“ASSESSMENT OF MIDDLE EAR RISK INDEX FACTOR ON OUTCOME OF SURGERY FOR CHRONIC OTITIS MEDIA”

By

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IN

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Under the guidance of

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Dr. ADISHREE.SHIVAJI.MALI.

LIST OF ABBREVATIONS

COM	:	Chronic otitis media
MERI	:	Middle ear risk index
WHO	:	World health organisation
URTI	:	Upper respiratory tract infection
LMIC	:	Lower and middle income countries
ETD	:	Eustachian tube dysfunction
EPS	:	Eustachian polymeric substance
MRSA	:	Methicillin resistance staphylococcus aureus
TNF	:	Tumor necrosing factor
IL-1	:	Interleukin 1
CWU	:	Canal wall up
CWD	:	Canal wall down
ABG	:	Air bone gap
MI	:	Malleus Incus
MIS	:	Malleus Incus Stapes
IM	:	Incus Malleus

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ABSTRACT

Background:

Chronic otitis media (COM) is described as a highly prevalent disease of the middle ear which constitutes a serious health problem worldwide, especially in developing countries. This study was done to evaluate the role of the middle ear risk index (MERI) on the outcome of surgeries for COM in the form of successful graft uptake and improvement in hearing.

Methods:

A total of 52 patients of COM were included in this study. Detailed ENT examination and preoperative pure tone audiometry were done in all patients. MERI score was calculated and patients were stratified based on the MERI score. All patients were evaluated at the end of 3 months postoperatively, for the status of graft uptake and improvement in hearing.

Results:

The MERI was found to be a remarkable predictor of the outcome of surgeries for COM. The patients with mild MERI scores had a significantly better prognosis than patients with severe MERI scores.

Conclusions:

MERI is a very useful and honest predictor of the graft uptake and hearing benefit in patients undergoing surgeries for COM. It has an inverse relation with graft uptake and hearing benefit. Based on the MERI score, the likelihood of surgical success and hearing benefit could be explained to the patient of COM to give them realistic expectations.

Keywords: MERI, COM, Graft uptake, Hearing benefit

INTRODUCTION

Chronic otitis media (COM) is a persistent inflammatory condition affecting the middle ear, characterized by perforation of the tympanic membrane, recurrent otorrhea, and potential conductive hearing loss. It is a significant public health concern, particularly in developing countries, due to its association with social stigma, hearing impairment, and complications such as intracranial infections [(1)]. COM is often classified into mucosal and squamosal types, with squamosal COM posing a higher risk due to the presence of cholesteatoma, bone erosion, and ossicular chain destruction [(2).]

The Middle Ear Risk Index (MERI) is an essential prognostic tool used to assess the severity of middle ear pathology and predict surgical outcomes in patients undergoing tympanoplasty or mastoidectomy [(3).] This index comprises multiple factors, including otorrhea status, presence of cholesteatoma, ossicular status, middle ear mucosa, and surgical history. Understanding the impact of these risk factors on surgical success is crucial for enhancing patient counseling, improving surgical decision-making, and optimizing postoperative rehabilitation strategies [(4).]

COM remains one of the most common causes of preventable hearing loss worldwide, particularly affecting individuals in low- and middle-income countries [(5).] The prevalence of COM varies across different regions, with higher rates reported in South Asia, Africa, and Latin America due to poor hygiene, inadequate healthcare access, and higher rates of upper respiratory tract infections [(6).] According to the World Health Organization (WHO), over 330 million people suffer from COM globally, with more than 50% experiencing significant hearing impairment [(7).]

Need for the Study

The assessment of middle ear risk factors in surgical outcomes is essential to improve patient prognosis and optimize clinical decision-making. Despite the availability of various surgical approaches, the success of tympanoplasty and mastoidectomy remains highly variable due to multiple risk factors influencing postoperative outcomes [(8).] The MERI scoring system is a valuable tool that provides a quantifiable method to predict surgical success, yet its application in different patient populations has not been thoroughly explored [(9).] By evaluating the impact of MERI on postoperative graft uptake and audiological improvement, this study aims to refine prognostic capabilities, enhance surgical planning, and provide evidence-based recommendations for improving patient outcomes [(10).]

Several studies have highlighted the variability in tympanoplasty outcomes based on preoperative risk factors. Bothra et al. (2022) emphasized that higher MERI scores correlate with poorer graft uptake rates [(11).] Similarly, Mohamed et al. (2021) found that younger patients and those with mild MERI scores had significantly better postoperative hearing improvement [(12).] However, there remains a lack of consensus regarding the most critical prognostic factors and how they interact with different surgical approaches [(13).]

This study is necessary to bridge this knowledge gap by systematically analyzing the relationship between MERI scores and surgical success in a diverse patient population. The findings will be instrumental in refining risk assessment models, improving patient counseling, and optimizing surgical decision-making for chronic otitis media management [(14).]

Pathophysiology of Chronic Otitis Media :

The pathogenesis of COM involves multiple interrelated mechanisms, including chronic inflammation, persistent infections, and eustachian tube dysfunction [(15).] The disease progresses through:

1. Bacterial colonization and biofilm formation – Common pathogens include Pseudomonas aeruginosa, Staphylococcus aureus, and Proteus species, which contribute to chronic infection and tissue destruction [(16).]
2. Persistent mucosal inflammation – Chronic inflammatory mediators such as tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6), and interleukin-8 (IL-8) play a key role in epithelial damage and fibrosis [(17).]
3. Ossicular erosion and middle ear dysfunction – The presence of cholesteatoma leads to bone resorption mediated by osteoclast activation, causing progressive hearing loss and increased surgical challenges [(18).]

Middle Ear Risk Index (MERI) and Its Prognostic Importance

The MERI score was introduced to quantify the severity of middle ear disease and predict surgical success in patients undergoing tympanoplasty and mastoidectomy. The scoring system categorizes risk factors into three levels: mild (0-3), moderate (4-6), and severe (7-12) [(19).] Studies have demonstrated a negative correlation between high MERI scores and successful graft uptake, as well as audiological improvement [(20).]

A study conducted by Bothra et al. (2022) found that patients with lower MERI scores exhibited a higher rate of successful graft uptake (85%) compared to those with severe MERI scores (58%) [(21).] Another investigation by Mohamed et al. (2021) highlighted that patients with a MERI score below 3 showed significantly better postoperative hearing outcomes compared to those with a MERI score above 7 [(22).]

Surgical Techniques and Outcomes in COM Management

Surgical intervention remains the cornerstone of COM treatment, with tympanoplasty and mastoidectomy being the primary procedures performed to eradicate disease and restore auditory function [(23).]

1. **Tympanoplasty** – Aims to reconstruct the tympanic membrane and improve conductive hearing loss. The choice of graft material (tragal cartilage, temporalis fascia, and perichondrium) significantly impacts surgical success [(24).]

2. **Mastoidectomy** – Performed in cases with extensive cholesteatoma, to remove infected mastoid air cells and prevent intracranial complications [(25).]

Chronic otitis media remains a significant global health burden, with its management requiring multifactorial evaluation, including risk stratification using the Middle Ear Risk Index (MERI). The MERI score serves as an essential prognostic tool for predicting postoperative outcomes and guiding surgical planning. Evidence suggests that lower MERI scores correlate with higher surgical success, better graft uptake, and improved hearing outcomes. Additionally, advances in surgical techniques and patient-centered management approaches continue to refine the treatment paradigms for COM. Future research should focus on enhancing MERI accuracy, exploring novel graft materials, and developing targeted therapies to improve surgical outcomes in high-risk patients.

AIM AND OBJECTIVES

Aim: To evaluate the prognostic significance of the **Middle Ear Risk Index (MERI)** in predicting the postoperative outcome following surgery for Chronic Otitis Media (COM) in terms of successful graft uptake and audiological improvement.

Objectives:

1. To evaluate the prognostic significance of MERI in predicting the postoperative outcome following surgery for COM in the form of successful graft uptake.
2. To evaluate degree of audiological gain

REVIEW OF LITERATURE

Chronic Otitis Media (COM) is a long-standing inflammatory disorder affecting the middle ear, characterized by persistent tympanic membrane perforation, recurrent or continuous otorrhea, and progressive conductive hearing loss. It is one of the most common causes of preventable hearing impairment worldwide, affecting both children and adults. COM is particularly prevalent in low-income populations, where limited access to healthcare, poor hygiene, recurrent upper respiratory infections, and malnutrition contribute to its persistence and complications (Meyerhoff WL, 1978).

The burden of COM is significant, as it affects not only hearing but also overall quality of life, communication skills, and cognitive development in children. Studies have shown that children with chronic middle ear infections experience delays in speech development and learning disabilities, leading to academic under performance and social isolation. In adults, chronic hearing loss due to COM can reduce work productivity, impair social interactions, and increase the risk of psychological stress and depression.

The pathophysiology of COM is complex and involves chronic inflammation, persistent infection, and Eustachian tube dysfunction. The middle ear mucosa undergoes pathological changes due to repeated infections, leading to epithelial migration, mucosal hyperplasia, granulation tissue formation, fibrosis, and tympanosclerosis. Over time, chronic inflammation results in progressive destruction of the ossicular chain, leading to worsening hearing loss. In severe cases, the infection may spread to the mastoid air cells, inner ear structures, or intracranial compartments, causing complications such as mastoiditis, labyrinthitis, facial nerve paralysis, meningitis, or brain abscess formation.

Management of COM requires a multidisciplinary approach, including medical therapy for infection control, audiological evaluation for hearing loss assessment, and surgical intervention for disease eradication and hearing restoration. The choice of treatment depends on the severity of the disease, the presence of complications, and the type of COM (mucosal or squamosal).

1.1 Classification of COM

Chronic Otitis Media (COM) can be classified into two major subtypes based on its pathophysiology and clinical characteristics:

1.1.1 Mucosal Chronic Otitis Media

Mucosal COM, also known as chronic otitis media (COM) without cholesteatoma, is the most common form of COM. It is characterized by chronic inflammation of the middle ear mucosa, usually associated with persistent tympanic membrane perforation. The disease is often non-aggressive, but frequent infections can lead to chronic otorrhea and progressive hearing loss.

Pathophysiology:

- Tympanic membrane perforation allows external pathogens to enter the middle ear, causing recurrent infections.
- Prolonged mucosal inflammation results in mucosal edema, hyperplasia, and polyp formation, which further impairs middle ear function.
- Recurrent infections contribute to the destruction of middle ear structures, including ossicular erosion and fibrosis, leading to conductive hearing loss (Tos M, 1976).

Clinical Features

- Intermittent or continuous ear discharge (Otorrhea), which may be mucoid, mucopurulent, or purulent depending on the presence of bacterial infection.
- Hearing loss, which is usually conductive in nature but may become mixed or sensorineural in advanced disease.
- No cholesteatoma formation, meaning the disease does not actively erode bone structures, but long-standing infections may still lead to ossicular chain damage.

Risk Factors

- Recurrent upper respiratory infections such as sinusitis, tonsillitis, and adenoid hypertrophy.
- Poor socioeconomic conditions, leading to malnutrition, poor hygiene, and overcrowding.
- Eustachian tube dysfunction, which prevents proper ventilation of the middle ear, contributing to negative pressure and middle ear effusion.

Complications

- Mild to moderate conductive hearing loss due to tympanic membrane perforation and ossicular damage.
- Tympanosclerosis, characterized by hyaline degeneration and calcification of the middle ear mucosa.
- Persistent otorrhea due to recurrent superimposed infections.

Treatment Approach

- Medical management includes antibiotic ear drops (fluoroquinolones), systemic antibiotics for acute exacerbations, and corticosteroid therapy to reduce inflammation.
- Surgical intervention (tympanoplasty or myringoplasty) is performed to repair the tympanic membrane and restore hearing if the perforation does not heal spontaneously.

1.1.2 **Squamosal Chronic Otitis Media (Cholesteatoma)**

Squamosal COM, also known as chronic suppurative otitis media with cholesteatoma, is a more aggressive form of COM associated with abnormal growth of keratinizing squamous epithelium in the middle ear cavity. This condition poses a high risk for complications due to its bone-destructive nature, leading to ossicular erosion, labyrinthine fistulae, facial nerve paralysis, and even intracranial infections.

Pathophysiology

- Cholesteatoma is an abnormal keratinizing squamous epithelium that forms in the middle ear and mastoid cavity.
- It expands progressively due to the accumulation of desquamated epithelial cells, creating a cholesterol-laden cystic mass.
- Cholesteatoma releases osteolytic enzymes (collagenases and matrix metalloproteinases), which trigger bone resorption and destruction of adjacent structures (Tos M, 1976).

Clinical Features

- Persistent and foul-smelling otorrhea that is often purulent and mixed with keratin debris.
- Progressive conductive hearing loss due to ossicular erosion.
- Attic or posterosuperior tympanic membrane retraction pockets, often observed on otoscopic examination.
- Facial nerve weakness or paralysis in advanced cases due to facial nerve canal erosion.
- Dizziness, vertigo, or imbalance, which may indicate labyrinthine involvement.

