chronic Ear Survey (CES) was used as an instrument to measure the impact of chronic otitis media and its treatment. The survey provided information regarding total ear-specific health, as well as subscore information regarding activity restriction, symptoms, and medical resource usage attributable to chronic otitis media. Application of the CES to a prospective, nonrandomized series of 147 patients revealed that patients with chronic otitis media have significantly decreased CES scores compared with unaffected controls and that surgical intervention provides a significant improvement in ear-specific outcomes.

- In a study by Richards M, Giannoni C[61] by the title, Quality-of-life outcomes after surgical intervention for otitis media, a prospective questionnaire-based outcome test was done to assess the change in disease-specific quality of life in children with recurrent acute otitis media and/or chronic otitis media with effusion treated with surgical intervention. Consecutive series of 123 children referred for surgical treatment of recurrent acute otitis media and/or chronic otitis media with effusion were included in the study. Surgery included bilateral myringotomy and tympanostomy tube placement either alone or with adenoidectomy. An otitis media disease-specific questionnaire was administered before and after surgical intervention. Comparison of the mean percentage change in total ear symptom score between presurgery and postsurgery scores at 1 and 6 months after surgery. The disease-specific quality of life of children with recurrent acute otitis media and/or chronic otitis media with effusion with appropriate surgical indications significantly improved after surgical intervention. The amount of parental worry concerning their children's ear problems also significantly improved following surgery, and most caregivers would opt again for tube placement.

- Health-related quality of life in children with otitis media was another study conducted by Brouwer CN, Maillé AR, Rovers MM, Grobbee DE, Sanders EA, Schilder AG[62] in 2005 where the available HRQoL instruments with respect to their results and their applicability in clinical practice and research of otitis media was analysed. The study concluded that recurrent or chronic otitis media is reported to have a substantial and negative effect on various domains of functional health status and health-related quality of life of children. The OM-6 appears to be the best available instrument to assess functional health status in children with OM in a research setting. However, the lack of true HRQoL instruments as well as incomplete data on their reliability and validity, limit both our current knowledge of HRQoL in OM and the application of current instruments in both research and clinical practice.

- In the same year Brouwer CN, Rovers MM, Maillé AR, Veenhoven RH, Grobbee DE, Sanders EA, Schilder AG[63] conducted a study "The impact of recurrent acute otitis media on the quality of life of children and their caregivers". The quality of life of 384 Dutch children aged 1-7 years with recurrent acute otitis media (AOM), and compare it with that of children from four reference populations: (i) children from a general population; (ii) children with mild-to-moderate asthma, (iii) children with mild-to-moderately severe chronic illness, and (iv) US children with persistent or recurrent otitis media was analysed.it was concluded that recurrent AOM has a considerable negative impact on the quality of life of children and causes concern to their caregivers. These effects are proportional to the severity of the condition. Professionals involved in the care of children with OM should be aware that OM not only affects physical functioning but also general well-being of the child and its family. These outcomes should therefore be included in the evaluation of the child with otitis media both in the clinical and research setting.

- Psychometric Qualities Of Questionnaires For The Assessment Of Otitis Media Impact, study done by Timmerman AA, Meesters CM, Speyer R, Anteunis LJ[64] questionnaires which have been developed to describe the effects of chronic OM on the daily

functioning of children was assessed. Psychometric properties have been evaluated, in addition to discriminative and evaluative qualities. A systematic review of publications pertaining to developed questionnaires related with chronic OM was done in the study. 15 questionnaires developed for children with recurrent or persistent OM, describing functional health status (FHS), while two questionnaires also evaluate the effect of tympanostomy tubes insertion. The questionnaires generally cover six impact areas (physical symptoms, child development, educational performance, emotional/practical burden and general health status) with physical symptoms being the most prominent were reviewed. The OM8-30, OMO-22 and OM-6 adequately reflect the multidimensional aspects of FHS in chronic OM. The OMO-22 and OM8-30 show the best psychometric properties for the discrimination of impact severity between children, while the OM-6 was found to have the best qualities for the evaluation of clinical change. Clinical applicability is crucial for the assessment of FHS in chronic OM, but requires a trade-off with necessary psychometric properties.

- Dornhoffer JL, Smith J, Richter G, Boeckmann J[65] published a study, Impact on quality of life after mastoid obliteration, where the long-term impact on quality of life (QOL) in patients undergoing mastoid obliteration surgery for a chronically draining cavity, using the Glascow Benefit Inventory (GBI) QOL survey was performed. Adult patients undergoing mastoid obliteration and restoration of the middle ear space with cartilage reconstruction of the tympanic membrane, with at least 3-year follow-up, were contacted by phone to solicit participation. Those who agreed to participate were mailed the GBI and consent documents with a prepaid self-addressed envelope. The GBI proved to be a valuable tool for evaluating patient satisfaction after revision surgery for a draining cavity. This information was helpful in understanding the impact of a draining cavity on an individual's life and may be beneficial in preoperative selection and counseling.

- Baumann I, Kurpiers B, Plinkert PK and Praetorius M[66] conducted the study : Development and validation of the Chronic Otitis Media Outcome Test 15 (COMOT-15). Measurement of health-related quality of life in patients with chronic otitis media.

COMOT-15 was found to be a reliable, valid and sensitive instrument for measurement of HR-QOL of COM patients. The results obtained with the questionnaire could be interpreted very well by the investigator. Also COMOT-15 should be used in otological outcomes research.

- Quality-of-life assessment after primary and revision ear surgery using the chronic ear survey conducted by Jung KH, Cho YS, Hong SH, Chung WH, Lee GJ, Hong SD[67] aimed in measuring subjective outcomes after primary and revision surgery for chronic ear disease. It was a prospective questionnaire-based outcome study. The Chronic Ear Survey, a disease-specific outcome survey, was administered preoperatively and at 1 year after surgery. Comparable objective outcomes are achieved after primary and revision surgery for chronic ear disease, but the improvement in quality of life is greater in the primary surgery group.

- Effect of type I tympanoplasty on the quality of life of children study done by Habesoglu TE, Habesoglu M, Deveci I, Kulekci S, Kalaycik C, Gokceer T, Egeli E[68] to assess the Quality-of-life issues related to chronic otitis media (COM) included physical symptoms, emotional symptoms, hearing loss, speech symptoms, social symptoms, and parents' emotional symptoms. In this study the effects of tympanoplasty on the quality of life of pediatric patients was evaluated. 56 of 78 pediatric patients with COM who were treated with type I tympanoplasty were reviewed. All patients were asked to fill out the COM-5 questionnaire with their parents, before operation and 6 months after operation. Preoperative and postoperative total ear scores, preoperative and postoperative ear scores with an intact tympanic membrane, preoperative and postoperative ear scores with a perforated tympanic membrane, and preoperative and postoperative audiological results were assessed. It was found that children with COM had a significant increase in their quality of life after successful tympanoplasty. Study also suggested that tympanoplasty was successful in pediatric patients with COM.

