“COMPARISON OF ADDITION OF 1.5% ACETIC ACID EAR WASH TO THE STANDARD MEDICAL TREATMENT IN ACTIVE MUCOSAL CHRONIC SUPPURATIVE OTITIS MEDIA : A HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL”

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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
CSOM	Chronic Suppurative Otitis Media
OM	Otitis Media
ROS	Reactive Oxygen Species
EPS	Extracellular Polymeric Substances
MRSA	Methicillin-resistant Staphylococcus aureus
MIC	Minimum Inhibitory Concentration
BEC	Biofilm Eradication Concentration
SNOSE	Sequentially Numbered Opaque Sealed Envelope
LCP	Large Central Perforation
MCP	Medium Central Perforation
SCP	Small Central Perforation
TM	Tympanic Membrane

ABSTRACT

Title:

Comparison Of Addition Of 1.5% Acetic Acid Ear Wash To The Standard Medical Treatment In Active Mucosal Chronic Suppurative Otitis Media

Objectives:

- The aim of this study was to evaluate the comparison of addition of 1.5% acetic acid ear wash to the standard medical treatment in active mucosal chronic suppurative otitis media.

Methods:

A one year study was undertaken and 80 patients were enrolled for the study, two groups were made by randomization which was performed using **Sequentially Numbered Opaque Sealed Envelope (SNOSE)**, with 40 patients in each group. Standard medical treatment was given in one group and intervention with acetic acid was done in the other group.

Results:

The study had a female predilection in cases, 66.25% (53/80) of the participants were female, while 33.75% (27/80) were male. One of the most important clinical indicators of CSOM is ear discharge, which indicates the degree of infection and the effectiveness of treatment. None of the 80 patients in our trial had no ear discharge at baseline (Day 1); instead, 31.25% had mild discharge, 53.75% had moderate discharge, and 15% had copious discharge. These results highlight the substantial inflammatory burden that exists initially. By Day 7, there was a noticeable change following the administration of the 1.5% acetic acid ear wash: 15% of patients saw full discharge resolution, mild discharge rose to 65%, and moderate discharge dropped to 20%, with no instances of copious discharge noted.

An interesting pattern emerged from our study's evaluation of ear pain. The high level of inflammation at work was evident on Day 1 as only 22.5% of patients reported no ear pain and 77.5% reported pain. When the 1.5% acetic acid ear wash was started in addition to the usual treatment, a notable improvement was observed. Of the patients, 52.5% were pain-free by Day 7, and by Day 14, an astounding 92.5% were pain-free, with only 7.5% still experiencing discomfort. Not only is this gradual decrease in ear pain clinically significant, but it also demonstrates how quickly acetic acid reduces inflammation.

Conclusion:

This study demonstrates that adding a 1.5% acetic acid ear wash to standard medical treatment significantly enhances clinical outcomes in active mucosal Chronic Suppurative Otitis Media (CSOM). Marked improvements were observed in ear discharge, pain relief, tympanic membrane condition, and condition of middle ear mucosa within 14 days. As Acetic acid wash is a simple OPD procedure, it is very cost-effective & patient compliance is excellent, it can be considered as a non-antibiotic adjunct to standard medical treatment of CSOM.

Keywords: CSOM, Acetic Acid, MRSA, Mucosal

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INTRODUCTION

"Chronic Suppurative Otitis Media (CSOM) is defined as persistent inflammatory condition of middle ear cleft characterized by recurrent otorrhea via a perforated ear drum. It remains a significant health concern globally, particularly in developing regions where access to healthcare resources may be limited. The disease not only causes considerable morbidity, including hearing loss and discomfort, but also carries the risk of severe complications such as mastoiditis, labyrinthitis, and intracranial infections if not managed properly. Effective management of CSOM involves addressing the underlying infection, reducing inflammation, and preventing recurrent episodes. While various treatment modalities have been employed, achieving optimal outcomes remains a challenge due to the persistent and often resistant nature of the infection." [1]