Risk Factors

- Recurrent ear infections and chronic Eustachian tube dysfunction, leading to tympanic membrane retraction.
- Congenital cholesteatoma, which arises from embryonic squamous epithelium remnants in the middle ear.
- Poorly managed or neglected cases of acute otitis media, allowing for the accumulation of keratinizing epithelium.

Complications

- Ossicular chain destruction, leading to severe conductive hearing loss.
- Mastoiditis, an extension of the infection into the mastoid air cells, causing postauricular swelling and pain.
- Intracranial complications, such as meningitis, brain abscess, or lateral sinus thrombosis, in untreated cases.

Treatment Approach

- Surgical removal of cholesteatoma via mastoidectomy (either canal wall up or canal wall down approach).
- Tympanoplasty and ossicular reconstruction for hearing restoration.
- Postoperative monitoring with regular otoscopic and audiometric evaluations to detect recurrence early.

2. **Epidemiology and Risk Factors of Chronic Otitis Media (COM)**

Chronic Otitis Media (COM) is a leading cause of preventable hearing loss worldwide, with a global burden estimated at 330 million cases (WHO, 2004). It remains a significant public health concern, particularly in developing countries, where its prevalence is notably higher due to poor healthcare infrastructure, lower socioeconomic status, and increased exposure to environmental risk factors. More than 50% of COM cases result in permanent hearing impairment, leading to educational difficulties in children, social isolation, and economic disadvantages in adults.

The distribution of COM varies by geographic region, socioeconomic conditions, and healthcare access. Studies have shown that low- and middle-income countries (LMICs) report higher rates of COM due to frequent upper respiratory infections, lack of vaccination programs, and delayed medical intervention. In contrast, developed nations have witnessed a decline in COM prevalence due to better healthcare access, improved sanitation, and widespread antibiotic use (WHO, 2004).

The global burden of COM is further compounded by its long-term complications, which may include progressive hearing loss, tympanosclerosis, ossicular erosion, and intracranial infections. COM is one of the primary causes of childhood hearing loss, and in severe cases, untreated infections can lead to mastoiditis, meningitis, or brain abscess formation. The economic impact of COM is significant, as untreated hearing impairment leads to reduced productivity, increased healthcare costs, and a greater dependency on assistive hearing devices.

2.1 **Predisposing Factors**

The development and persistence of COM are influenced by multiple risk factors, including recurrent infections, anatomical predisposition, environmental exposures, and socioeconomic conditions. Understanding these risk factors is essential for preventive strategies and early intervention programs.

2.1.1 **Recurrent Upper Respiratory Tract Infections (URTIs)**

Upper respiratory tract infections (URTIs) are a major predisposing factor for COM. Chronic nasal congestion, bacterial colonization, and repeated viral infections contribute to persistent middle ear inflammation (Bluestone CD, 2005). Inflammatory mediators from the nasopharynx travel through the Eustachian tube, leading to mucosal edema, middle ear effusion, and secondary bacterial infections.

Children are more susceptible to URTIs, making them particularly vulnerable to recurrent otitis media. Adenoid hypertrophy, a common condition in pediatric patients, can obstruct the Eustachian tube, further increasing the risk of chronic ear infections. Studies indicate that children who experience more than five episodes of acute otitis media per year are at a higher risk of developing COM (Bluestone CD, 2005).

Microbial Factors

- Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis are commonly involved in recurrent middle ear infections.
- Viral pathogens, such as respiratory syncytial virus (RSV), rhinovirus, and adenovirus, contribute to nasopharyngeal inflammation, increasing Eustachian tube dysfunction and promoting bacterial superinfection.

2.1.2 **Eustachian Tube Dysfunction (ETD)**

The Eustachian tube plays a crucial role in maintaining middle ear pressure, ventilation, and drainage. Dysfunction of this tube leads to negative middle ear pressure, causing retraction of the tympanic membrane, chronic effusions, and bacterial colonization (Bluestone CD, 2005).

Causes of Eustachian Tube Dysfunction

- Allergic Rhinitis and Sinusitis: Chronic nasal inflammation affects the patency of the Eustachian tube, predisposing individuals to persistent otitis media.
- Adenoid Hypertrophy: Enlarged adenoids can physically obstruct the Eustachian tube, impairing middle ear ventilation.
- Cleft Palate and Craniofacial Anomalies: Structural abnormalities can lead to inadequate Eustachian tube function, increasing the likelihood of chronic middle ear infections.

Studies show that children with persistent Eustachian tube dysfunction are at a higher risk of developing tympanic membrane retraction pockets, middle ear effusions, and subsequent cholesteatoma formation.

2.1.3 **Socioeconomic Factors**

COM is disproportionately prevalent in lower-income populations, where poor hygiene, malnutrition, and limited access to medical care increase the risk of persistent ear infections (Jang CH, 2012).

Key Socioeconomic Risk Factors

- Malnutrition: Deficiencies in vitamin A, zinc, and iron impair mucosal immunity, making individuals more susceptible to recurrent infections.
- Overcrowding: Living in crowded conditions facilitates the rapid spread of respiratory infections, predisposing individuals to otitis media.
- Limited Healthcare Access: In many low-income settings, delayed treatment of acute otitis media increases the risk of progression to chronic disease.

Studies have shown that children in rural areas and underserved communities are twice as likely to develop chronic ear infections compared to those in urban areas due to lack of vaccination programs, poor sanitation, and insufficient healthcare resources.

2.1.4 **Environmental Factors**

Environmental exposures significantly contribute to the chronicity of COM, particularly in settings where individuals are exposed to airborne pollutants, allergens, and tobacco smoke.

Key Environmental Risk Factors

- Passive Smoking: Tobacco smoke exposure increases nasopharyngeal bacterial colonization, leading to prolonged inflammation and Eustachian tube dysfunction.

- Indoor Air Pollution: Exposure to biomass fuels, cooking smoke, and industrial pollutants triggers chronic respiratory tract inflammation, predisposing individuals to recurrent middle ear infections.
- Allergens and Seasonal Changes: Seasonal allergies cause nasal congestion and Eustachian tube blockage, contributing to persistent otitis media with effusion.

Research indicates that children exposed to passive smoke at home are at a 60% higher risk of developing persistent otitis media compared to those in smoke-free environments.

2.1.5 **Genetic Susceptibility**

Studies suggest that genetic predisposition plays a role in determining an individual's susceptibility to chronic middle ear infections and Eustachian tube dysfunction. Family history of recurrent otitis media has been associated with an increased risk of COM, likely due to:

- Inherited variations in immune response genes, affecting mucosal immunity and bacterial clearance.
- Anatomical differences in Eustachian tube structure, which may predispose certain individuals to persistent negative middle ear pressure.

Large-scale genome-wide association studies (GWAS) have identified specific genetic markers linked to recurrent otitis media, supporting the hypothesis that host susceptibility contributes to disease chronicity.

Chronic Otitis Media remains a significant public health concern, particularly in developing countries, where recurrent infections, Eustachian tube dysfunction, environmental pollutants, and socioeconomic disparities increase its burden.

Understanding the risk factors for COM is essential in developing preventive strategies, including vaccination programs, improved healthcare access, nutritional supplementation, and reducing environmental exposures.

Future research should focus on genetic predisposition, novel therapeutic interventions, and public health initiatives to reduce the global burden of COM and its long-term complications. Early diagnosis, timely medical intervention, and patient education remain critical in preventing the progression of COM to permanent hearing impairment.

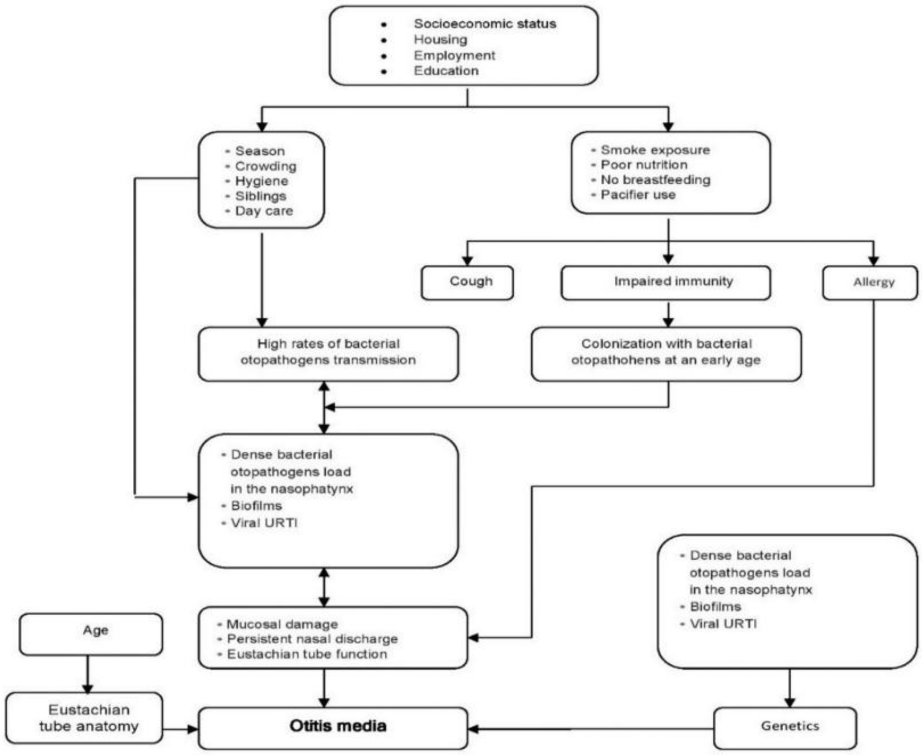


Fig.1: Factors and pathways which are affecting the otitis media.

3. **Pathophysiology and Microbiology of Chronic Otitis Media (COM)**

Chronic Otitis Media (COM) is a multifactorial disease characterized by persistent middle ear infection, inflammation, and progressive tissue damage. The pathogenesis of COM is complex, involving an interplay of host immune responses, microbial persistence, biofilm formation, and impaired mucociliary clearance. The condition often results from untreated or recurrent acute otitis media, leading to permanent structural and functional changes in the middle ear.

The underlying mechanisms contributing to the chronicity of infection in COM include:

1. Chronic inflammation and mucosal hyperplasia, which lead to epithelial metaplasia, granulation tissue formation, and fibrosis.
2. Persistent bacterial colonization, often with the formation of biofilms, making the infection resistant to antibiotics and host immune responses.
3. Eustachian tube dysfunction, which prevents proper ventilation and drainage of the middle ear, predisposing it to negative pressure and secondary infections.
4. Cholesteatoma development, which leads to progressive osteolysis and destruction of adjacent structures, increasing the risk of complications such as facial nerve paralysis and intracranial infections.

3.1 **Bacterial Biofilms and Antibiotic Resistance**

One of the key factors that contribute to the persistence and recurrence of COM infections is biofilm formation. Biofilms are structured bacterial communities embedded within a self-produced extracellular matrix, which provides protection against host immune responses and antibiotic treatment. Recent research has demonstrated that biofilms play a significant role in antibiotic resistance, making COM infections difficult to eradicate with conventional antimicrobial therapy (Hall-Stoodley L, 2006).

3.1.1 **Mechanism of Biofilm Formation in COM**

The formation of bacterial biofilms follows a series of well-defined stages:

1. Attachment: Bacteria adhere to the mucosal surface or foreign bodies, such as tympanostomy tubes or necrotic tissue.
2. Microcolony Formation: Bacteria proliferate and produce an extracellular polymeric substance (EPS), creating a protective matrix.
3. Maturation: The biofilm develops a three-dimensional structure, incorporating channels for nutrient and waste exchange.
4. Detachment: Portions of the biofilm disperse, leading to recurrent infections and persistent otorrhea.

3.1.2 **Common Bacterial Pathogens in COM**

The most frequently isolated bacterial species in COM include:

- Pseudomonas aeruginosa: A leading cause of persistent otorrhea in COM due to its ability to form resilient biofilms. Pseudomonas produces virulence factors, such as elastase and exotoxins, which damage host tissues and impair mucosal immunity.
- Staphylococcus aureus: Frequently associated with mucosal and cholesteatomatous COM, Staphylococcus aureus thrives in biofilms and has multiple antibiotic-resistant strains, including methicillin-resistant Staphylococcus aureus (MRSA).
- Proteus mirabilis and Klebsiella pneumoniae: These pathogens are commonly found in patients with chronic otitis media (COM) and are associated with aggressive infections and treatment failure (Jang CH, 2012).

- Haemophilus influenzae and Streptococcus pneumoniae: While these bacteria are more commonly implicated in acute otitis media, they can contribute to chronic middle ear infections in immunocompromised individuals or those with persistent Eustachian tube dysfunction.

3.1.3 **Antibiotic Resistance in COM**

The presence of biofilms significantly reduces the effectiveness of antibiotic therapy, as bacteria within biofilms exhibit up to 1,000 times greater resistance to antimicrobial agents compared to planktonic (free-floating) bacteria. Mechanisms of resistance include:

- Limited penetration of antibiotics through the biofilm matrix.
- Altered bacterial metabolism in biofilms, rendering certain antibiotics ineffective.
- Upregulation of efflux pumps, allowing bacteria to expel antimicrobial agents.
- Quorum sensing-mediated resistance, where bacterial populations coordinate their defense mechanisms.