- In a study, General and disease-specific quality of life in patients with chronic

suppurative otitis media --a prospective study, done by Baumann I, Gerendas B, Plinkert PK, Praetorius M[69], prospective audiological data and data on general and disease-specific quality of life with validated quality of life measurement instruments to assess the impact of the disease on health-related quality of life (HR-QOL) was collected. 121 patients were included in the study. Patients were clinically examined in the hospital before and 6 months after surgery including audiological testing. They filled in the quality of life questionnaires SF-36 and Chronic Otitis Media Outcome Test 15 (COMOT-15) pre-operatively and 6 and 12 months post-operatively, respectively. It was concluded that tympanoplasty did lead to a significant improvement of disease-specific HR-QOL in patients with CSOM while general HR-QOL did not change. Very well correlations were found between the subscale hearing function from the COMOT-15 questionnaire and audiological findings. Revision surgery seems to be a predictor for a worse outcome.

- In a retrospective multicentric study, Comparison of quality of life outcomes following different mastoid surgery techniques by Joseph J, Miles A, Ifeacho S, Patel N, Shaida A, Gatland D, Watters G, Kiverniti E[70] the subjective change in quality of life using the Glasgow Benefit Inventory, relative to the type of mastoid surgery was undertaken. 157 patients who underwent mastoid surgery from 2008 to 2012 were included.it was found that the choice of mastoid surgery technique should be determined by clinical need and surgeon preference. There is no improvement in quality of life for most patients following mastoid surgery.

- Effect of Type 1 Tympanoplasty on the Quality of Life of CSOM patients a study by Bhatia K, Vaid L, Taneja HC[71] presents an analysis of the impact of the surgery on the patient subjectively and its correlation with objective outcomes. 45 patients were selected to fill the chronic otitis media-5 (COM-5) questionnaire and underwent pure tone audiometry preoperatively. All the patients underwent Type 1 tympanoplasty by using temporalis fascia graft. The status of the ossicles was checked and documented intraoperatively. Patients requiring ossicular reconstruction or with attico antral disease were excluded. Patients were followed up for a period of 6 months and those with an intact graft after 6 months were included in the study. These patients were again made to

fill the questionnaire and undergo pure tone audiometry postoperatively. Marked improvement was observed in subjective scores as documented by the questionnaire, pre- and postoperatively with the mean improvement in total scores being 7.89 ± 4.81 on a Visual Analogue Scale. Also significant improvement was achieved in closure of air-bone gap with the mean improvement being 14.73 ± 8.58 dB. Significant correlation was found between subjective and objective scores in most patients.

This study showed that Type 1 tympanoplasty brings about a significant improvement in the quality of life of chronic suppurative otitis media patients. Most patients showed a marked improvement in subjective scores which correlated well with the objective findings of the status of the graft and improvement in air-bone gap. Asymptomatic patients with less preoperative scores showed less improvement in subjective scores which did not correlate with the objective outcomes.

- The Chronic Otitis Media Questionnaire 12 was developed initially in the UK to assess patient-reported health-related quality of life associated with chronic otitis media. The study International recognition of the Chronic Otitis Media Questionnaire 12 by Kosyakov SI, Minavnina JV, Phillips JS, Yung MW[72] aimed to determine whether this tool is applicable to the Russian population, which has a materially different healthcare system. A total of 108 patients with different forms of chronic otitis media completed the Russian Chronic Otitis Media Questionnaire 12. The Russian version of the Chronic Otitis Media Questionnaire 12 was found to be a reliable tool for the assessment of health-related quality of life in patients with chronic otitis media. This sets the scene for international collaboration, using this tool to assess the effectiveness of surgical treatments even amongst countries with different healthcare systems.

Part II

AIMS AND OBJECTIVES OF STUDY

1) To assess the quality of life in patients with chronic otitis media

Chronic otitis media is a pathological condition that affects the quality of life of the individual in terms of ear discharge, pain, reduced hearing and other factors. The aim of this study is to assess the quality of life in patient with CSOM.

2) To assess the quality of life of the study patients within the study groups before and after undergoing surgical treatment for the same.

Tympanoplasty with or without mastoidectomy is an effective and safe procedure to tackle the problems of CSOM. It is more of a quality of life improvement surgery aiming in controlling the infection due to CSOM and to restore the hearing. Hence it is equally important to know the surgical outcome in terms of quality of life improvement in those patient undergoing the procedure, not only to counsel them before surgery but also to for the surgeon in decision making.

MATERIALS AND METHOD

Data for the study was collected from the patients undergoing surgery in the Department of Otorhinolaryngology at Manipal Hospital, Bangalore, Karnataka. The patients are divided into three groups :

GROUP A: those undergoing tympanoplasty

GROUP B: those undergoing tympanoplasty with mastoidectomy and

GROUP C: those undergoing revision surgeries

Study Area

The study was conducted in the Department of Otorhinolaryngology , Manipal Hospital,old Airport Road Bangalore.This is a 650 bedded multispecialty hospital comprising of intensive care units,outpatient departments,adult and paediatric emergency units. Approximately 100-150 patients visit the ENT OPD every day. The patients included in the study were initially assessed in the OPD. They were asked to fill up the COMOT -15 questionnaire before the surgery. They were admitted one day prior to the surgery, underwent pre anaesthetic check up and basic blood investigations. Post operatively the patients were called for follow ups after 1st

week and 2nd week and then after three months when the COMOT-15 questionnaire ws given to assess the quality o life after the surgery and were also subjected to audiometriy record the hearing status.

Study Population

It is a prospective, observational, comparative study. All the patients aged between 15 -60 years with duration of disease more than three months diagnosed as safe type of COM or cholestiatoma who were planned for surgery.

Sample Size with Justification

Based on previous literature survey findings, and the incidence of COM in our population, total of 60 patients were included in the study, with 20 patients in each group A, B and C.

GROUP A: those undergoing tympanoplasty with or without ossicular reconstruction

GROUP B: those undergoing tympanoplasty and mastoidectomy with or without ossicular reconstruction

GROUP C: those undergoing revision surgery, either tympanoplasty or tympanoplasty with mastoidectomy.

Sample Technique

Patients who were treated at the Department of Otolaryngology, Manipal Hospital, Bangalore fulfilling the inclusion criteria were asked to participate in the study. Data collection was performed prospectively at two times of measurement (TM): pre-operatively (TM1) and 3 months after surgery (TM2)

Study Period

The study period was between February 2016 to February 2017.

Data Collection Technique And Tools

A preformed questionnaire was handed over to the patient which includes the personal details and complaints. Audiometry and imaging findings were noted. Patient were handed the COMOT-15 questionnaire before the surgery. Patient was asked to follow up 3 months after surgery and fill in the same questionnaire.

Methodology

The patients were allocated to the three study groups, considering the inclusion and exclusion criteria. Personal data was collected from all three groups followed by clinical examination and investigations. The measurement of disease-specific QOL was performed using the Chronic Otitis Media Outcome Test 15 (COMOT-15) (annexure 1).

Inclusion Criteria:

- Age between 15 -60 years.
- Duration of disease >3 months
- Patients with safe type of COM.
- Patients having COM with cholesteatoma.

Exclusion Criteria:

- COM with complications such as mastoid abscess, labyrinthine fistula, facial nerve palsy and intra cranial involvement.
- COM in congenital atretic ears
- Patients with profound/ severe hearing loss.