"The standard medical treatment for active mucosal CSOM typically involves the use of topical and systemic antibiotics, along with aural toilet to maintain ear hygiene. Topical antibiotics, often combined with corticosteroids, are preferred due to their ability to deliver high drug concentrations directly to the site of infection while minimizing systemic side effects. Systemic antibiotics may be indicated in cases with extensive disease or complications. However, the overuse and misuse of antibiotics have contributed to the emergence of multidrug-resistant pathogens, complicating the treatment landscape. Consequently, there is a growing interest in exploring adjunctive therapies that can enhance the effectiveness of standard treatments and potentially reduce the reliance on antibiotics." [2]

One such adjunctive therapy that has garnered attention is the use of acetic acid ear washes. Acetic acid, a weak organic acid, has been recognized for its antimicrobial properties and has long history in otology for management of ear infections. Its mechanism of action involves lowering pH of ear canal, creating an environment that is hostile to the growth of many pathogenic organisms, including Pseudomonas aeruginosa and Staphylococcus aureus, are commonly implicated in CSOM. Additionally, acidifying effect of acetic acid can help disrupt biofilms, which are structured communities of bacteria that are notoriously difficult to eradicate and contribute to the chronicity of infections.[3]

The potential benefits of adding a 1.5% acetic acid ear wash to the standard medical treatment for active mucosal CSOM warrant careful consideration. By incorporating an acetic acid ear wash, it is hypothesized that the microbial load within the ear can be more effectively controlled, thereby reducing the frequency and severity of discharge and inflammation. This could, in turn, improve patient outcomes by accelerating the resolution of symptoms and potentially shortening the duration of antibiotic therapy.[4]

"The mucosal form of CSOM is characterized by persistent inflammation and infection of the middle ear mucosa, often accompanied by mucopurulent discharge. The warm, moist environment of the ear, coupled with the presence of a perforated tympanic membrane, provides an ideal setting for bacterial colonization and biofilm formation. Standard antibiotic treatments may not always penetrate biofilms effectively, allowing residual bacteria to persist and cause recurrent infections. The acidification of the ear environment with acetic acid can disrupt these biofilms and enhance the effectiveness of antimicrobial agents." [5]

Moreover, the use of acetic acid is aligned with the principles of antimicrobial stewardship, which emphasize the need to minimize antibiotic use to reduce growing threat of antibiotic resistance. By reducing the microbial load and creating an inhospitable environment for bacterial growth, acetic acid ear washes may decrease the need for prolonged or repeated courses of antibiotics. This is particularly important in the context of CSOM, where the chronic nature of the disease often necessitates long-term management.[6]

"The addition of acetic acid ear washes to standard treatment protocols also has practical advantages. Acetic acid is easily available, inexpensive, and safe when used appropriately. These attributes make it an attractive option, especially in resource-limited settings where access to new conservative treatments and expensive antibiotics can be constrained. The low cost and ease of administration of acetic acid ear washes could make them a valuable component of community-based ear care programs aimed at reducing the burden of CSOM."[7]

However, the incorporation of acetic acid ear washes into clinical practice is not without challenges. Patient compliance with ear wash protocols can be variable, and the potential for irritation or discomfort with the use of acidic solutions must be carefully managed. Proper patient education on the correct technique for administering ear washes and the importance of adherence to the prescribed regimen is essential for achieving optimal outcomes. Additionally, clinicians must be vigilant in monitoring for any adverse effects, such as exacerbation of symptoms or allergic reactions, and adjust treatment plans accordingly.[8]

"The theoretical framework for evaluating the effectiveness of 1.5% acetic acid ear washes in CSOM also involves considerations of clinical endpoints and patient-reported outcomes. Key measures of success include the resolution of ear discharge, reduction in the severity of inflammation, improvement in hearing function, and overall patient satisfaction. Comparative studies that assess these outcomes in patients receiving standard treatment alone versus those receiving standard treatment with adjunctive acetic acid ear washes are essential for establishing the efficacy and safety of this approach."[9]

AIMS AND OBJECTIVES

The aim of this study was to evaluate the comparison of addition of 1.5% acetic acid ear wash to the standard medical treatment in active mucosal chronic suppurative otitis media.