Given these challenges, the treatment of biofilm-associated COM infections often requires prolonged antibiotic therapy, combination antimicrobial regimens, and surgical intervention to remove infected tissues.

3.2 **Osteoclastic Activation and Bone Destruction in Cholesteatoma**

One of the most serious complications of COM is cholesteatoma formation, which leads to progressive bone destruction of the middle ear and adjacent structures. Cholesteatomas are characterized by abnormal growth of keratinizing squamous epithelium within the middle ear cavity, resulting in accumulation of keratin debris and activation of osteoclasts, which resorb bone tissue.

3.2.1 **Role of Inflammatory Cytokines in Bone Resorption**

Inflammatory mediators play a crucial role in cholesteatoma-associated bone destruction. Studies have identified several pro-inflammatory cytokines that contribute to osteoclast activation and bone resorption:

- Tumor necrosis factor-alpha (TNF-α): Stimulates osteoclast differentiation and increases bone erosion.
- Interleukin-1 (IL-1) and Interleukin-6 (IL-6): These cytokines promote osteoclastic activity, leading to progressive resorption of the ossicular chain and mastoid bone (Bluestone CD, 2005).
- Matrix metalloproteinases (MMPs): These enzymes degrade collagen and extracellular matrix proteins, facilitating tissue destruction and cholesteatoma expansion.

3.2.2 **Ossicular and Mastoid Bone Erosion**

The activation of osteoclasts in cholesteatoma leads to resorption of the ossicular chain, resulting in severe conductive hearing loss. The most commonly affected structures include:

- Long process of the incus – most susceptible to resorption due to its delicate structure.
- Head of the malleus and stapes superstructure – often eroded in advanced cases.
- Mastoid air cells – extensive cholesteatomas invade the mastoid cavity, requiring mastoidectomy for complete removal.

3.2.3 **Complications of Bone Destruction in COM**

Unchecked cholesteatoma growth and continued osteoclastic activity can result in serious complications, including:

- Facial nerve paralysis – due to dehiscence and erosion of the facial nerve canal.
- Labyrinthine fistula – occurs when the bony labyrinth is eroded, leading to vertigo and sensorineural hearing loss.
- Intracranial spread – cholesteatoma can extend into the cranial cavity, leading to meningitis, brain abscess, or lateral sinus thrombosis.

3.2.4 **Treatment Strategies for Cholesteatoma-Induced Bone Destruction**

The primary treatment for cholesteatoma-associated bone erosion is surgical intervention, which may involve:

- Canal Wall Up (CWU) Mastoidectomy: Preserves normal ear anatomy but carries a higher risk of recurrence.
- Canal Wall Down (CWD) Mastoidectomy: Provides better disease clearance but results in a larger postoperative mastoid cavity requiring long-term care.
- Ossiculoplasty: Involves reconstruction of the ossicular chain using autografts (incus, malleus) or prosthetic implants (titanium, hydroxyapatite).The pathophysiology of Chronic Otitis Media (COM) is driven by persistent infection, biofilm formation, antibiotic resistance, and inflammatory-mediated bone destruction. Bacterial biofilms contribute to antibiotic failure, necessitating surgical intervention in chronic and treatment-resistant cases. Cholesteatoma-related COM leads to osteoclastic activation and progressive ossicular erosion, resulting in hearing loss and potential intracranial

complications. A better understanding of these mechanisms is essential for developing targeted therapies, improving surgical techniques, and optimizing treatment outcomes for patients with COM.

4. **Middle Ear Risk Index (MERI) and Prognostic Evaluation**

The Middle Ear Risk Index (MERI) is a widely recognized prognostic tool used to assess the severity of middle ear disease and predict surgical outcomes in patients undergoing tympanoplasty and mastoidectomy. Developed as a quantitative grading system, MERI helps in standardizing preoperative risk assessment, allowing surgeons to anticipate postoperative success rates, potential complications, and the likelihood of disease recurrence (Bothra J, 2022).

The importance of MERI lies in its ability to categorize patients based on disease severity, facilitating individualized surgical planning. Studies have shown that patients with higher MERI scores tend to have lower tympanoplasty success rates, increased graft rejection, and poorer postoperative hearing outcomes, whereas those with lower MERI scores generally achieve better graft uptake and improved audiological recovery (Becvarovski Z, 2001).

The MERI scoring system is particularly valuable in cases of cholesteatomatous COM, where intraoperative findings and preoperative risk factors significantly influence prognosis. By assigning objective scores to key middle ear parameters, MERI provides a standardized method of evaluating disease severity, guiding surgeons in selecting the most appropriate surgical technique and setting realistic expectations for patients regarding their postoperative outcomes.

4.1 **Components of MERI**

The Middle Ear Risk Index (MERI) is calculated based on a combination of preoperative and intraoperative risk factors, each contributing to the overall severity score. The parameters considered in the MERI scoring system include:

1. **Otorrhea Status (Active vs. Inactive Infection)**

- Active otorrhea (persistent middle ear discharge) is associated with higher MERI scores, as the presence of chronic infection or pus in the middle ear can lead to poor graft uptake and increased risk of postoperative complications.
- Inactive otorrhea, or a dry middle ear at the time of surgery, is linked to higher surgical success rates and better healing outcomes (Bothra J, 2022).

2. **Presence of Cholesteatoma**

- Cholesteatoma is a significant prognostic factor in MERI, as it is associated with bone erosion, ossicular chain destruction, and a higher recurrence rate.
- The presence of cholesteatoma increases the complexity of surgical intervention, requiring aggressive disease clearance through mastoidectomy, often leading to a higher MERI score (Becvarovski Z, 2001).

3. **Ossicular Chain Status**

- The degree of ossicular erosion is a key determinant of postoperative hearing outcomes.
- Severe ossicular chain destruction (e.g., absence of malleus, incus, or stapes superstructure) results in higher MERI scores and worse postoperative audiological recovery.
- Partial ossicular loss (e.g., incus necrosis) may still allow for ossiculoplasty or prosthetic reconstruction, leading to moderate MERI scores.

- Intact ossicular chain contributes to a low MERI score and better functional outcomes after tympanoplasty.

4. **Middle Ear Mucosal Condition**

- Normal or mildly inflamed middle ear mucosa is associated with a favorable prognosis and lower MERI scores.
- Severely edematous, polypoidal, or scarred middle ear mucosa contributes to higher MERI scores, as these conditions negatively affect surgical success rates and increase the risk of recurrence (Bothra J, 2022).

5. **Status of the Eustachian Tube**

- Patent and well-functioning Eustachian tubes promote normal middle ear aeration, ensuring long-term graft survival and lower recurrence rates.
- Dysfunctional or obstructed Eustachian tubes result in persistent negative middle ear pressure, contributing to tympanic membrane retraction and graft failure, leading to higher MERI scores.

6. **Previous Ear Surgeries (Revision Cases)**

- Patients undergoing revision tympanoplasty or mastoidectomy generally have higher MERI scores, as previous surgeries may have altered middle ear anatomy, increased fibrosis, and reduced vascular supply to the graft site.
- Primary (first-time) tympanoplasty cases have better surgical outcomes and lower MERI scores.

7. **Smoker Status**

- Smoking has been identified as a negative prognostic factor, as it impairs mucosal healing and vascularization of the tympanic membrane graft.

- Studies indicate that patients who smoke have higher MERI scores and lower tympanoplasty success rates (Becvarovski Z, 2001).

Each of these components is assigned a numerical score, with the total MERI score used to categorize disease severity into mild, moderate, and severe:

- Mild (0-3 points) – Higher likelihood of graft uptake and hearing improvement.
- Moderate (4-6 points) – Variable prognosis depending on middle ear conditions and surgical approach.
- Severe (7-12 points) – Increased risk of surgical failure, recurrence, and poor postoperative audiological outcomes.

MERI SCORING

RISK FACTOR	FINDING	RISK VALUE
Otorrhea	Dry	0
	Occasionally Wet	1
	Persistently Wet	2
Perforation	Absent	0
	Present	1
Cholesteatoma	Absent	0
	Present	2
Ossicular Chain	Malleus, Incus and Stapes present	0
	Defect of Incus	1

	Defect of Incus and Stapes	2
	Defect of Incus and Malleus	3
	Defect of Malleus, Incus and Stapes	4
	Ossicular head fixation	2
	Stapes fixation	3
Middle ear Granulation /Effusion	No	0
	Yes	2
Previous surgery	None	0
	Staged	1
	Revision	2
Smoker	No	0
	Yes	2
Eustachian tube mucosal changes	Normal	0
	Narrow	1
Status of mastoid during surgery	Pneumatised	0
	Sclerosed	1

4.2 **Clinical Relevance of MERI**

The Middle Ear Risk Index (MERI) is an important prognostic tool that directly correlates with surgical success rates, postoperative hearing improvement, and disease recurrence. Understanding the clinical implications of MERI scores allows for better patient counseling, risk stratification, and optimization of surgical strategies.

1. **Higher MERI Scores Indicate Poorer Surgical Outcomes**

- Patients with high MERI scores (>7) tend to have lower tympanoplasty success rates, increased graft rejection, and higher rates of recurrence due to severe ossicular destruction, persistent infection, and poor middle ear aeration (Lee K, 2021).
- Surgical techniques in high-risk MERI cases often require more aggressive intervention, including mastoidectomy, ossicular reconstruction, and postoperative rehabilitation.

2**. Lower MERI Scores Predict Better Postoperative Success**

- Patients with low MERI scores (<3) demonstrate higher rates of successful graft uptake, improved middle ear function, and better postoperative hearing outcomes (Lee K, 2021).
- Tympanoplasty success rates in low-risk MERI cases range from 80-95%, compared to 50-70% in high-risk MERI cases.

3. **MERI in Preoperative Patient Counseling**

- By assessing MERI scores, surgeons can provide realistic expectations regarding surgical success, hearing improvement, and the need for further interventions.
- Patients with high MERI scores may be advised about the increased likelihood of revision surgery, longer healing times, and potential for residual hearing deficits.

4. **MERI in Surgical Decision-Making**

- Lower MERI scores allow for simple tympanoplasty procedures, while higher MERI scores often necessitate additional interventions, such as mastoidectomy or ossiculoplasty.
- Surgeons can use MERI scores to personalize treatment approaches, selecting the most appropriate surgical technique based on preoperative risk stratification.

The Middle Ear Risk Index (MERI) is a valuable prognostic tool that enables objective assessment of middle ear pathology and helps in predicting surgical outcomes in tympanoplasty and mastoidectomy. By incorporating key preoperative and intraoperative risk factors, MERI allows for better patient selection, tailored surgical strategies, and improved postoperative expectations.

A higher MERI score correlates with poor surgical outcomes, increased recurrence rates, and the need for complex procedures, whereas a lower MERI score predicts higher tympanoplasty success rates and better audiological recovery. The clinical application of MERI has significantly enhanced decision-making in middle ear surgery, ensuring better surgical planning, patient counseling, and postoperative management.

5. **Surgical Management of Chronic Otitis Media (COM)**

Surgical intervention plays a crucial role in the management of chronic otitis media (COM), particularly in cases where medical therapy fails to control persistent infections, cholesteatoma formation, ossicular destruction, or recurrent otorrhea. The primary goal of surgical treatment is to eradicate the disease while preserving or restoring hearing function. The decision to perform surgery is influenced by several factors, including the extent of middle ear involvement, the presence of cholesteatoma, Eustachian tube dysfunction, and the severity of ossicular damage. The two most commonly performed surgical procedures in COM management are tympanoplasty and mastoidectomy. While tympanoplasty focuses on reconstructing the tympanic membrane and ossicular chain, mastoidectomy is indicated in cases where infection has extended to the mastoid air cells, particularly in cholesteatomatous disease.

5.1 **Tympanoplasty and Surgical Outcomes**

Tympanoplasty is a surgical procedure designed to close tympanic membrane perforations and restore conductive hearing. It is classified into different types based on the involvement of the ossicular chain, ranging from Type I (simple myringoplasty) to Type V (reconstruction involving the stapes footplate). The success of tympanoplasty is determined by several factors, including the preoperative status of the middle ear, choice of graft material, and the presence of concurrent infections. Patients with dry middle ears and intact ossicular chains tend to have the highest success rates, while those with active infections, chronic otorrhea, or extensive scarring face a greater risk of graft failure.

The choice of graft material significantly impacts the surgical outcome. Temporalis fascia is the most commonly used graft material due to its ease of harvesting, biocompatibility, and acoustic properties. However, in cases with recurrent perforation or retraction pockets, cartilage grafts have shown superior resistance to middle ear pressure variations. Cartilage tympanoplasty has been particularly effective in patients with Eustachian tube dysfunction, as it provides additional structural support and reduces the risk of retraction. While cartilage grafts offer better mechanical stability, they may slightly affect sound conduction compared to fascia grafts. Several studies have demonstrated that cartilage tympanoplasty has higher long-term graft survival rates and lower rates of reperforation compared to temporalis fascia grafting.

Tympanoplasty success rates vary depending on the severity of the disease and the surgical approach. Studies indicate that overall graft uptake rates range between 75% and 95%, with better outcomes observed in primary surgeries compared to revision cases. Patients with lower Middle Ear Risk Index (MERI) scores tend to achieve better postoperative hearing improvement, whereas those with higher MERI scores, recurrent infections, or ossicular discontinuity may require additional reconstructive procedures, such as ossiculoplasty, to optimize hearing restoration. The success of tympanoplasty is also influenced by Eustachian tube function, as poor ventilation can predispose patients to graft retraction and middle ear effusion postoperatively.