Operative Procedure

Tympanoplasty

Figure 20: Micro instruments used in tear surgeries

Operative technique: patient was positioned supine on the operating table with the head facing opposite to the ear being operated. Post aural area was prepared by shaving about 0.5cm behind the ear under aseptic precautions. The area was painted with betadine solution and parts draped. Post aural William wildes incision is made. Incision deepened and temporalis fascia graft approximatele 2x2cm harvested. Posterior tympanomeatal flap is elevated with round knife, flag knive and flap elevator. Margins of the perforation are freshened. Ossicular chain status is checked. In case of ossicular chain discontinuity, cartilage tympanoplasty is done. Graft is placed by under lay technique to achieve either a type I or III tympanoplasty. Tympanomeatal flap and the graft is supported with gelfoam. External auditory canal antibiotic wick is placed. Post aural wound is closed in three layers. Mastoid bandage is applied. On post op day 1, bandage is removed, dressing is done. Patient is assessed for any post aural hematoma, wound dehiscence, facial palsy or vestibular symptoms and discharged.

Tympanoplasty with mastoidectomy

All the patients underwent either cortical mastoidectomy with tympanoplasty or modified radical mastoidectomy with canal wall down procedure with or without ossiccular chain reconstruction or radical mastoidectomy with or without ossiccular chain reconstruction.

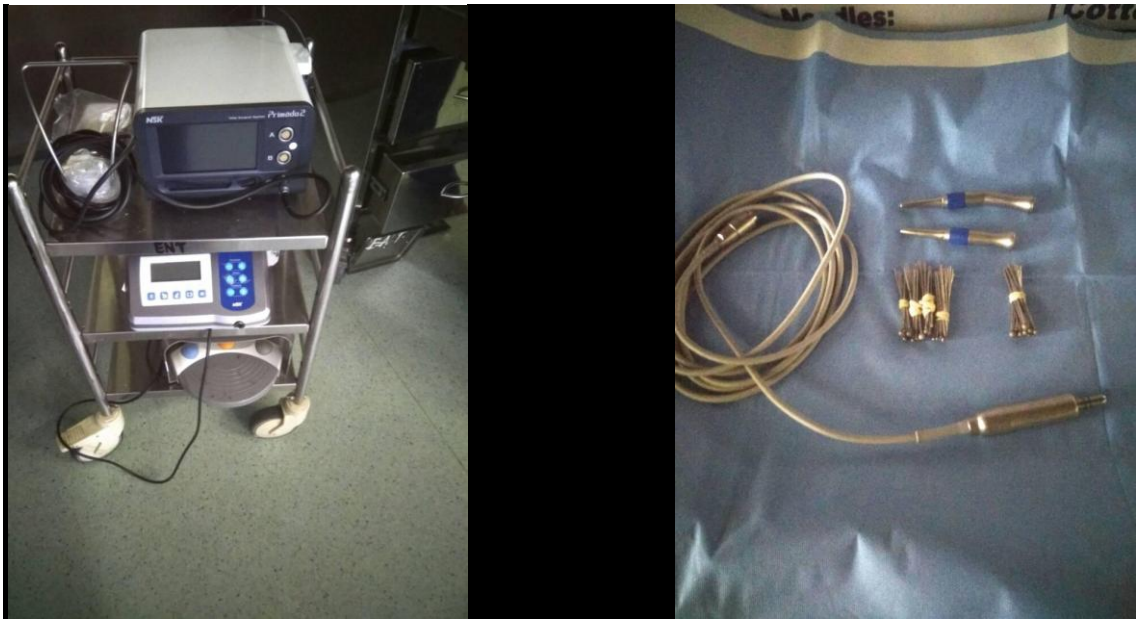


Figure21 and 22: Drill set with straight and quadrangular hand piece and various drill bits.

Operative technique: patient was positioned supine on the operating table with the head facing opposite to the ear being operated. Endaural incision was made, temporalis fascia graft harvested, 3x3cm and the tympanomeatal flap elevated. Canal wall down mastoidectomy done by drilling over the posterior wall of external auditory canal. Mastoid antrum is exteriorised. Margins of perforation freshened. Ossicular status checked and reconstruction done wherever necessary. Graft placed by underlay technique, part of the graft draping the cavity as well. Gel foam placed as support. . External auditory canal antibiotic wick is placed. endaural wound is closed in three layers. Mastoid bandage is applied. On post op day 1, bandage is removed, dressing is done. Patient is assessed for any post aural hematoma, wound dehiscence, facial palsy or vestibular symptoms and discharged.

Fig 23: Performing MRM under the microscope. Mastoid is being opened using drill.

DATA ANALYSIS AND RESULTS

Parameters Studied Were

1. Pre operative parameters
2. Confirmation of diagnosis and finalization of the procedure
3. COMOT-15 score
4. Audiometry

Post operative parameters

1. COMOT-15 score
2. Audeometry

Statistical analysis

- Data was expressed as percentage, mean ± S.D, standard error of mean and range.
- Kolmogorove-Smirnove analysis was performed for checking linearity of the data
- Student's paired t test was used to check the significance of difference between repeated measures of parameters (COMOT 15 and PTA) in parametric data
- ANOVA followed by Tukey's HSD test was used to test the significance of difference between means of COMOT 15 and PTA between more than two groups in parametric data.
- P value <0.05 was considered as statistically significant.
- SPSS© for windows™ Vs 17, IBM™ Corp NY and Microsoft excel™ 2007, Microsoft® Inc USA was used perform the statistical analysis.

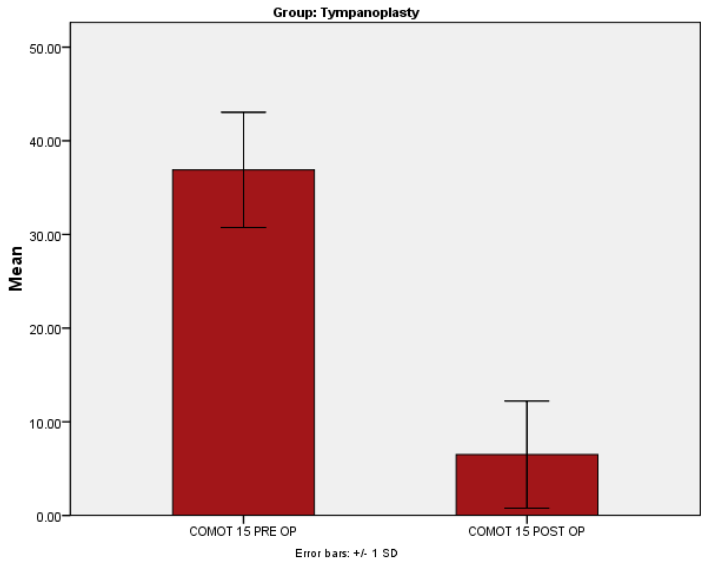
Total of 60 patients were evaluated from February 2016

Study design: Comparative three group study

Table1: Comparison of Pre and post op COMOT 15 value in subjects who underwent Tympanoplasty (GROUP A)