REVIEW OF LITERATURE

2. Introduction to Chronic Suppurative Otitis Media (CSOM)

Chronic Suppurative Otitis Media (CSOM) is a long-standing inflammatory condition of middle ear cleft, characterized by recurrent or persistent otorrhea via perforated ear drum. Unlike acute ear infections, which are typically self-limiting, CSOM is associated with prolonged infection and inflammation that can persist for months or even years without appropriate management.[10] It is a significant public health issue due to its potential complications and association with hearing impairment.[11,12]

Epidemiology of CSOM underscores its significance as a global health issue. The condition disproportionately affects individuals in low- and middle-income countries, where healthcare services and sanitation may be inadequate. According to the World Health Organization (WHO), CSOM affects approximately 65 to 330 million people worldwide, with about 60% of cases associated with significant hearing loss. Children are particularly vulnerable to CSOM due to the anatomical and functional immaturity of their Eustachian tubes, which makes them more prone to ear infections and fluid retention in middle ear.[13]

Addressing global burden of CSOM requires effective and comprehensive treatment strategies. Primary aim of management is to control infection, decrease inflammation, promote healing of the tympanic membrane, and restore hearing function.[14] Standard medical treatment typically involves a combination of aural toilet, topical antibiotics, and, in some cases, systemic antibiotics. Aural toilet is essential for clearing ear discharge and debris, thereby improving the effectiveness of other treatments. Topical antibiotics are preferred for their ability to deliver high drug concentrations directly to the infection site, reducing systemic side effects.[15]

Despite the availability of these treatment options, the management of CSOM remains challenging. The disease's chronic nature, the presence of biofilms that protect bacteria from antibiotics, and the emergence of multidrug-resistant pathogens contribute to treatment failures. Inadequate patient follow up to treatment further complicates management. These challenges underscore the need for adjunctive therapies and innovative approaches for improving treatment outcomes and reduce the disease burden.[16]

“Adjunctive therapies, such as acetic acid ear washes, have gained attention for their potential role in enhancing treatment outcomes for CSOM. Acetic acid, has antimicrobial with biofilm-disrupting action that can help reduce the microbial load and create an environment less conducive to bacterial growth. Incorporating such therapies into treatment protocols may reduce the reliance on antibiotics, addressing concerns related to antibiotic resistance.” [17]

The importance of effective treatment strategies for CSOM cannot be overstated. Timely and appropriate management reduces side effects, hearing loss, and enhances quality of life for affected individuals. For children, effective treatment is crucial for supporting language development, academic achievement, and social interactions. For adults, it can help maintain productivity, social engagement, and emotional well-being.[18,19]

2.1 Pathophysiology of Active Mucosal CSOM

The pathophysiology of active mucosal Chronic Suppurative Otitis Media (CSOM) involves complex interplay of anatomical, functional, and microbial factors which contribute to persistent infection with inflammation of the middle ear mucosa. It is important to understand the mechanisms for developing effective treatment strategies and managing this challenging condition. This section delves into the anatomy and functional aspects of the middle ear, mechanisms of chronic infection and mucosal inflammation, and the role of biofilm formation in treatment resistance.[20]

"Middle ear is a small, air-filled cavity located within temporal bone of the skull, bounded laterally by the tympanic membrane and medially by the bony labyrinth of the inner ear. The middle ear has ossicles—the malleus, incus, and stapes—which are responsible for transmitting sound vibrations from tympanic membrane to oval window of the cochlea. The Eustachian tube connects middle ear to nasopharynx and plays a crucial role in equalizing pressure between the middle ear and the external environment. The middle ear mucosa is lined by respiratory epithelium which has ciliated columnar cells, goblet cells, and basal cells. This mucosal lining is essential for maintaining the health of the middle ear by providing a barrier against pathogens, facilitating mucociliary clearance, and producing antimicrobial substances."[21]