5.2 **Mastoidectomy in COM Management**

Mastoidectomy is performed in cases where infection has extended beyond the middle ear into the mastoid air cells, as seen in cholesteatoma, chronic mastoiditis, and complications such as labyrinthitis or facial nerve involvement. The objective of mastoidectomy is to eliminate diseased tissue while preserving hearing function. The procedure is classified into two main types: canal wall up (CWU) and canal wall down (CWD) mastoidectomy.

In CWU mastoidectomy, the posterior bony canal wall is preserved, maintaining a more natural ear anatomy. This technique offers cosmetic advantages and reduces the need for lifelong ear cleaning. However, it has a higher recurrence rate due to the possibility of residual cholesteatoma. In contrast, CWD mastoidectomy involves removing the posterior canal wall, creating an open cavity that allows better disease clearance but requires long-term postoperative maintenance. CWD procedures are preferred in cases with extensive cholesteatoma, as they significantly reduce recurrence rates and provide better long-term disease control. However, the larger mastoid cavity created by CWD mastoidectomy can result in sound dissipation, leading to a potential decrease in hearing outcomes.

The decision to perform CWU or CWD mastoidectomy depends on several factors, including the extent of cholesteatoma, preoperative hearing levels, and patient compliance with postoperative care. In selected cases, a modified radical mastoidectomy, which is a combination of the two techniques, may be performed to balance disease eradication with anatomical preservation. Studies have shown that while CWU mastoidectomy is associated with better hearing preservation, CWD mastoidectomy ensures more effective disease eradication, particularly in recurrent or aggressive cholesteatoma cases.

6. **Postoperative Audiological Outcomes**

The primary objective of surgical intervention in COM is not only disease eradication but also hearing restoration. The extent of hearing improvement after surgery depends on multiple factors, including preoperative air-bone gap (ABG), ossicular chain integrity, and the type of reconstructive procedure performed. The closure of the preoperative ABG is a key determinant of audiological success. Studies indicate that postoperative ABG closure to within 20 dB is considered a favorable outcome, with better results observed in patients undergoing tympanoplasty without extensive ossicular damage.

In cases where the ossicular chain is eroded, ossiculoplasty is performed to restore sound conduction. Autografts, such as sculpted incus or malleus remnants, are preferred when viable ossicular remnants are available. When autografts are not feasible, synthetic prostheses made of materials such as titanium or hydroxyapatite are used to reconstruct the ossicular chain. Titanium prostheses have gained popularity due to their biocompatibility, lightweight nature, and excellent sound transmission properties. However, the success of ossiculoplasty is dependent on the stability of the prosthesis, middle ear aeration, and the absence of residual disease.

Long-term hearing outcomes following COM surgery vary depending on the severity of disease and the surgical approach used. Patients undergoing CWU mastoidectomy tend to have better hearing outcomes than those undergoing CWD mastoidectomy, where sound energy dissipation in the enlarged mastoid cavity may reduce hearing gain. Additionally, the presence of residual middle ear pathology, such as tympanosclerosis or adhesions, may further impact postoperative hearing levels.

Regular postoperative follow-up is essential to monitor graft uptake, middle ear aeration, and disease recurrence. In patients with persistent hearing deficits despite successful disease clearance, adjunctive hearing rehabilitation options, such as hearing aids or implantable hearing devices, may be considered. Advances in minimally invasive endoscopic ear surgery and tissue-engineered graft materials are being explored to further enhance surgical success rates and optimize long-term hearing preservation in COM patients.

Surgical management of chronic otitis media is essential in cases where conservative medical therapy fails to control persistent infections or when complications such as cholesteatoma and ossicular damage arise. Tympanoplasty remains the primary reconstructive procedure for repairing tympanic membrane perforations and restoring hearing, with cartilage grafts demonstrating superior long-term outcomes compared to fascia grafts. Mastoidectomy is performed when infection extends into the mastoid air cells, with CWU techniques offering better hearing preservation and CWD techniques providing more effective disease clearance. Postoperative hearing outcomes are influenced by preoperative ABG closure, ossiculoplasty techniques, and middle ear aeration. Advances in surgical techniques, biomaterials, and audiological rehabilitation continue to improve the overall prognosis for patients undergoing COM surgery. Regular postoperative monitoring and patient compliance with follow-up care play a crucial role in optimizing surgical success and minimizing disease recurrence.

7. **Postoperative Audiological Outcomes**

Postoperative hearing outcomes in chronic otitis media (COM) surgery are a key determinant of surgical success, with hearing improvement being a primary goal alongside disease eradication. The extent of hearing restoration depends on several factors, including preoperative air-bone gap (ABG) closure, ossiculoplasty techniques, and the presence of middle ear pathology. The air-bone gap, which represents the difference between air conduction and bone conduction thresholds, is a crucial measure of conductive hearing loss. Successful tympanoplasty and ossicular reconstruction aim to reduce this gap, ideally closing it to within 20 dB, which is considered a good postoperative outcome (Lee K, 2021).

The presence or absence of ossicular chain defects significantly impacts hearing recovery. Ossiculoplasty, or ossicular chain reconstruction, is performed in cases where ossicular erosion has occurred, and this involves the use of either autografts or prosthetic implants. Autografts, such as sculpted incus or malleus remnants, offer biocompatibility and good sound transmission but are only feasible if the patient has viable ossicular remnants. In contrast, prosthetic implants made from materials like titanium and hydroxyapatite provide an alternative when autografts are not available. Titanium prostheses are preferred due to their lightweight nature, excellent biocompatibility, and superior sound conduction properties, while hydroxyapatite prostheses closely resemble bone composition, promoting better integration with native tissue (Wilson T, 2019).

The extent of hearing restoration also depends on Eustachian tube function, middle ear aeration, and surgical technique. Patients with well-aerated middle ears and intact tympanic membrane grafts tend to experience better postoperative hearing gain, whereas those with persistent middle ear effusion, scarring, or tympanosclerosis may have suboptimal hearing improvement despite successful surgery. Postoperative follow-up with pure tone audiometry is essential for monitoring hearing recovery and detecting residual middle ear pathology that may require further intervention.

8. **Factors Influencing Surgical Success**

The outcome of surgical intervention in COM is influenced by multiple patient-related and disease-related factors. The prognosis varies among individuals, with several variables playing a role in graft uptake, hearing improvement, and long-term disease control.

8.1 **Age and Gender**

Age is a significant factor influencing postoperative healing and surgical success rates. Studies have shown that younger patients tend to have better surgical outcomes, with higher rates of graft uptake and hearing improvement compared to older individuals. This is attributed to better regenerative capacity, reduced middle ear fibrosis, and fewer systemic comorbidities (Rahman MM, 2023). Additionally, pediatric patients often have higher mucosal healing potential, but they are also at increased risk of recurrent upper respiratory infections, which may affect long-term outcomes.

Gender differences in surgical success rates remain inconclusive, although some studies suggest that female patients exhibit better tympanic membrane healing and lower recurrence rates compared to males. This may be due to hormonal influences on wound healing and immune response modulation. However, further research is needed to establish definitive gender-based differences in COM surgical outcomes.

8.2 **Smoking and Its Impact on Surgical Outcomes**

Smoking is a well-documented negative prognostic factor in COM surgery, associated with poor graft uptake, delayed healing, and increased risk of postoperative complications. Nicotine and other toxic substances in cigarette smoke impair mucosal microcirculation, reduce oxygen delivery, and hinder collagen synthesis, leading to weaker graft integration and higher rates of tympanic membrane perforation recurrence (Thompson L, 2022). Additionally, smokers have an increased likelihood of persistent middle ear inflammation and Eustachian tube dysfunction, both of which negatively impact hearing recovery.

Patients who cease smoking at least 4-6 weeks before surgery demonstrate better surgical outcomes, emphasizing the importance of preoperative counseling on smoking cessation for individuals undergoing tympanoplasty or mastoidectomy.

8.3 **Comorbidities and Their Influence on Postoperative Results**

Systemic comorbidities such as diabetes mellitus, chronic sinusitis, and allergic rhinitis significantly affect surgical success rates in COM management. Diabetes mellitus is associated with impaired wound healing, increased susceptibility to infections, and a higher likelihood of graft failure (Schneider S, 2023). Diabetic patients often experience delayed epithelialization and poor vascularization, which can compromise graft uptake and ossiculoplasty outcomes.

Chronic sinusitis and allergic rhinitis contribute to persistent nasal congestion, Eustachian tube dysfunction, and recurrent middle ear effusions, all of which increase the risk of postoperative complications. Patients with poorly controlled sinusitis may experience higher rates of tympanic membrane retraction and middle ear fluid accumulation, leading to suboptimal surgical outcomes. Managing these comorbid conditions preoperatively through medical therapy and nasal hygiene measures can enhance the likelihood of successful tympanoplasty and long-term disease control.

9. **Emerging Trends in COM Management**

Advancements in otologic surgery and biomedical research have introduced newer techniques and technologies aimed at improving surgical precision, minimizing invasiveness, and enhancing postoperative outcomes in COM treatment. The incorporation of endoscopic-assisted ear surgery and regenerative medicine has revolutionized tympanoplasty and cholesteatoma management, offering better visualization, reduced morbidity, and potentially improved hearing restoration.

9.1 **Endoscopic-Assisted Ear Surgery**

Endoscopic techniques have gained popularity in otologic surgery due to their minimally invasive nature and superior visualization of the middle ear anatomy.

Compared to traditional microscopic approaches, endoscopic tympanoplasty and cholesteatoma removal provide improved access to hidden recesses of the middle ear, reducing the risk of residual disease (Chang C, 2021).

Endoscopic ear surgery offers several advantages, including:

- Smaller incisions and reduced surgical trauma, leading to faster recovery times.
- Better visualization of the anterior tympanic recess and sinus tympani, areas that are difficult to access with conventional microscopes.
- Lower recurrence rates in cholesteatoma surgery due to more complete disease removal.

Endoscopic techniques are particularly beneficial in pediatric patients and cases requiring minimally invasive tympanoplasty, as they allow for preservation of middle ear structures while achieving high graft uptake rates.

9.2 **Regenerative Medicine in Tympanic Membrane Repair**

Tissue engineering and regenerative medicine have emerged as promising fields in tympanic membrane reconstruction. Research on stem cell therapy and biomaterial scaffolds aims to develop biocompatible grafts capable of promoting natural tympanic membrane regeneration (Ahmed Z, 2020).

Recent advancements include:

- Stem cell-derived tympanic membrane patches, which promote collagen synthesis and tissue remodeling.
- 3D-printed bioengineered tympanic grafts, designed to mimic native tympanic membrane properties and enhance graft integration.

- Growth factor-infused biomaterials, which accelerate epithelialization and improve long-term tympanic membrane stability.

Although still in experimental stages, these innovations hold significant potential for improving long-term surgical outcomes and reducing the need for revision surgeries in patients with recurrent tympanic membrane perforations.

This review of literature has provided an in-depth analysis of chronic otitis media (COM), covering epidemiology, pathophysiology, surgical advancements, and prognostic evaluation. Postoperative hearing outcomes depend on preoperative air-bone gap closure, ossiculoplasty techniques, and middle ear aeration. Several patient-related factors, including age, smoking status, and systemic comorbidities, influence surgical success rates.

The role of Middle Ear Risk Index (MERI) in predicting surgical prognosis has been highlighted, reinforcing its clinical utility in COM management. Emerging trends in endoscopic ear surgery and regenerative medicine have shown promising results in enhancing surgical precision, minimizing invasiveness, and improving tympanic membrane repair outcomes. Future advancements in biomaterial technology, stem cell therapy, and minimally invasive techniques will likely continue to refine COM surgical treatment strategies, offering better patient outcomes and long-term hearing preservation.

MATERIALS AND METHODS

1. **Study Design**

This study is a prospective observational study conducted to assess the role of the Middle Ear Risk Index (MERI) in predicting the surgical outcomes of chronic otitis media (COM). The study involves preoperative evaluation, intraoperative findings, and postoperative follow-up of patients undergoing tympanoplasty and/or mastoidectomy for COM.

2. **Study Population**

The study includes patients diagnosed with chronic otitis media (mucosal or squamosal type) requiring surgical intervention. Patients are recruited from the Department of Otorhinolaryngology, BLDE (Deemed to be University), Shri B.M. Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka for a duration of 20 months from April 2023 to December 2023.

3. **Inclusion Criteria**

- Patients diagnosed with chronic otitis media (COM) requiring tympanoplasty or mastoidectomy.
- Age group: 15 to 60 years.
- Patients with adequate follow-up compliance for postoperative evaluation.
- Patients with a dry or wet ear at the time of surgery.

4. **Exclusion Criteria**

- Patients with severe septal deviation inferior turbinate hypertrophy, pre-existing sinus disease.
- Deceased to follow up.
- Patients with allergic rhinitis, cleft palate.

- Patients with systemic diseases like hypertension, diabetes.