Paired Samples Statistcs

	Mean	N	Std. Deviation	Std. Error Mean	T	P value
COMOT 15 PRE OP	36.9000	20	6.15502	1.37630		
COMOT 15 POST OP	6.5000	20	5.71701	1.27836	18.86	<0.0001

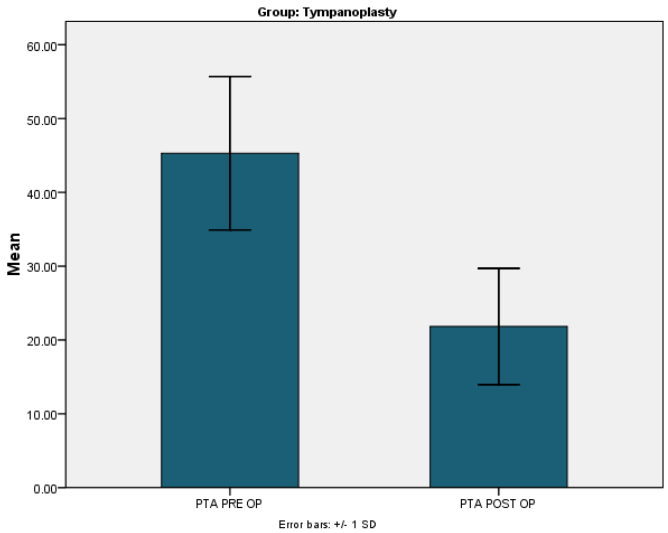


Comparison of Pre and post op COMOT 15 value in subjects who underwent Tympanoplasty was performed using paired t test. COMOT 15 value was found to be reduced significantly post-op compared to pre-op ($p<0.0001$)

Table2: Comparison of Pre and post op PTA value in subjects who underwent Tympanoplasty (GROUP A)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	T	P value
Pair 1	PTA PRE OP	45.2950	20	10.39213	2.32375	11.239	<0.0001
	PTA POST OP	21.8300	20	7.88263	1.76261		

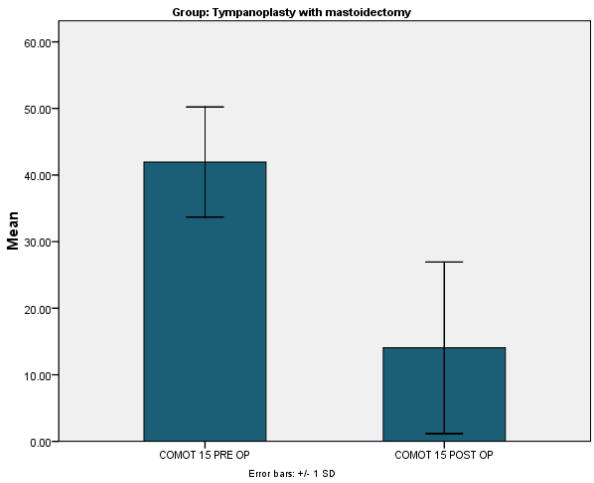


Comparison of Pre and post op PTA value in subjects who underwent Tympanoplasty was performed using paired t test. PTA was found to improve significantly post-op compared to pre-op ($p<0.0001$)

Table3: Comparison of Pre and post op COMOT 15 value in subjects who underwent Tympanoplasty with Mastoidectomy (GROUP B)

Paired Samples Statistics[a]

		Mean	N	Std. Deviation	Std. Error Mean	T	P value
Pair 1	COMOT 15 PRE OP	41.9500	20	8.27472	1.85028	18.86	<0.0001
	COMOT 15 POST OP	14.0500	20	12.89421	2.88323		



Comparison of Pre and post op COMOT 15 value in subjects who underwent Tympanoplasty with mastoidectomy was performed using paired t test. COMOT 15 value was found to be reduced significantly post-op compared to pre-op ($p<0.0001$)

Table4: Comparison of Pre and post op PTA value in subjects who underwent Tympanoplasty with mastoidectomy (GROUP B)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	T	P value
Pair 1	PTA PRE OP	50.7800	20	9.88990	2.21145	11.23	
	PTA POST OP	28.5000	20	15.93242	3.56260		<0.0001

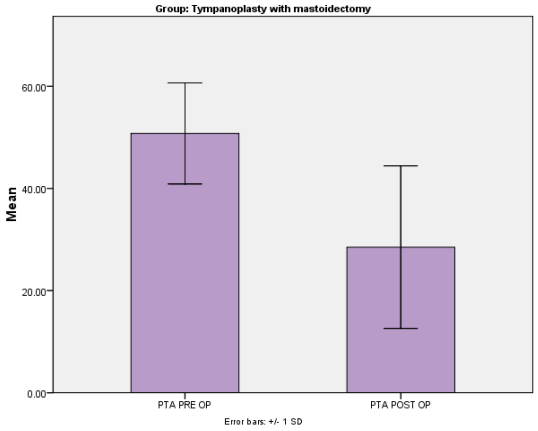
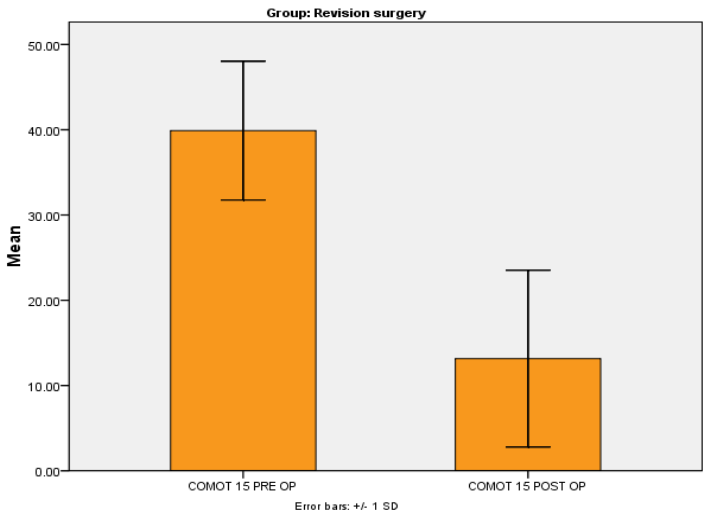


Table: Comparison of Pre and post op PTA value in subjects who underwent Tympanoplasty with mastoidectomy was performed using paired t test. PTA was found improve significantly post-op compared to pre-op ($p<0.0001$)

Table5: Comparison of Pre and post op COMOT 15 value in subjects' whounderwent Revision surgery (GROUP C)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	T	P value
Pair 1	COMOT 15 PRE OP	39.8947	19	8.14381	1.86832	18	<0.0001
	COMOT 15 POST OP	13.1579	19	10.36695	2.37834		

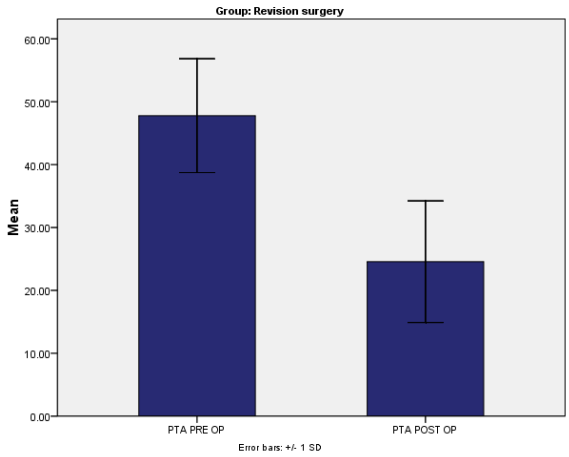


Comparison of Pre and post op COMOT 15 value in subjects who underwent Revision surgery was performed using paired t test. COMOT 15 value was found to be reduced significantly post-op compared to pre-op ($p<0.0001$)