In active mucosal CSOM, the integrity of the ear drum is compromised, leading to a perforation that allows pathogens to gain access to the middle ear cavity. This disruption of the natural barrier function, coupled with impaired Eustachian tube function, creates a favorable environment for the colonization and persistence of pathogenic microorganisms. The chronic inflammation observed in CSOM is characterized by appearance of immune cells, such as lymphocytes, neutrophils, and macrophages, infiltrating the middle ear mucosa. These immune cells release pro-inflammatory cytokines and chemokines, which further amplify the inflammatory response and contribute to tissue damage.[22]

The persistent mucosal inflammation in CSOM is driven by several factors, including microbial infection, host immune responses, and environmental influences. One of the key mechanisms underlying chronic infection is the ability of pathogens to evade host immune defenses and establish a persistent presence within the middle ear. Common pathogens implicated in CSOM include Pseudomonas aeruginosa, Staphylococcus aureus, and various anaerobic bacteria.[23] These microorganisms have evolved various strategies to resist immune clearance, including the production of virulence factors, evasion of phagocytosis, and inhibition of complement activation.[24]

"A critical factor that contributes to the treatment resistance observed in CSOM is the formation of biofilms. Biofilms are structured communities of microorganisms that are embedded within an extracellular polymeric matrix. This matrix, composed of polysaccharides, proteins, and nucleic acids, provides a protective environment for the bacteria, shielding them from host immune responses and antimicrobial agents. Biofilm formation is a well-recognized feature of chronic bacterial infections, including CSOM." [25]

Formation of biofilms in the middle ear mucosa begins with initial attachment of planktonic bacteria to mucosal surface or other available substrates, such as damaged tissue or foreign bodies. Once attached, the bacteria undergo phenotypic changes and begin to produce the extracellular matrix that forms the structural framework of the biofilm. As the biofilm matures, it develops a complex architecture with microcolonies and fluid-filled channels that facilitate the exchange of nutrients and waste products.[26]

"Biofilms provides advantages to the bacteria, including increased resistance to antibiotics with enhanced survival in hostile environments. The matrix provides a physical barrier that limits the penetration of antimicrobial agents, reducing their efficacy. Additionally, the bacteria within biofilms exhibit altered metabolic states and gene expression patterns that further enhance their resistance to antibiotics. For example, slow-growing or dormant bacteria within the biofilm are less susceptible to antibiotics that target actively dividing cells. These factors contribute to the persistence of infection in CSOM and make biofilm-associated infections challenging to eradicate." [27]

The presence of biofilms in CSOM has significant clinical implications. Biofilm-associated infections are more likely to be resistant to standard antibiotic treatments, leading to prolonged disease duration and increased risk of complications. Moreover, the disruption of biofilms is essential for achieving complete resolution of infection and preventing recurrence. Strategies to address biofilm formation in CSOM include the use of agents that can disrupt the biofilm matrix, enhance the penetration of antibiotics, or target biofilm-specific bacterial processes.[28]

"Acetic acid, for example, has been shown to have biofilm-disrupting properties in addition to its antimicrobial effects. By lowering the pH of the ear environment, acetic acid can create conditions that are less conducive to biofilm formation and bacterial survival. This provides a theoretical basis for the use of acetic acid ear washes as an adjunctive treatment for CSOM." [29,30]

"In addition to biofilm formation, other factors contribute to the persistence of inflammation and infection in CSOM. These include the presence of inflammatory mediators, impaired mucociliary clearance, and the development of granulation tissue. The chronic inflammatory environment can lead to the formation of granulation tissue, which further obstructs the middle ear cavity and impairs the drainage of secretions. This creates a vicious cycle of inflammation, infection, and tissue damage." [31]

Impaired mucociliary clearance is another important factor in the pathophysiology of CSOM. The cilia of the respiratory epithelium play a crucial role in transporting mucus and trapped pathogens out of the middle ear and into the nasopharynx.[32,33] In CSOM, the function of the cilia may be compromised due to chronic inflammation, epithelial damage, and the presence of thick, viscous secretions. This impairment of mucociliary clearance further contributes to the accumulation of pathogens and the persistence of infection.[34]