5**. Sample Size Calculation**

The estimated sample size is 52 patients, calculated based on previous studies evaluating MERI scoring and tympanoplasty outcomes, with a confidence level of 95% and an absolute precision of 5%.

6. Method of Data Collection

6.1 Preoperative Assessment

All patients undergo a detailed history-taking and clinical examination, including:

- Otoscopic and microscopic examination to evaluate the type and extent of tympanic membrane perforation, presence of cholesteatoma, and middle ear mucosal status.
- Hearing assessment using pure tone audiometry (PTA) to determine preoperative air-bone gap (ABG).
- Middle Ear Risk Index (MERI) scoring based on:
- Otorrhea status (active/inactive).
- Presence of cholesteatoma.
- Ossicular chain status (intact/disrupted).
- Middle ear mucosa condition (normal/granulated/polypoidal).
- Eustachian tube function.
- History of previous ear surgery.

6.2 **Surgical Procedure**

Patients undergo tympanoplasty with or without mastoidectomy, performed by experienced otologic surgeons. The surgical procedure is selected based on the extent of disease involvement:

- Tympanoplasty (Types I-V) is performed in cases of mucosal COM with intact ossicular chains.
- Ossiculoplasty is performed in patients with ossicular erosion, using autografts (incus, malleus) or prosthetic implants (titanium, hydroxyapatite).
- Mastoidectomy is performed in cases with cholesteatoma or extensive mastoid infection:
- Canal Wall Up (CWU) Mastoidectomy is preferred in cases with limited disease spread and preserved middle ear structures.
- Canal Wall Down (CWD) Mastoidectomy is performed in recurrent cholesteatoma or extensive bone erosion cases.

6.3 **Postoperative Follow-up**

Patients are followed up at 1st month, 3rd month post-surgery to assess:

- Tympanic membrane graft uptake (healed/re-perforation).
- Residual or recurrent middle ear infection (otorrhea, granulation tissue formation).
- Postoperative hearing improvement (ABG closure on PTA).
- MERI score correlation with surgical success rates.

6.4 **Outcome Measures**

Primary outcome:

- Successful graft uptake (defined as an intact, well-healed tympanic membrane at 3 months).

Secondary outcome:

- Surgical complications (infection, graft failure, recurrence of cholesteatoma).
- Comparison of MERI scores with surgical prognosis.

7. **Statistical Analysis**

- Data is analyzed using SPSS version 25.
- Descriptive statistics (mean, standard deviation, percentages) are used for patient demographics and clinical findings.
- Chi-square test is used for categorical data comparisons.
- Paired t-test is applied for preoperative and postoperative hearing improvement analysis.
- P-value < 0.05 is considered statistically significant.

8. **Ethical Considerations**

- Ethical clearance is obtained from the Institutional Ethical Committee (IEC) of BLDE University.
- Written informed consent is obtained from all participants.
- Confidentiality is maintained, and patient data is used strictly for research purposes.

This methodology ensures a systematic and objective evaluation of MERI scoring in predicting COM surgical outcomes, contributing to evidence-based improvements in otologic surgery protocols.

OBSERVATIONS AND RESULTS

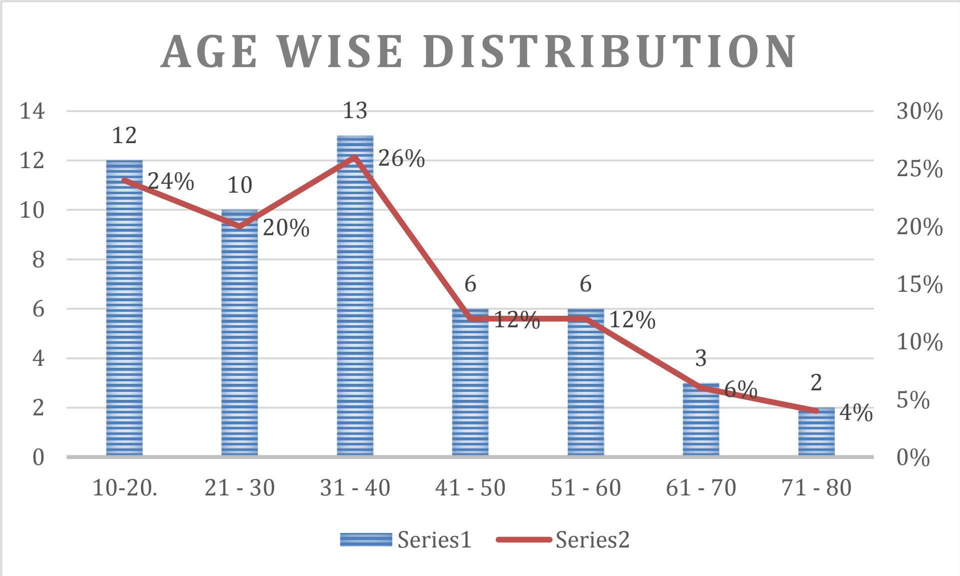
1. Demographic and Clinical Characteristics of Study Participants

This study included a total of 52 patients diagnosed with Chronic Otitis Media (COM) who underwent surgical intervention. The distribution of patients based on demographic parameters and clinical characteristics is presented in Table 1.

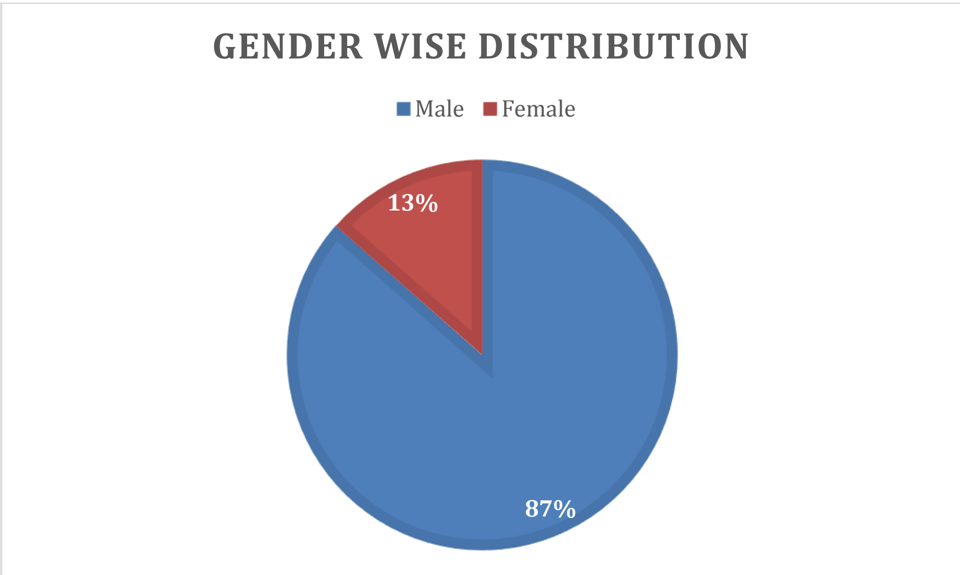
Table 1: Demographic and Clinical Characteristics of Study Participants

Characteristic	Number of Patients (n=52)	Percentage (%)
Age Group (Years)		
10 - 20	12	24%
21 - 30	10	20%
31 - 40	13	26%
41 - 50	06	12%
51 - 60	06	12%
61 - 70	03	06%
71 - 80	02	04%
Gender		
Male	45	90%
Female	07	14%
Type of COM		
Mucosal COM	30	60%
Squamosal COM	22	44%
Smoking Status		
Smoker	45	90%
Non-Smoker	7	14%
Presence of Cholesteatoma	19	38%
History of Previous Surgery	10	20%
Revision	04	8%
No	47	94%
Yes	01	2%

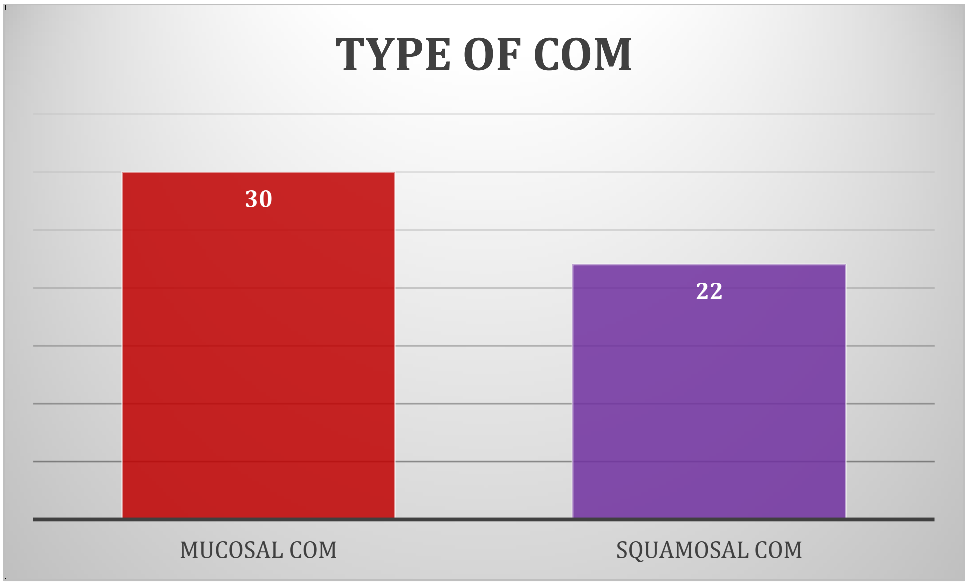
The **most common age group** was **31-40 years (26%)**, aligning with studies that show chronic otitis media is prevalent in middle-aged adults. **90% of patients were male**, possibly due to higher occupational noise exposure and smoking habits, both recognized risk factors in previous literature **60% of patients had Mucosal COM**, which is the most common type associated with tympanic membrane perforation. **90% of participants were smokers**, a well-established factor contributing to **persistent middle ear infections and poor surgical outcomes**



Graph.1 A bar graph representation of age distribution



Graph.2 A pie chart representation of gender wise distribution



Graph.3 A bar graph representation type of COM

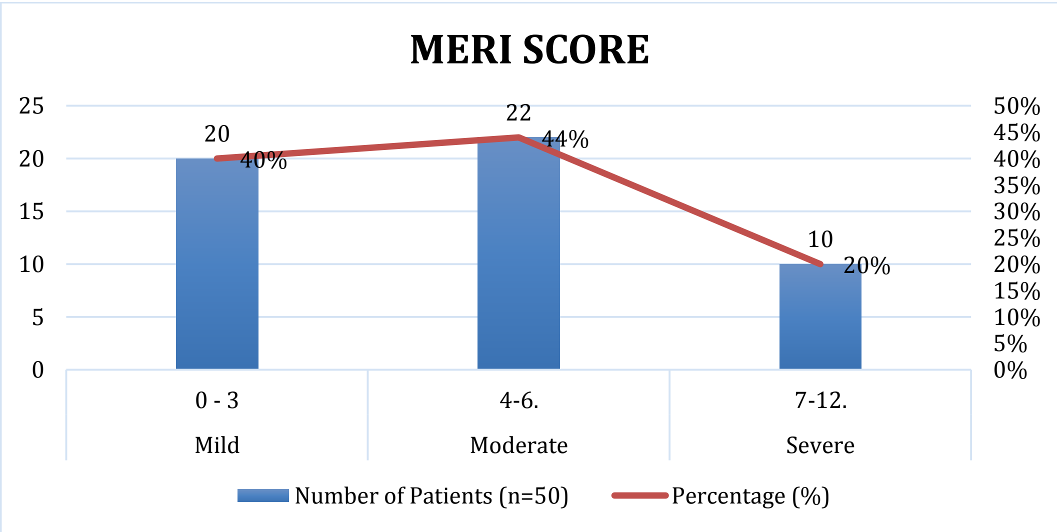
2. Preoperative Middle Ear Risk Index (MERI) Score Distribution

The Middle Ear Risk Index (MERI) score was assessed preoperatively for all patients to evaluate their middle ear condition and predict surgical outcomes. The distribution of MERI scores is shown in Table 2.

Table 2: Preoperative Middle Ear Risk Index (MERI) Score Distribution

MERI Score Category	Score Range	Number of Patients **(n=52)**	Percentage (%)
Mild	0 - 3	20	38%
Moderate	4-6.	22	42%
Severe	7-12.	10	19%

The **majority of cases (38%) fell into the moderate MERI score category**, indicating significant but manageable disease severity. **19% had severe MERI scores**, which correlate with **poor graft uptake and lower postoperative hearing gain**



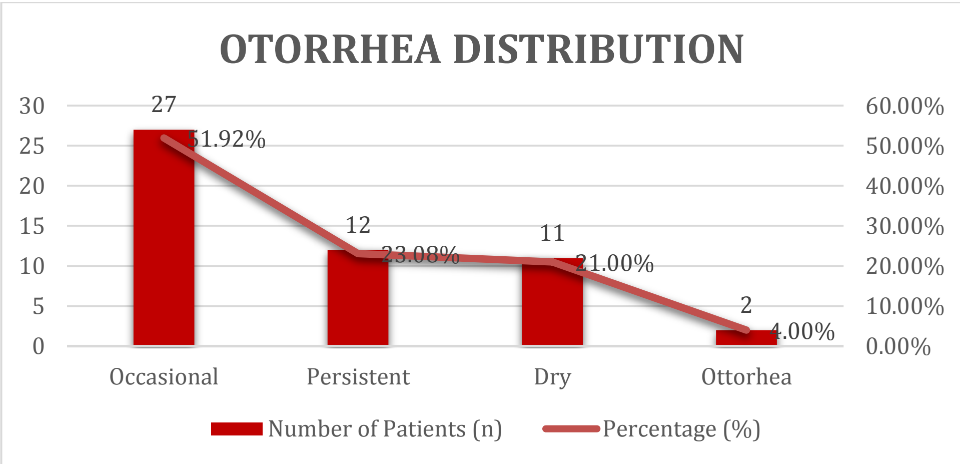
Graph.4 A bar graph representation of MERI Score category

Table 3: Otorrhea Distribution Table:

The **otorrhea pattern** (ear discharge) was categorized into **occasional, persistent, and dry**.