Table6: Comparison of Pre and post op PTA value in subjects who underwent Revision surgery (GROUP C)

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean	T	P Value
Pair 1	PTA PRE OP	47.7800	20	9.05600	2.02498	19	<0.0001
	PTA POST OP	24.5650	20	9.67663	2.16376		

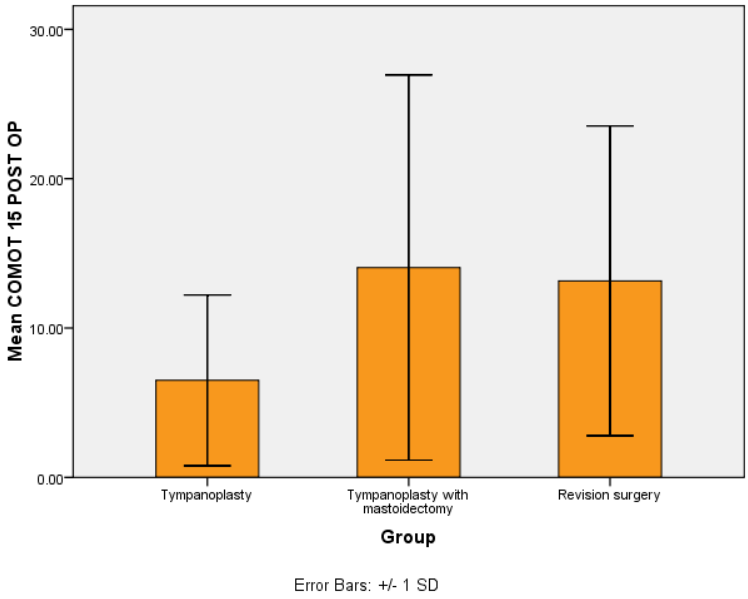


Comparison of Pre and post op PTA value in subjects who underwent Revision surgery was performed using paired t test. PTA was found to improve significantly post-op compared to pre-op ($p<0.0001$)

Table7: Comparison of post op COMOT 15 in individuals between various surgical processes

COMOT 15 POST OP	N	Mean	S.D.	S.E.	95% Confidence Interval for Mean		Min	Max	F	P value
					Lower	Upper				
Tympanoplasty	20	6.50	5.72	1.28	3.82	9.18	1	23		
Tympanoplasty with mastoidectomy	20	14.05	12.894	2.88	8.01	20.08	3.00	59.00	3.318	.043

Revision surgery	20	13.16	10.37	2.38	8.16	18.15	2	50		
Total	60	8.64	8.04	1.05	6.55	10.74	1	50		

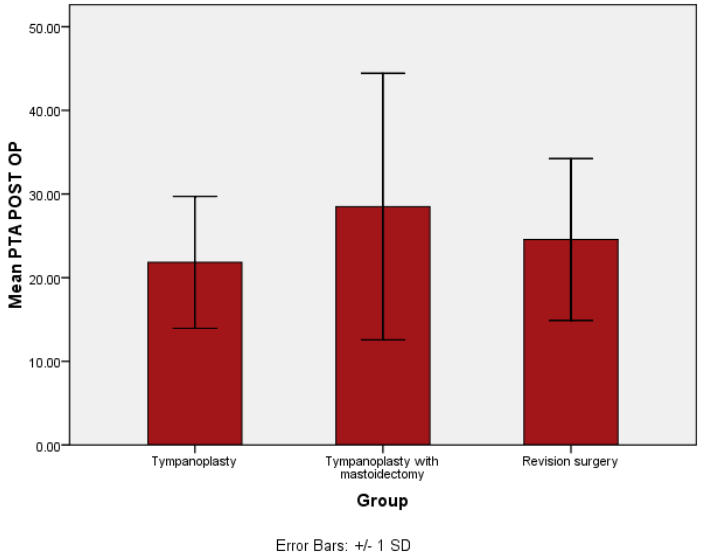


Comparison of COMOT 15 in post op individuals between various surgical processes was performed using ANOVA. No significant difference was noted between three groups.

Table8: Comparison of Post-op PTA between various surgical processes

PTA POST OP	N	Mean	S.D.	S.E.	95% Confidence Interval for Mean		Min	Max	F	P value
					Lower	Upper				
Tympanoplasty	20	21.83	7.88	1.76	18.14	25.52	15	43		

Tympanoplasty with mastoidectomy	20	28.50	15.93	3.56	21.04	35.95	15.00	90.00	1.647	0.202
Revision surgery	20	24.57	9.68	2.16	20.04	29.09	15	58.3		
Total	60	22.74	8.48	1.09	20.55	24.93	15	58.3		

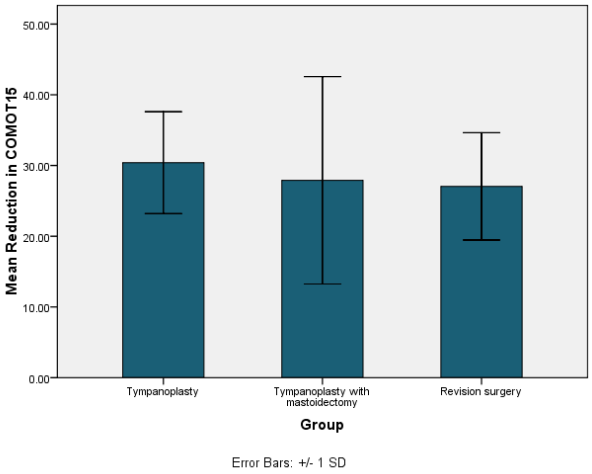


Comparison of Post-op PTA between various surgical processes was performed using ANOVA. No significant difference was noted between three groups.

Table9: Comparison of reduction in COMOT 15 between various surgical processes

Reduction in COMOT15	N	Mean	S.D.	S.E.	95% Confidence Interval for Mean		Min	Max	F	P value
					Lower	Upper				
Tympanoplasty	20	30.40	7.21	1.61	27.03	33.77	20	45		

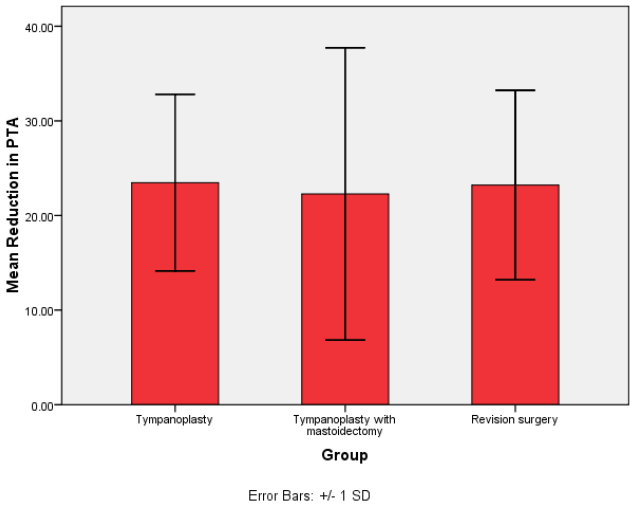
Tympanoplasty with mastoidectomy	20	27.90	14.66	3.27	21.03	34.76	-14.00	43.00		
Revision surgery	20	27.05	7.59	1.70	23.50	30.60	12	39	0.56	0.57
Total	60	29.28	7.39	0.95	27.38	31.19	12	45		



Comparison of reduction in COMOT 15 between various surgical processes was performed using ANOVA. No significant difference was noted between three groups.