2.2 Standard Medical Treatment of Active Mucosal CSOM

The management of CSOM aims to eradicate the infection, control inflammation, prevent complications, and restore hearing.[35,36] Standard medical treatment primarily involves antibiotic therapy, ear cleaning, and anti-inflammatory measures. The treatment strategy depends on the severity of the infection, the microbial profile, and the patient's response to therapy.[37-40]

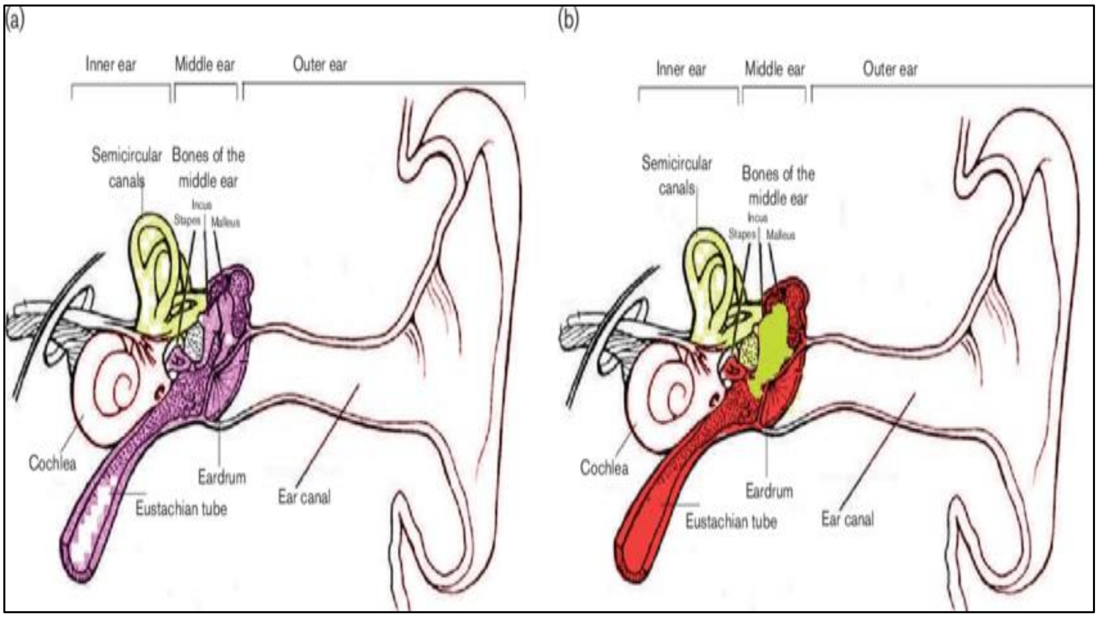


Figure 1: CSOM Pathology

Role of Topical Versus Systemic Treatments

Topical Therapy:

- **Advantages:**[41]
    - Delivers high antibiotic concentration directly to the infection site.
    - Minimizes systemic side effects such as gastrointestinal disturbances and nephrotoxicity.
    - More effective for superficial infections within the ear canal and middle ear.
- **Disadvantages:**[42]
    - Ineffective in cases of deep-seated infections or involvement of the mastoid.
    - May be difficult to administer in pediatric or non-cooperative patients.

Systemic Therapy:

- **Advantages:**[43]
  - Essential in severe infections spreading beyond middle ear and suspected complications (e.g., mastoiditis, meningitis, intracranial abscesses).
  - Useful in patients who cannot tolerate topical treatment due to allergy or tympanic membrane closure.
- **Disadvantages:**[44]
  - Higher risk of systemic side effects such as nephrotoxicity, ototoxicity, and gastrointestinal disturbances.
  - Longer duration of treatment may lead to antibiotic resistance.