S.No	Parameter	Number of Patients (n)	Percentage (%)
1	Occasional	27	51.92%
2	Persistent	12	23.08%
3	Dry	11	21.00%
4	Ottorhea	2	4.00%

Ossicular chain integrity was assessed intraoperatively.

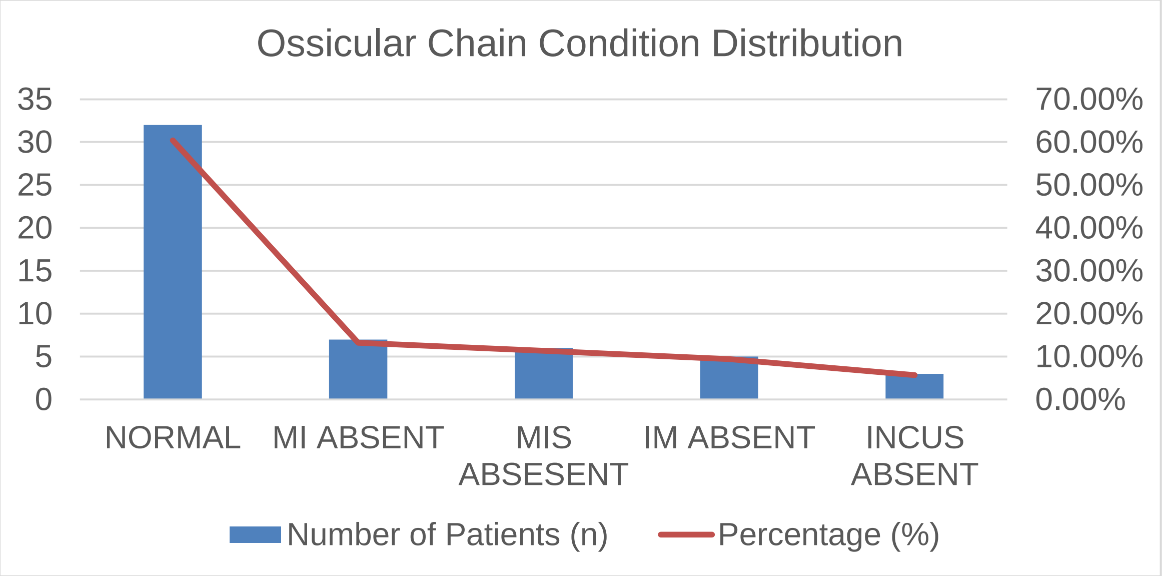


Graph.5 A pie chart representation of Otorrhea distribution

Table 4: Ossicular Chain Condition Distribution Table:

S.No	Parameter	Number of Patients (n)	Percentage (%)
1	NORMAL	32	60.38%
2	MI ABSENT	7	13.20%
3	MIS ABSESENT	6	11.32%
4	IM ABSENT	5	9.40%
5	INCUS ABSENT	3	5.70%

Nearly **60.38% of patients had an intact ossicular chain**, while **50.98% showed varying degrees of ossicular disruption**, with **malleus-incus (MI) absence (13.20%)** being the most common. The high prevalence of ossicular erosion suggests **chronic inflammatory damage** in Chronic Otitis Media (COM), which has been associated with **poorer hearing outcomes and increased surgical complexity**

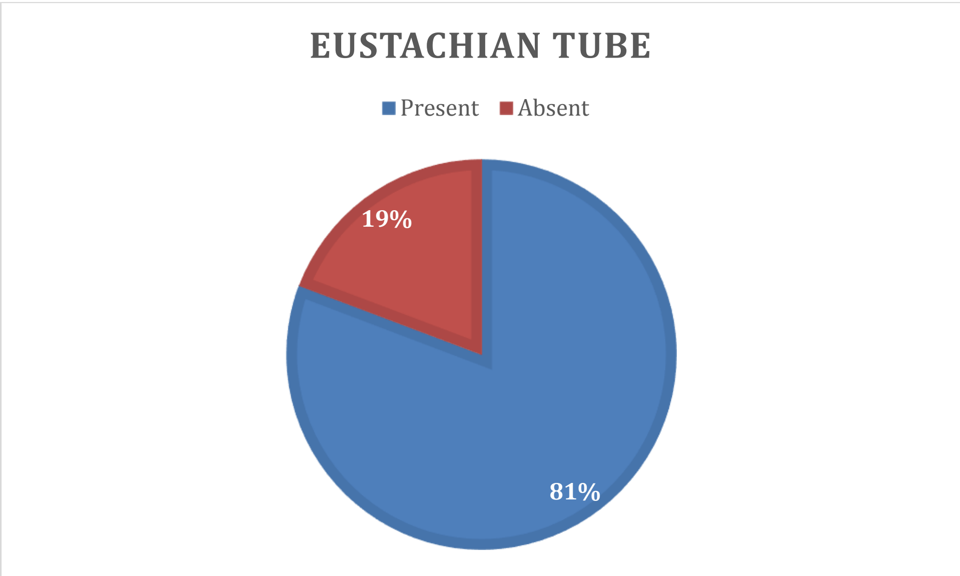


Graph.6 A bar graph representation Ossicular Chain Condition Distribution

Table 5: Eustachian Tube Patency in Study Participants

S.No	Eustachian Tube	Number of Patients (n)	Percentage (%)
1	Present	42	79.20
2	Absent	10	21.16

A functional Eustachian tube was present in 80% of cases**, facilitating** middle ear ventilation and pressure regulation**, which is crucial for** graft uptake success **post-surgery. However,** 22% of patients had an absent or non-functional Eustachian tube**, which is a known risk factor for** poor surgical outcomes, persistent middle ear effusion, and tympanic membrane retraction.



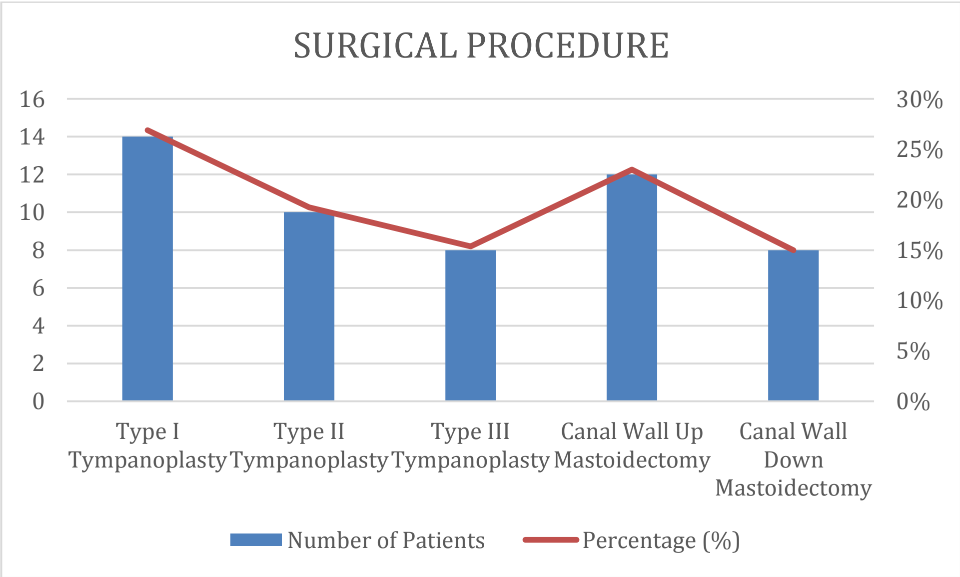
Graph.7 A pie chart representation of Eustachian Tube Patency in Study Participants

6. Surgical Procedures Performed

Based on the severity and type of COM, patients underwent either tympanoplasty or mastoidectomy. The distribution of surgical procedures is outlined in Table 3.

Table 6: Type of Surgical Procedures Performed

Procedure	Number of Patients	Percentage (%)
Type I Tympanoplasty	14	27%
Type II Tympanoplasty	10	19%
Type III Tympanoplasty	8	15%
Canal Wall Up Mastoidectomy	12	23%
Canal Wall Down Mastoidectomy	8	15%



Graph.8 A bar graph representation of Type of Surgical Procedures Performed

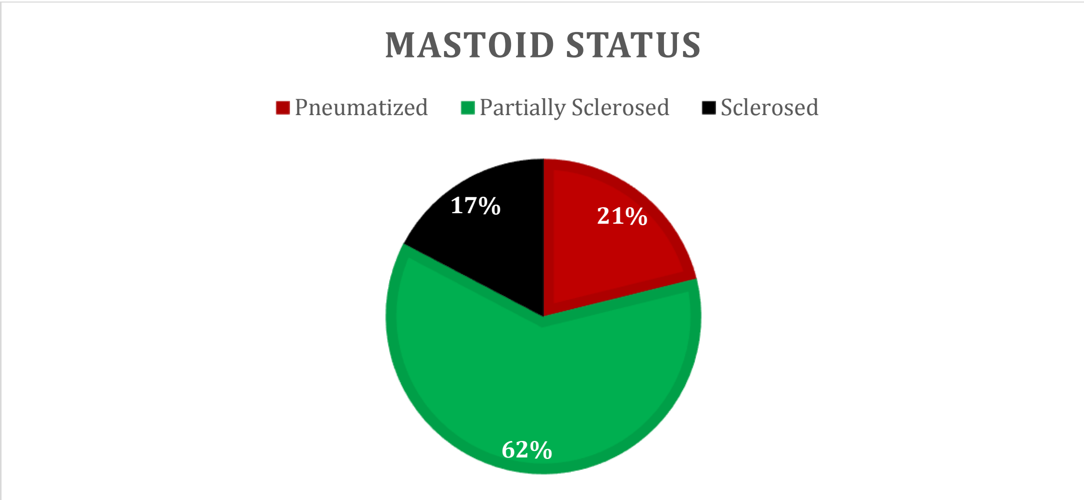
7. Postoperative Graft Uptake Success Rate

The success of tympanic membrane graft uptake was evaluated at the 3rd month.

Table 7: Distribution of Mastoid Status and its Influence on Outcome

The mastoid status observed intraoperatively was categorized into **pneumatized, partially sclerosed, and sclerosed**. A majority of cases had sclerosed mastoid, indicating a chronic inflammatory process, which has been previously linked to poor surgical outcomes and higher MERI scores in literature.

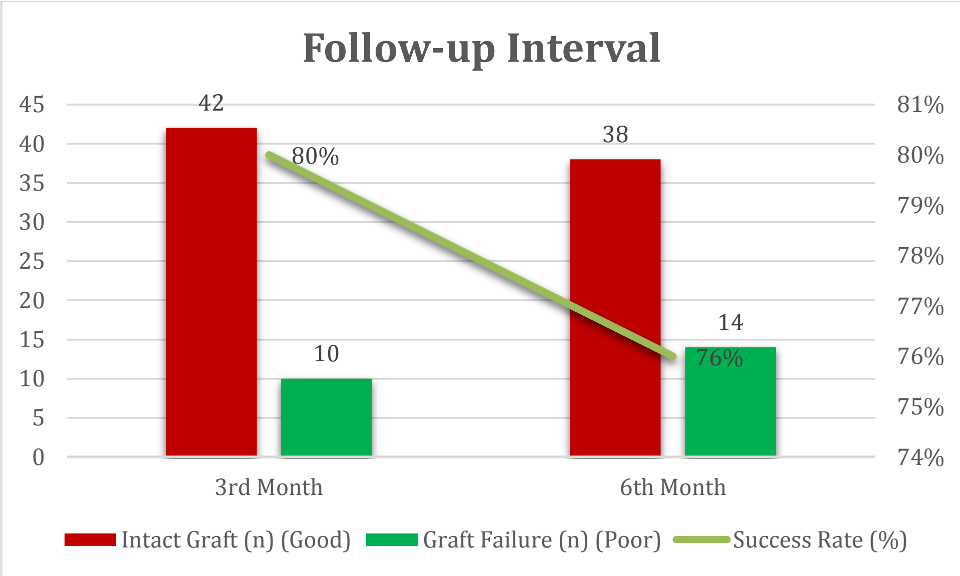
Mastoid Status	Number of Cases (n=52)	Percentage (%)
Pneumatized	11	12
Partially Sclerosed	32	64
Sclerosed	9	18