Table10: Comparison of reduction of PTA between various surgical processes

Reduction in PTA	N	Mean	S.D.	S.E.	95% Confidence Interval for Mean		Min	Max	F	P value
					Lower	Upper				
Tympanoplasty	20	23.47	9.34	2.09	19.10	27.84	3.3	36.7	0.055	0.94
Tympanoplasty with mastoidectomy	20	22.28	15.44	3.45	15.05	29.50	-20.00	41.00		
Revision surgery	20	23.22	10.01	2.24	18.53	27.90	-5	40		
Total	60	23.38	9.40	1.21	20.95	25.81	-5	40		



Comparison of reduction of numeric value of PTA between various surgical processes was performed using ANOVA. No significant difference was noted between three groups.

DISCUSSION

Otorhinolaryngology has forever been an evolving field with new advances and technologies making its way day in and day out. There has always been research towards improving the patient care and improving the quality of life of the patient. It is therefore important to not only measure objectively the success of various surgeries but also to subjectively measure and analyze various parameters that determine patient satisfaction. Equally important is to know which procedure gives the best results.

COM is common pathology reporting in ENT clinics. Patients commonly present with reduced hearing discharge and pain during an active infection or with reduced hearing which affects them in daily activities and work. Tympanoplasty is one of the most commonly performed ear surgeries. With better patient education and awareness the number of patients opting to undergo the procedure has increased tremendously. And for the same reason the expectation of the patients about the outcome of these surgeries have also gone up.

In this study we have analysed the impact of COM in the quality of life of patients and compared it to the improvement in their quality of life post surgery. Attempt has been made to determine which procedure benefits the best in terms of COMOT 15 improvement and PTA improvement.

In pre antibiotic era, cortical mastoidectomy was performed simply to let out the pus in mastoid cavity and to reduce the bacterial load. With the advent of better antibiotics and better understanding of the anatomy the concept of ear surgeries have shifted from a life saving surgery to quality of life improving surgery. The expectations from the patients have shifted from eradication of disease to improvement of hearing. For the same reason the various pathological subtypes of COM identified and treated has also increased with different procedures being adopted for different cases. This is purely based on the type of disease, extent of disease and the surgical expertise. Hence the need to compare the quality of life improvement in various scenarios by means of our study: **Quality-of-Life Outcomes For Surgical Intervention In Chronic Otitis Media.**

COMOT 15

Significant reduction in the COMOT -15 values were obtained after surgery in all three groups (Group A: 36.9 to 6.5, Group b: 41.95 to 14.05 and Group C: 39.8947 to 12.1579; p value < 0.001) which shows that there is a subjective improvement in quality of life after surgery, even in revision surgery group.

Similar result was obtained in the study conducted by Baumann I et al who found that there is a significant improvement of disease-specific HR-QOL in patients with CSOM while general HR-QOL did not change. Very well correlations were found between the subscale hearing function from the COMOT-15 questionnaire and audiological findings.

"Effect of Type 1 Tympanoplasty on the Quality of Life of CSOM" patients a study by Bhatia K, Vaid L, Taneja HC presents an analysis of the impact of the surgery on the patient subjectively and its correlation with objective outcome. This study showed that Type 1 tympanoplasty brings about a significant improvement in the quality of life of chronic suppurative otitis media patients similar to our study

When the three groups A, B and C were compared it was found that there was no statistically significant difference in COMOT 15 value post op between these groups (Group A- 6.50, Group B- 14.05 and Group C- 13.16, p value 0.043)

This proves that a person undergoing tympanoplasty, mastoid tympanoplasty or revision surgery has equal chances of improvement in quality of life.

Dissimilar results were obtained in the study done by Baumann I et al who found there was a difference of opinion in case of revision surgeries, which was a predictor for worse outcome.

When the three groups A, B and C were compared it was found that there was no statistically significant difference in reduction in COMOT 15 value post op between these groups (Group A- 30.04, Group B- 27.90 and Group C- 27.05, p value 0.57)

Quality-of-life assessment after primary and revision ear surgery using the chronic ear survey conducted by Jung KH, Cho YS, Hong SH, Chung WH, Lee GJ, showed comparable objective outcomes are achieved after primary and revision surgery for chronic ear disease similar to our study, but the improvement in quality of life is greater in the primary surgery group dissimilar to our study where the outcome in all three groups are equal.

PTA:

Significant improvement in post op PTA value was obtained in all the three group swith improvement in pure tone average, the value of which reduces numerically (Group A: 45.295 to 2.8300, Group B: 50.7800 to 28.500 and Group C: 47.7800 to 24.5650, p value < 0.001). This improvement is well appreciated by the patients subjectively, which is evident in post operative reduction in COMOT 15 value.

Most patients in the study done by Bhatia K, Vaid L, Taneja HC showed a marked improvement in subjective scores which correlated well with the objective findings of improvement in air-bone gap similar to our study.

In the study done by Baumann I et al correlations were found between the subscale hearing function from the COMOT-15 questionnaire and audiological findings similar to our study.

When the three groups A, B and C were compared it was found that there was no statistically significant improvement in PTA value post op (Group A- 21.83, Group B- 28.5 and Group C- 24.57, p value 0.202)

When the three groups A, B and C were compared it was found that there was no statistically significant difference in improvement in PTA value post op (Group A- 23.47, Group B- 22.28 and Group C- 23.22, p value 0.94)

DRAWBACKS OF OUR STUDY

Special consideration for cases with mixed hearing loss was not done. One of the causes for reduced post op satisfaction in terms of hearing is sensorineural component of hearing loss which does not improve after surgery.

Demographic parameters were not analysed. There can be difference in the way symptoms are subjectively analysed among males and females and also among different age groups.

A larger study group would have validated the study better especially while comparing different types of mastoidectomies. The smaller group in this case does not prove statistically significant in inter group comparisons.

Co morbidities were not given special consideration. Low immune status as in the case of diabetes mellitus can compromise the rate of healing. Also systemic causes of sensorineural component in hearing loss were not excluded.

The follow up period especially in Group B and Group C is not long enough to assess cavity related problems. A re evaluation with COMOT 15 after 6 months and 1 year needs to be considered for long term picture.

RECOMMENDATIONS

Surgeries for COM these days is performed to improve the a quality of life. It is important to counsel the patient pre operatively not just in terms of hearing improvement, but also in terms of discharge, discomfort, communication difficulties experienced etc. A surgeon can, to some extent guarantee a significant post operative satisfaction. At the same time, consideration should be given to the disease extent and the procedure the surgeon is confident performing, keeping in mind that post operative improvement in quality of life is equal in all cases.