Limitations and Challenges of Current Standard Treatments

Despite the availability of antibiotics and therapeutic options, several challenges exist in managing active mucosal CSOM.[40]

1. Antibiotic Resistance[41]

- The widespread use of antibiotics has led to emerging resistance, particularly against Pseudomonas aeruginosa and methicillin-resistant Staphylococcus aureus.
- Multidrug-resistant strains necessitate the use for combination therapy or second-line antibiotics, which may have more side effects.

2. Ototoxicity of Certain Antibiotics[42]

- Aminoglycosides are effective but pose a high risk of cochlear and vestibular toxicity, leading to hearing loss and balance disorders.
- Patients with recurrent infections requiring prolonged therapy face a higher risk of permanent auditory damage.

3. Incomplete Resolution and Recurrence[43]

- Despite treatment, many patients experience persistent or recurrent otorrhea, leading to chronic inflammation and further hearing impairment.
- Poor adherence to treatment, lack of proper ear hygiene, and inadequate follow-up contribute to high recurrence rates.

4. Biofilm Formation in Chronic Infections[44]

- Bacterial biofilms on the middle ear mucosa make infections resistant to antibiotics and immune system attacks.
- Biofilms contribute to the chronic nature of CSOM, necessitating alternative treatments such as antibiofilm agents and surgical intervention.

5. Limited Efficacy in Severe Cases[38]

- Standard treatment is often insufficient in patients with complications, including cholesteatoma, mastoiditis, or intracranial infections.
- In such cases, surgical interventions like mastoidectomy may be required.

6. Patient Compliance and Access to Care[39]

- Many patients, particularly in low-resource settings, face barriers to treatment, including cost, availability of medications, and access to specialized care.
- Poor compliance with treatment regimens and inconsistent follow-ups lead to suboptimal outcomes.

2.3 Antibiotic Resistance and the Need for Adjunctive Therapies

Antibiotic resistance is a growing global health concern, affecting various infections, including otitis media (OM). OM, a common bacterial infection of the middle ear, is frequently treated with antibiotics. Excess use of these medications leads to the emergence of antibiotic-resistant pathogens, making treatment increasingly difficult. Addressing this crisis requires the development of adjunctive therapies and strategies to mitigate resistance in clinical practice.[45]

Rising Concerns of Antibiotic-Resistant Pathogens in Otitis Media

One of the most common diseases in both adults and children, OM is frequently brought on by bacteria like Moraxella catarrhalis, Haemophilus influenzae, and Streptococcus pneumoniae. While antibiotics have been effective in treating OM, widespread and sometimes unnecessary use has driven the evolution of resistant bacterial strains.[46]