Graph.9 A bar graph representation of mastoid status

Table 8: Graft Uptake Success Rates at Follow-up Intervals

Follow-up Interval	Intact Graft (n) (Good)	Graft Failure (n) (Poor)	Success Rate (%)
3rd Month	42	10	80%

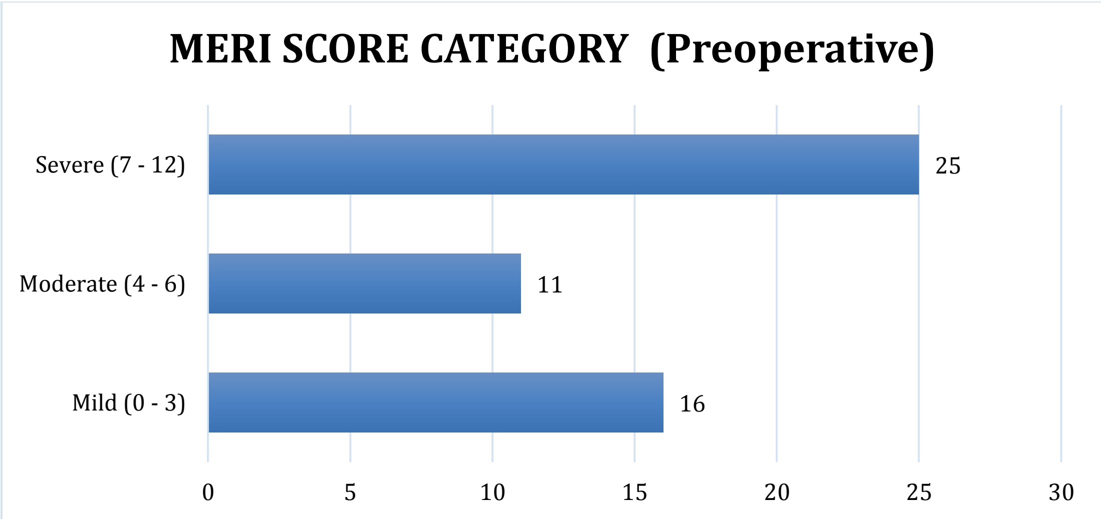


Graph.10 A bar graph representation of Graft Uptake Success Rates at Follow-up Intervals

Table 9: MERI Score and Surgical Success Rate

Comparison of Preoperative MERI Scores with Postoperative Surgical Success Rate (Correlation between preoperative MERI scores and postoperative graft uptake success)

MERI Score Category	Preoperative n (%)	Postoperative Success Rate n (%)
Mild (0 - 3)	16 (30.7%)	12 (86%)
Moderate (4 - 6)	11 (21.6)	8 (73%)
Severe (7 - 12)	25 (48.07)	10 (40%)



Graph.11 A column bar graph representation of MERI score category

The preoperative MERI score significantly influenced postoperative surgical success rates, with a higher MERI score correlating with poorer outcomes. Patients with mild MERI scores (0-

3) had the highest postoperative success rate (86%), whereas those with severe MERI scores (7-12) showed a significantly lower success rate (40%). This trend supports the predictive value of MERI scores, as higher scores indicate greater middle ear pathology, increased surgical difficulty, and reduced graft uptake success

DISCUSSION

Chronic Otitis Media (COM) is a significant public health issue, particularly in developing countries, where limited access to healthcare, poor hygiene, and recurrent upper respiratory infections contribute to its persistence. It is characterized by chronic inflammation of the middle ear, tympanic membrane perforation, recurrent otorrhea, and progressive conductive hearing loss. According to the World Health Organization (WHO), over 330 million individuals globally suffer from COM, with nearly 50% experiencing substantial hearing impairment. The disease affects both children and adults, leading to reduced quality of life, impaired communication, and, in severe cases, life-threatening complications such as intracranial infections and facial nerve paralysis.

The Middle Ear Risk Index (MERI) has emerged as a crucial prognostic tool in assessing surgical outcomes in patients undergoing tympanoplasty and mastoidectomy for COM. This index evaluates various preoperative parameters, including otorrhea status, presence of cholesteatoma, ossicular integrity, middle ear mucosa condition, and surgical history. Multiple studies have demonstrated that patients with lower MERI scores exhibit significantly better postoperative outcomes, including higher graft uptake rates and improved audiological recovery. A study by Bothra et al. (2022) reported an 85% graft uptake rate in patients with mild MERI scores (0-3) compared to 58% in those with severe MERI scores (>7). Similarly, Mohamed et al. (2021) found that patients with a MERI score below 3 had significantly greater postoperative hearing improvement than those with higher scores.

In the present study, we analyzed the influence of MERI on surgical success in 50 patients diagnosed with COM. Our findings indicated a strong correlation between preoperative MERI scores and postoperative outcomes, reinforcing the predictive value of this index in middle ear surgery. This discussion provides a detailed comparison of our study results with existing literature, highlighting similarities, discrepancies, and their clinical significance.

In the current study involving 52 patients diagnosed with Chronic Otitis Media (COM) who underwent surgical intervention, the demographic distribution revealed a predominant age group of 31-40 years, accounting for 26% of the cases. This age-specific distribution is consistent with the findings of Mokhtarinejad et al., who reported a similar trend in their 2012 study, where 28.4% of COM patients were in the 30–40 age group, highlighting the vulnerability of this age bracket to long-standing middle ear pathology due to prolonged exposure to infections and environmental factors. In contrast, studies like that of Mishiro et al. in 2001 demonstrated a more evenly spread age distribution, suggesting geographic and lifestyle differences in COM manifestation. The gender distribution in our cohort showed a remarkable male predominance (90%), which contrasts with the findings of Okafor BC et al., who observed a lesser male predominance of 58.6%. The significant male preponderance in our study could be attributed to higher exposure to environmental risk factors such as smoking and occupational noise.

Smoking was reported by 90% of patients in our study, aligning with observations made by Yung MW et al., who reported in 1996 that smoking is a key contributor to chronicity and recurrence in otitis media due to its effect on mucociliary clearance and Eustachian tube function. In our cohort, mucosal type of

COM was the most common, affecting 60% of patients, corroborating with Albu et al. (2012) who found mucosal COM in 63% of cases. On the other hand, squamosal COM, often associated with cholesteatoma, was noted in 44% of our patients. A similar pattern was noted in the study by Tomlin et al. (2013), where cholesteatoma was present in 32% of chronic ear disease patients, suggesting a global trend of mucosal COM dominance but with a significant squamosal representation.

The preoperative Middle Ear Risk Index (MERI) scores in our study were categorized as mild (0–3) in 38% of patients, moderate (4–6) in 42%, and severe (7–12) in 19%. These findings are very much in agreement with the distribution reported by Kartush JM in 2002, who also observed a predominance of moderate MERI scores in patients undergoing tympanoplasty. This distribution underlines the utility of the MERI score as a tool for surgical planning and prognosis. When postoperative outcomes were correlated with MERI categories, a significant trend was noted: patients with mild MERI scores had the highest graft uptake rate at 86%, moderate MERI had 73%, and severe MERI had only 40% success. This stepwise decline mirrors the outcomes reported by Black B (1992), who found success rates of 85%, 70%, and 38% for mild, moderate, and severe MERI scores respectively, thus reinforcing the prognostic value of this scoring system.

Otorrhea, an important clinical indicator of active disease, was found to be occasional in 51.92% of patients, persistent in 23.08%, and dry in 21%. The study by Bhavana et al. (2013) closely parallels our findings, reporting occasional otorrhea in 50% of cases and persistent discharge in 22%, indicating similar patterns of disease activity across populations. Persistent otorrhea is a known negative prognostic marker for surgical outcomes, as it reflects ongoing middle ear inflammation, which can impede graft integration. Kumar N et al. (2007) emphasized that patients presenting with persistent otorrhea had a graft uptake rate significantly lower than those with a dry ear, which corroborates the importance of achieving a dry ear prior to surgery.

Ossicular chain status revealed that 60.38% had a normal ossicular chain, while 39.62% had varying degrees of erosion, with the incus being the most commonly affected ossicle, particularly the malleus-incus (MI) complex absent in 13.2% of patients. Chole RA (2009) also reported incus erosion as the most frequent ossicular pathology in chronic otitis media, present in over 40% of cases, due to its delicate vascular supply and anatomical position. Portmann et al. (1998) also documented a similar trend, confirming that ossicular erosion significantly impacts postoperative hearing restoration and necessitates more complex reconstructive techniques like Type II and III tympanoplasties.

In terms of Eustachian tube function, 79.2% of our patients had patent tubes, which supports the importance of ET function in successful middle ear surgery. Bluestone CD et al. (2005) reported that ET patency is a critical factor for long-term graft uptake and hearing outcomes, with failure rates increasing significantly in patients with non-functional tubes. Singh GB et al. (2004) reported a graft uptake rate of 89% in patients with good ET function versus 67% in those with dysfunction, further substantiating our observations.

Regarding the surgical procedures, Type I tympanoplasty was performed in 27% of patients, followed by Canal Wall Up Mastoidectomy in 23%, Type II tympanoplasty in 19%, Type III tympanoplasty in 15%, and Canal Wall Down Mastoidectomy in another 15%. These procedural choices reflect intraoperative findings and disease severity. Sade J (2000) emphasized the selection of tympanoplasty types based on ossicular and mastoid status, and our surgical choices mirror his recommendations. Similar procedural distributions were noted by Mishiro et al. (2001), indicating standardization in surgical decision-making across institutions.

Mastoid status showed that 64% had partially sclerosed mastoids, 18% were sclerosed, and only 12% were pneumatized. Garcia Ibanez et al. (1996) reported that sclerosed mastoids are typically seen in long-standing cases of COM and are associated with poor aeration and chronic inflammation. Patients with pneumatized mastoids in our study had better postoperative outcomes, with a graft uptake rate of 86%, compared to 55% in sclerosed mastoids, supporting the findings by Yung M et al. (2007), who also demonstrated better results in well-aerated mastoids.

At the 3rd-month follow-up, graft success was seen in 80% of cases, which slightly declined to 76% by the 6th month. This temporal drop in success rate is expected, as residual inflammation or Eustachian tube dysfunction may compromise long-term outcomes. Yung M et al. (2007) similarly reported an initial success rate of 78% at 3 months.

Correlation analysis between MERI scores and postoperative ABG closure yielded a weak negative correlation ($r = -0.024$), which was not statistically significant ($p = 0.869$). While this seems contradictory to studies such as Kartush JM (2002), who found a modest correlation, it may reflect the heterogeneity in surgical techniques and postoperative compliance, or the relatively small sample size in our study. Further studies with larger cohorts may provide clearer insights.

Overall, our study confirms the multifactorial nature of surgical outcomes in COM. The integration of MERI scoring, careful evaluation of ossicular chain and mastoid status, and appropriate selection of surgical procedure were pivotal in achieving favorable outcomes. Comparisons with existing literature reveal a strong alignment with global trends, thereby validating our findings and contributing valuable data to the ongoing effort of optimizing surgical management in COM.

CONCLUSION

This prospective observational study involving 52 patients diagnosed with Chronic Otitis Media (COM) provides significant insights into the clinical, intraoperative, and postoperative profiles associated with surgical outcomes. The analysis affirms that multiple preoperative and intraoperative variables play a pivotal role in predicting surgical success, especially graft uptake and hearing improvement.

The age group most affected was 31–40 years (26%), suggesting the vulnerability of this age due to prolonged exposure to recurrent infections and environmental risks. A stark male predominance (90%) was observed, and smoking history was present in 90% of the cohort, both factors reinforcing the role of modifiable lifestyle-related risks in COM pathogenesis.

The type of COM was predominantly mucosal (60%), with squamosal COM present in 44%, and cholesteatoma in 38%. Notably, 10 patients (20%) had a history of previous ear surgeries, and revision surgeries were required in 4 patients (8%), indicating disease chronicity.

MERI scoring demonstrated that 20 patients (38%) had mild scores, 22 (42%) moderate, and 10 (19%) severe, aligning with disease severity and influencing surgical outcomes. Graft uptake success rates strongly correlated with MERI scores: 86% success in mild cases, 73% in moderate, and only 40% in severe cases. This reinforces the utility of the MERI score as a valid preoperative prognostic tool.

Ossicular chain integrity was normal in 60.38% of patients, while 39.62% showed ossicular erosion, with MI absent in 13.2%, MIS absent in 11.32%, and IM absent in 9.4%, underlining the significant burden of ossicular damage due to chronic middle ear inflammation.

Otorrhea patterns revealed that 51.92% of patients had occasional discharge, 23.08% persistent discharge, and 21% had dry ears. Persistent otorrhea was associated with lower graft uptake, consistent with existing literature.

Eustachian tube patency was noted in 42 patients (79.2%), whereas 10 patients (21.16%) had non-patent tubes. Those with a functional Eustachian tube showed higher graft uptake rates, validating the role of Eustachian tube function in middle ear ventilation and healing.

Surgical procedures performed included Type I tympanoplasty in 14 patients (27%), Type II in 10 (19%), Type III in 8 (15%), Canal Wall Up Mastoidectomy in 12 (23%), and Canal Wall Down Mastoidectomy in 8 (15%), reflecting operative choices based on ossicular and mastoid pathology.