SUMMARY

Chronic otitis media (COM) is a common disease, defined as a chronic inflammation in the mucosa of the middle ear and/or mastoid which affects approximately 2% of the population. It is associated with significant functional limitations of hearing. This frequently results in communication problems impeding social interaction and professional life. In patients with severe hearing loss even a withdrawal from social activities can be observed frequently. In addition, further symptoms of CSOM such as persistent discharge from the ear, pain or frequent doctor visits may result in impairment of quality of life of the patients.

The main purposes of surgical intervention in COM are to remove the intractable pathologic

tissue and restore the normal functions of the middle ear as a sound conductor and the mastoid cavity as an air reservoir, the clinical outcome measurements of ear surgery have been based on disease control rate and audiological result. But the assessment of treatment results on the basis of functional diagnostics, survival rates, or similar parameters alone does not mirror subjective experiences of the patients. Hence, the importance of measuring subjectively assessed quality of life (QOL) is steadily increasing in clinical medicine.

Aim and objective of the study was to assess the quality of life in patients with chronic otitis media and to assess the quality of life of the study patients within these groups before and after undergoing surgical treatment for the same.

Data was collected from 60 patients in total who underwent surgery in the Department of Otorhinolaryngology at Manipal Hospital, Bangalore, Karnataka and were divided into three groups:

GROUP A: those undergoing tympanoplasty – 20 patients

GROUP B: those undergoing tympanoplasty with mastoidectomy – 20 patients

GROUP C: those undergoing revision surgery– 20 patients

Data collection was performed prospectively at two times of measurement (TM): pre-operatively (TM1) and 3 months after surgery (TM2). Each time the patient was asked to fill up the COMOT 15 questionnaire and the PTA was measured.

COMOT 15

Significant reduction in the COMOT -15 values were obtained after surgery in all three groups which shows that there is a subjective improvement in quality of life after surgery, even in revision surgery group.

When the three groups A, B and C were compared it was found that there was no statistically significant difference in COMOT 15 value post op between these groups

This proves that a person undergoing tympanoplasty, mastoid tympanoplasty or revision surgery has equal chances of improvement in quality of life.

When the three groups A, B and C were compared it was found that there was no statistically significant difference in reduction in COMOT 15 value post op between these groups.

PTA:

Significant improvement in post op PTA value was obtained in all the three group swith

improvement in pure tone average, the value of which reduces numerically. This improvement is well appreciated by the patients subjectively, which is evident in post operative reduction in COMOT 15 value.

When the three groups A, B and C were compared it was found that there was no statistically significant improvement in PTA value post op. When the three groups A, B and C were compared it was found that there was no statistically significant difference in improvement in PTA value post op.

This proves that a person undergoing tympanoplasty, mastoid tympanoplasty or revision surgery has equal chances of improvement in quality of life.

A surgeon can, to some extent guarantee a significant post operative satisfaction. At the same time, consideration should be given to the disease extent and the procedure the surgeon is confident performing, keeping in mind that post operative improvement in quality of life is equal in all cases.

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ANNEXURE A

STUDY PROFORMA

Quality-of-Life Outcomes After Surgical Intervention for Chronic Otitis Media, Otitis media with Mastoiditis and Revision cases

1. NAME:

2. AGE:_____yrs
3. SEX: MALE FEMALE

4. OCCUPATION INVOLVING EXPOSURE TO LOUD SOUND:
YES NO

5. OP/IP NO:
6. DOA:
7. DOD:
8. POSTAL ADDRESS:

9. PHONE NUMBER:
10. X RAY B/L MASTOIDS DONE:
YES NO
IF YES, MASTOIDITIS:

PRESENT ABSENT
11. CT TEMPORAL BONE DONE:
YES NO
IF YES, MASTOIDITIS:
PRESENT ABSENT

12. AUDIOMETRIC FINDINGS: Pure Tone Average (500-4000 kHz)

1. HEARING LOSS: PRESENT ABSENT

2. TYPE: CONDUCTIVE/ SENSORY NEURAL/ MIXED HEARING LOSS

3. SEVERITY:
PRE OP: / MILD/ MODERATE/ MOD. SEVERE/ SEVERE/ PROFOUND
POST OP:NL/ MILD/ MODERATE/ MOD. SEVERE/ SEVERE/ PROFOUND

DETAILS OF SURGERY:
1. DATE:
2. TYPE OF ANAESTHESIA: GA: LA:
3. SURGICAL TECHNIQUE EMPLOYED:
TYMPANOPLASTY/CORTICAL MASTOIDECTOMY +TYMPANOPLASTY/REVISION SURGERY

PARAMETER EVALUATED	PRE OP	POST OP
AUDIOMETRY		
COMOT 15 SCORE		

CHRONIC OTITIS MEDIA OUTCOME TEST-15 (COMOT-15)

Following you will find a list of symptoms and social/emotional effects of your otitis media . We would like to know more about these issues and would appreciate your answers of these questions to the best of your knowledge. There are no right or false answers, and only you can provide us this information. Please rate your problems as they have been over the past three months. Thank you for your participation. Please do not hesitate to ask any of us for assistance if necessary.

Considering how severe the issue is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale:	No issue at all	Very mild issue	Mild or slight issue	Moderate issue	Severe issue	Problem as bad as it can be
1. Discharge from the ear	0	1	2	3	4	5
2. Earache	0	1	2	3	4	5
3. Ear pressure / fullness of the ear	0	1	2	3	4	5
4. Tinnitus (ringing in the ear)	0	1	2	3	4	5
5. Headache	0	1	2	3	4	5
6. Hearing loss	0	1	2	3	4	5
7. I have difficulties to understand someone speaking from a larger distance	0	1	2	3	4	5
8. I have difficulties to understand something in a noisy surrounding area	0	1	2	3	4	5
9. I have difficulties to understand when people are speaking simultaneously	0	1	2	3	4	5
10. My Hearing loss makes me feel depressive / sad	0	1	2	3	4	5
11. Because of my hearing loss I fear to misunderstand other people	0	1	2	3	4	5
12. My hearing loss does cause embarrassing situations	0	1	2	3	4	5
13. I am scared that my ear problems will increase in the future	0	1	2	3	4	5
14. Overall assessment of the impact of the ear disease on quality of life	0	1	2	3	4	5
For question 15 please notice that we would like to know the number of your visits to the doctor concerning you ears during the last six months	None	One visit	Two visits	Three visits	Four visits	More than four visits
15. Frequency of doctor visits for problems with my ear(s)	0	1	2	3	4	5

PATIENT INFORMATION SHEET

STUDY TITLE: QUALITY OF LIFE OUTCOMES FOR SURGICAL INTERVENTION IN CHRONIC OTITIS MEDIA.

PURPOSE, BACKGROUND AND REASON OF STUDY-

I am approaching you on behalf of Dr.V T ANAND, under whose guidance I, Dr.LAKSHMI V, DNB resident in ENT, Manipal Hospital is doing a study on - QUALITY OF LIFE OUTCOMES FOR SURGICAL INTERVENTION IN CHRONIC OTITIS MEDIA. CSOM is a common disease in our country and affects the quality of life of the patient.

I am going to give you information and invite you to be a part of this research. There may be words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

PROCEDURE

You will be asked to provide your personal details. Your audiometric findings before and three months after surgery will be taken into account. You will be asked to fill in a simple self explanatory questionnaire before and after surgery

RISKS AND BENEFITS

Side Effects

There are no side effects of this study as you are not subjected to any invasive procedures or blood investigations.

Risks

There are no risks involved with the procedure.

Benefits

The benefit of this study is to measure a subjective improvement in quality of life after you undergo the surgery.

VOLUNTARY PARTICIPATION

Participant selection

This facility is being offered to all patients who attend ENT OPD at Manipal Hospital, Bangalore, and have been advised to undergo surgery for CSOM.

Voluntary Participation

Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital. You may change your mind later and stop participating even if you agreed earlier.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital. Details regarding your surgery or post surgery follow up will not be recorded for study purpose.

PRIVACY, CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

Confidentiality

The information collected from the project will be kept confidential to all but the researchers and the DNB board.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research

CONTACT DETAILS

WHOM TO CONTACT

1. Investigator:

Dr. Lakshmi V

Ph: 9880551768

2. Guide:

Dr V T Anand

Ph: 9845091426

ANNEXURE B

SUBJECT INFORMED CONSENT FORM (ICF)

STUDY TITLE: Quality-of-Life Outcomes For Surgical Intervention In Chronic Otitis Media

SUBJECTS'S HOSPITAL NO:_____

SUBJECT'S NAME:_____

DATE OF BIRTH / AGE: _____

		SUBJECT INITIAL BOX
1	The content of the above consent form and the procedure has been explained to me in a language _____ known to me and I have understood the same.	
2	I understood that my participation in the study is voluntary and that I am free to withdraw any time, without my medical care or legal rights being affected.	
3	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	
4	I agree to take part in the above study	
5	I have received a copy of the signed and dated informed Consent Form.	

Informed Consent Signatures

Subject's Signature _____ Date / Time _____

Or Thumb impression. (Person signing to complete)

Signature of _____ Date / Time _____

The Investigator (Person signing to complete)

Witness signature

ANNEXURE C

KEY TO MASTER CHART WITH MASTER CHART

Group A- Tympanoplasty

Group B- Tympanoplasty with mastoidectomy

Group C – Revision surgery

MASTER CHART

Sl no	COMOT 15 PRE OP	COMOT 15 POST OP	PTA PRE OP	PTA POST OP	PROCEDURE
1	34	13	50	25	Type I tympanoplasty
2	34	10	50	25	Type I tympanoplasty
3	27	3	50	20	Type I tympanoplasty
4	27	5	30	20	Type I tympanoplasty
5	39	17	55	25	Type I tympanoplasty
6	41	3	55	43	Type I tympanoplasty
7	43	23	51	35	Type I tympanoplasty
8	45	3	35	25	Type I tympanoplasty
9	37	2	60	35	Type I tympanoplasty

10	38	7	48.3	15	Type I tympanoplasty
11	45	11	40	15	Type I tympanoplasty
12	35	4	18.3	15	Type I tympanoplasty
13	41	6	50	15	Type I tympanoplasty
14	36	6	50	20	Type I tympanoplasty with ossiculoplasty
15	46	1	50	20	Type I tympanoplasty
16	44	5	53.3	16.6	Type I tympanoplasty
17	32	3	40	16	Type I tympanoplasty
18	26	1	30	15	Type I tympanoplasty
19	33	2	40	16	Type I tympanoplasty
20	35	5	50	20	Type I tympanoplasty

GROUP B

SL NO	COMOT 15 PRE OP	COMOT 15 POST OP	PTA PRE OP	PTA POST OP	PROCEDURE
1	49	6	55	20	Modified radical mastoidectomy
2	45	59	70	90	cartilage palisading and type 3 tympanoplasty
3	41	3	66	25	Atticotomy with type 3 tympanoplasty

4	17	5	26.6	20	Cortical mastoidectomy with cartilage palisading and type 3 tympanoplasty
5	25	19	55	25	Cortical mastoidectomy with type 1 tympanoplasty
6	38	5	48	24	Modified radical mastoidectomy with meatoplasty with cartilage type 3 tympanoplasty
7	40	35	35	45	Cortical mastoidectomy with type 1 tympanoplsty
8	48	8	45	30	Cortical mastoidectomy with type 1 tympanoplasty
9	46	9	40	15	MRM cartilage palisading and type 3 tympanoplasty
10	39	6	55	20	Cortical mastoidectomy cartilage palisading and type 3 tympanoplasty
11	49	10	50	30	MRM cartilage palisading and type 3 tympanoplasty
12	50	11	48	16	Atticotomy with type 3 tympanoplasty
13	48	18	55	20	MRM cartilage palisading and type 3 tympanoplasty
14	47	20	55	30	Cortical mastoidectomy with type 1 tympanoplasty
15	48	16	60	28	cartilage palisading and type 3 tympanoplasty

16	40	15	58	20	MRM cartilage palisading and type 3 tympanoplasty
17	38	11	50	30	Atticotomy with type 3 tympanoplasty
18	42	10	50	26	MRM cartilage palisading and type 3 tympanoplasty
19	46	9	48	26	Cortical mastoidectomy with type 1 tympanoplasty
20	43	6	46	30	MRM cartilage palisading and type 3 tympanoplasty

GROUP C

SL NO	COMOT 15 PRE OP	COMOT 15 POST OP	PTA PRE OP	PTA POST OP	PROCEDURE
1	45	8	53.3	58.3	Modified radical mastoidectomy with titanium torp
2	64	50	70	40	Radical mastoidectomy without ossicular reconstruction
3	48	24	33.3	26	Cortical mastoidectomy with type 1 tympanoplasty
4	33	2	45	20	Cortical mastoidectomy with type 3 tympanoplasty
5	48	`15	50	28	Cortical mastoidectomy with type 3 tympanoplasty
6	40	5	38	15	Type 1 tympanoplasty
7	32	9	40	18	Cortical mastoidectomy with type 3 tympanoplasty

8	30	6	40	15	Type 1 tympanoplasty
9	38	7	45	20	Cortical mastoidectomy with type 1 tympanoplasty
10	44	7	50	26	Type 3 tympanoplasty
11	40	15	40	25	Cortical mastoidectomy with type 1 tympanoplasty
12	30	18	50	21	Type 3 tympanoplasty
13	45	13	50	26	Cortical mastoidectomy with type 3 tympanoplasty
14	48	9	55	20	Cortical mastoidectomy with type 1 tympanoplasty
15	38	15	60	26	Cortical mastoidectomy with type 3 tympanoplasty
16	33	10	50	20	Type 3 tympanoplasty
17	39	9	48	22	Cortical mastoidectomy with type 1 tympanoplasty
18	40	11	40	26	Type 3 tympanoplasty
19	38	17	38	19	Type 3 tympanoplasty
20	33	15	60	20	Cortical mastoidectomy with type 1 tympanoplasty