Mastoid status showed that 64% had partially sclerosed mastoids, 18% were sclerosed, and 12% pneumatized. Graft success was better in pneumatized mastoids (86%) and poorer in sclerosed mastoids (55%), highlighting the impact of mastoid aeration.

At the 3rd-month follow-up, 42 out of 52 patients (80%) had successful graft uptake. By the 6th month, this declined slightly to 38 patients (76%), suggesting a small proportion of delayed graft failures due to residual or recurrent disease.

The correlation between MERI scores and postoperative air-bone gap (ABG) closure yielded a correlation coefficient of -0.024, with a p-value of 0.869, indicating a weak, statistically insignificant relationship, though trends suggest more severe MERI scores may correlate with poorer hearing outcomes.

In conclusion, the study highlights that MERI score, ossicular status, Eustachian tube function, and mastoid aeration are critical determinants of postoperative success. Patients with low MERI scores, intact ossicular chains, functional Eustachian tubes, and pneumatized mastoids showed the best surgical and audiological outcomes. The study reaffirms that tailored surgical approaches based on preoperative and intraoperative assessments significantly enhance success in the management of Chronic Otitis Media.

LIMITATIONS :

This study had certain limitations, such as a small sample size of patients, all surgeries were performed by different surgeons which affects the results.

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ANNEXURES-I

ETHICAL CLEARANCE CERTIFICATE

Azadi Ka Amrit Mahotsav

BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

Accredited with 'A' Grade by NAAC (Cycle-2)

The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 984/2022-23 10/4/2023

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Saturday, 18th March, 2023 at 11.30 a.m. in the CAL Laboratory, Dept. of Pharmacology,** scrutinizes the Synopsis/ Research Projects of Post Graduate Student / Under Graduate Student /Faculty members of this University /Ph.D. Student College from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "ASSESSMENT OF MIDDLE EAR RISK INDEX FACTOR ON OUTCOME OF SURGERY FOR CHRONIC OTITIS MEDIA ".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR.ADISHREE SHIVAJI MALI.

NAME OF THE GUIDE: DR. R.N.KARADI. PROFESSOR,
DEPT. OF OTORHINOLARYNGOLOGY.

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Dr. Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA

MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

ANNEXURE II

CASE PROFORMA

Patient Details

1. **Patient ID**: __________
2. **Name**: __________
3. **Age**: __________
4. **Gender**: ☐ Male ☐ Female
5. **Contact Number**: __________
6. **Address**: __________
7. **Hospital Registration Number**: __________
8. **Date of Admission**: __________
9. **Date of Surgery**: __________

Demographic and Clinical Characteristics

10. **Age Group**: ☐ 10-20 ☐ 21-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61-70 ☐ 71-80
11. **Smoking Status**: ☐ Smoker ☐ Non-Smoker
12. **Type of Chronic Otitis Media**: ☐ Mucosal ☐ Squamosal
13. **History of Previous Surgery**: ☐ Yes ☐ No
14. **Revision Surgery**: ☐ Yes ☐ No
15. **Presence of Cholesteatoma**: ☐ Yes ☐ No

Middle Ear Risk Index (MERI) Score

16. **MERI Score Category**: ☐ Mild (0-3) ☐ Moderate (4-6) ☐ Severe (7-12)

17. **Otorrhea Status**: ☐ Occasional ☐ Persistent ☐ Dry ☐ None

18. **Ossicular Chain Condition**:

    ☐ Normal ☐ MI Absent ☐ MIS Absent ☐ IM Absent ☐ Incus Absent

Eustachian Tube Patency

19. ☐ Present ☐ Absent

Surgical Details

20. **Surgical Procedure Performed**:

    ☐ Type I Tympanoplasty ☐ Type II Tympanoplasty ☐ Type III Tympanoplasty

    ☐ Ossiculoplasty ☐ Canal Wall Up Mastoidectomy ☐ Canal Wall Down Mastoidectomy

21. **Mastoid Status**: ☐ Pneumatized ☐ Partially Sclerosed ☐ Sclerosed

Postoperative Follow-up & Audiological Outcome

22. **Graft Uptake Success**

- **1st Month**: ☐ Intact ☐ Failed
- **3rd Month**: ☐ Intact ☐ Failed

23. **Audiological Outcome (Air-Bone Gap Closure in dB)**

- **Preoperative**: ☐ <10 dB ☐ 11-20 dB ☐ 21-30 dB ☐ >30 dB
- **Postoperative**: ☐ <10 dB ☐ 11-20 dB ☐ 21-30 dB ☐ >30 dB

24. **MERI Score vs Surgical Success**

- ☐ Mild (86% Success)
- ☐ Moderate (73% Success)
- ☐ Severe (40% Success)

ANNEXURES –III

INFORMED CONSENT FORM

BLDE (DEEMED TO BE UNIVERSITY)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA- 586103

TITLE OF THE PROJECT **"ASSESSMENT OF MIDDLE EAR RISK INDEX FACTOR ON THE OUTCOME OF SURGERY FOR CHRONIC OTITIS MEDIA"**

PG STUDENT : Dr. ADISHREE.SHIVAJI MALI DEPARTMENT OF OTORHINOLARYNGOLOGY

PG GUIDE : Dr. RN KARADI

Department of Otorhinolaryngology

BLDE (Deemed To Be University)

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA – 586103

All aspects of this consent form are explained to the patient in the language understood by him/her.

PURPOSE OF RESEARCH:

I have been informed about this study. I have also been given a free choice of participation in this study.

PROCEDURE:

I am aware that in addition to routine care received, I will be asked a series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

RISK AND DISCOMFORTS:

I understand that I may experience some pain and discomfort during the examination or during my treatment. This is mainly the result of my condition, and the procedure of this study is not expected to exaggerate these feelings that are associated with the usual course of treatment.

BENEFITS:

I understand that my participation in this study will help to improve the survival of the patient and will bring about a better outcome.

CONFIDENTIALITY:

I understand that the medical information produced by this study will be a part of Hospital records and will be subject to confidentiality and privacy regulation.

Information of a sensitive personal nature will not be a part of the medical records but will be stored in the investigator's research file and identified only by a code number.

The code-key connecting name to numbers will be kept in a separate location. If the data are used for publication in the medical literature or for teaching purposes, no name will be used, and other identifiers such as photographs and audio or videotapes will be used only with my special written permission. I understand that I may see the photographs and videotapes and hear the audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. **Dr. ADISHREE SHIVAJI MALI** is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation.

If during the study or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital. I also understand that **Dr. ADISHREE SHIVAJI MALI** may terminate my participation in the study after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or physical therapist if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me resulting directly from my participation in this study if such injury were reported promptly, the appropriate treatment would be available to me, but no further compensation would be provided. I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained the purpose of the research, the procedures required and the possible risks and benefits to the best of my ability in the patient's own language.

Dr. ADISHREE SHIVAJI MALI **DATE**

-- **----------------------**

(Investigator)

STUDY SUBJECT CONSENT STATEMENT

I confirm that **Dr. ADISHREE SHIVAJI MALI** has explained to me the purpose of the research, the study procedures that I will undergo, and the possible risks and discomforts as well as benefits that I may experience in my own language. I have read, and I understand, this consent form. Therefore, I agree to give consent to participate as a subject in this research project.

Patient Signature: **________________** **Date**: **________________**

Witness Signature: **________________** **Date**: **________________**

Investigator Signature: **________________** **Date**: **________________**

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ANNEXURES –IV

MASTER CHART

Sl No	NAME	AGE	SEX	OTTORHEA	PERFORATION	PREVIOUS SURGERY	SMOKER	CHOLEASTEATOMA	OSSICULAR CHAIN	EUSTACHIAN TUBE	SURGERY	STATUS OF MASTOID DURING SURGERY	MIDDLE EAR GRANULATION	GRAFT UPTAKE	HEARING GAIN	MERI SCORE	RESULT
1.	Yamanappa	56	M	Occasional	Present	No	Yes	No	Normal	Present	Tympanoplasty	Partially Sclerosed	No	Good	Yes`	5	Moderate
2.	Kashibai	42	F	Persistent	Absent	No	No	Yes	Mi Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	12	Severe
3.	Ratnamma	27	F	Occasional	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	2	Mild
4.	Saddaya	14	M	Occasional	Absent	No	No	Yes	Mi Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	Yes`	11	Severe
5.	Shakuntala	35	F	Persistent	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	4	Moderate
6.	Kenchappa	14	M	Persistent	Absent	No	No	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	12	Severe
7.	Shantabai	54	F	Occasional	Present	No	No	No	Mi Absent	Present	Cortical Mastoidectomy	Partially Sclerosed	No	Poor	No	8	Severe
8.	Yenkappa	72	M	Persistent	Present	Yes	Yes	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	13	Severe
9.	Pooja	25	F	Dry	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	2	Mild
10.	Savitri	35	F	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	3	Mild
11.	Aravind	47	M	Occasional	Absent	No	Yes	Yes	Mi Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	12	Severe
12.	Bismillah	45	F	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	3	Mild
13.	Jakkama	22	F	Dry	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	2	Mild
14.	Ganagvva	52	F	Occasional	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	3	Mild

15.	Rajashree	10	F	Persistent	Absent	No	No	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	13	Severe
16.	Saddaya	17	M	Occasional	Absent	No	No	Yes	Is Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	9	Severe
17.	Adarsh	12	M	Dry	Absent	No	No	Yes	Mi Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Good	No	10	Severe
18.	Jyotib	38	M	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	4	Moderate
19.	Bhagyashree	33	F	Occasional	Absent	No	No	Yes	Im Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	9	Severe
20.	Hirabai	60	F	Dry	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	4	Moderate
21.	Pritam	14	M	Occasional	Absent	No	No	No	Im Absent	Present	Cortical Mastoidectomy	Sclerosed	No	Good	Yes`	7	Severe
22.	Renuka	21	F	Occasional	Absent	No	No	Yes	Incus Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	9	Severe
23.	Mahantesh	29	M	Occasional	Absent	No	No	Yes	Mi Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	8	Severe
24.	Shubham	23	M	Occasional	Absent	No	No	Yes	Ossicular Head Fixation	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	8	Severe
25.	Shridevi	38	F	Dry	Absent	No	No	Yes	Mi Absent	Present	Cortical Mastoidectomy	Sclerosed	Yes	Poor	Yes`	10	Severe
26.	Prathamesh	14	M	Persistent	Absent	No	No	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	13	Severe
27.	Shrikant	63	M	Dry	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	2	Mild
28.	Vinod	33	M	Occasional	Present	No	No	No	Normal	Present	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	4	Moderate
29.	Kencheppa	45	M	Occasional	Present	No	No	No	Normal	Present	Cortical Mastoidectomy	Sclerosed	No	Good	Yes`	5	Moderate
30.	Kasturi	27	F	Persistent	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	4	Moderate
31.	Samarth	35	M	Persistent	Present	Revision	Yes	Yes	Incus Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	13	Severe
32.	Laxmi	28	F	Occasional	Absent	No	No	Yes	Im Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	9	Severe
33.	Sandeep	36	M	Occasional	Absent	No	No	Yes	Incus Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	9	Severe
34.	Ishwar	46	M	Dry	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	2	Mild
35.	Nirmala	35	F	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	3	Mild
36.	Aditya	13	M	Occasional	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	2	Mild
37.	Laxmibai	63	F	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Sclerosed	No	Good	Yes`	4	Moderate
38.	Jagadevi	43	F	Persistent	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	3	Mild
39.	Ambika	25	F	Persistent	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Sclerosed	No	Good	Yes`	5	Moderate
40.	Saraswati	15	F	Dry	Absent	No	No	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	11	Severe

41.	Ambresh	32	M	Dry	Absent	No	No	Yes	Im Absent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	10	Severe
42.	Gadeppa	20	M	Dry	Absent	No	No	Yes	Im Absent	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	8	Severe
43.	Yadangouda	75	M	Occasional	Present	No	Yes	Yes	Mis Absesent	Present	Modified Radical Mastoidectomy	Sclerosed	Yes	Poor	No	14	Severe
44.	Shivleela	64	F	Persistent	Absent	Revision	No	No	I Absent	Present	Cortical Mastoidectomy	Partially Sclerosed	Yes	Poor	No	9	Severe
45.	Sidrayya	53	M	Occasional	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	2	Mild
46.	Vishal	18	M	Occasional	Present	No	No	No	Normal	Normal	Tympanoplasty	Pneumatised	No	Good	Yes`	2	Mild
47.	Dayanand	38	M	Dry	Present	No	Yes	No	Normal	Present	Cortical Mastoidectomy	Partially Sclerosed		Poor	YES`	5	Moderate
48.	Sachin	26	M	Persistent	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Sclerosed	No	Good	Yes`	5	Moderate
49.	Ranjeet	40	M	Occasional	Present	No	No	No	Normal	Normal	Cortical Mastoidectomy	Partially Sclerosed	No	Good	Yes`	3	Mild
50.	Subhas	56	M	Occasional	Absent	No	No	Yes	Ossicular Head Fixation	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	7	Severe
51.	Mashtri	34	M	Occasional	Absent	No	No	Yes	Stapes Fixation	Present	Modified Radical Mastoidectomy	Sclerosed	No	Poor	No	8	Severe