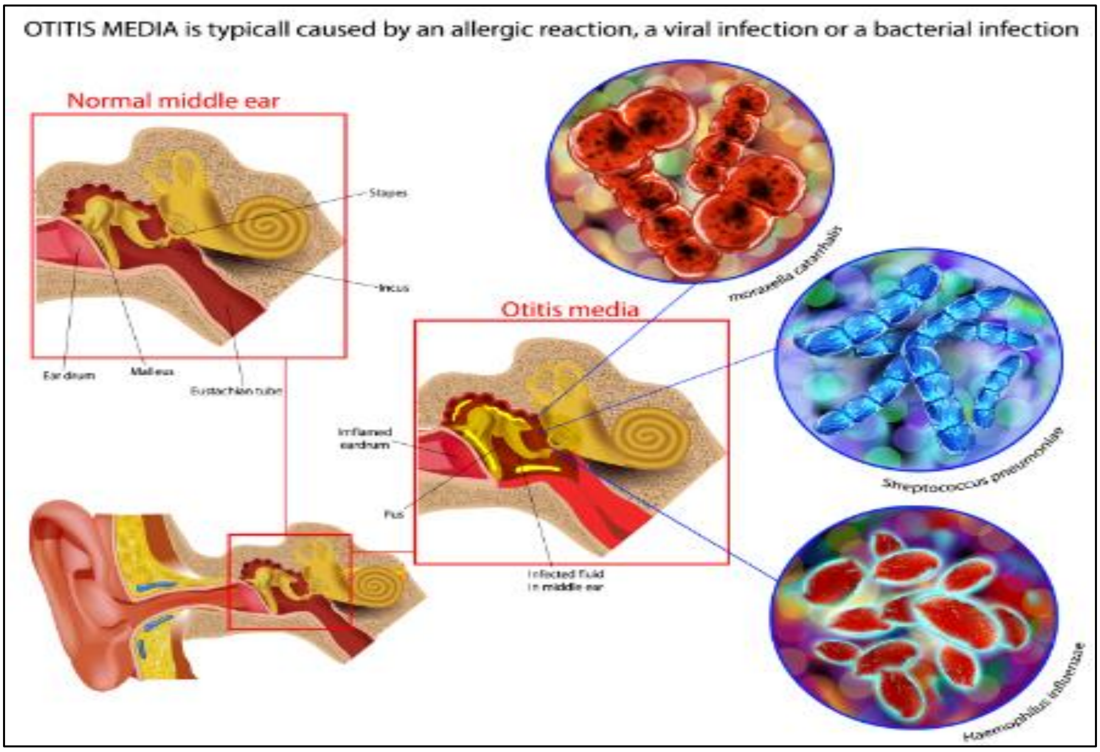


Figure 2: Otitis Media Pathology

Causes of Antibiotic Resistance in Otitis Media

1. **Overprescription of Antibiotics**: Many cases of OM are viral rather than bacterial, meaning antibiotics are ineffective. However, antibiotics are often prescribed unnecessarily, promoting resistance.[47-49]

2. **Incomplete Courses of Antibiotics**: Patients sometimes stop taking antibiotics once symptoms subside rather than completing the full course, leading to the survival of partially resistant bacteria.[50,51]

3. **Use of Broad-Spectrum Antibiotics**: The frequent use of these drugs instead of targeted therapy increases selective pressure, allowing resistant strains to flourish.[52-55]

4. **Bacterial Adaptation and Biofilm Formation**: Many OM pathogens form biofilms, which protect bacteria from antibiotics and host immune responses, leading to persistent infections.[56-58]

5. **Horizontal Gene Transfer**: Bacteria can exchange resistance genes, accelerating the spread of antibiotic-resistant strains.[59-63]

4. Research and Development of New Antibiotics

The pharmaceutical industry must prioritize the development of novel antibiotics targeting resistant strains. Government incentives and funding for antibiotic research can accelerate the discovery of new drugs.[64]

2.4 Theoretical Basis for the Use of Acetic Acid in CSOM Management

"Chronic suppurative otitis media (CSOM) is a persistent infection of the middle ear, often characterized by otorrhea, ear drum perforation with inflammation. It is a significant global health issue, specially in low-resource settings. The management of CSOM involves eradicating the infection, reducing inflammation, and preventing complications.Various topical agents, including antibiotics and antiseptics, are used in treatment. Acetic acid, a simple organic acid, has emerged as an effective alternative due to its antimicrobial properties, ability to disrupt biofilms, and impact on pH regulation within the ear canal. This paper discusses the theoretical basis for the use of acetic acid in CSOM treatment by exploring its chemical properties, antimicrobial action, mechanism of action against pathogenic microorganisms, and influence on pH balance and microbial biofilms." [65]

Chemical Properties and Antimicrobial Action of Acetic Acid

"Acetic acid (CH_3COOH) is widely used in medical applications due to its antiseptic and antimicrobial properties. It is a colorless liquid with a pungent smell which is soluble in water, forming an acidic solution. Acetic acid is commonly found in vinegar at concentrations of 4–8%, but for medicinal purposes, concentrations ranging from 1% to 5% are used for antimicrobial therapy." [66]

"Acetic acid exhibits antimicrobial property against wide variety of bacteria, fungi, and viruses. It is effective against Gram-negative bacteria like *Pseudomonas aeruginosa* and *Escherichia coli*, which are often implicated in CSOM. Additionally, it demonstrates activity against Gram-positive bacteria like *Staphylococcus aureus*, including methicillin-resistant *Staphylococcus aureus* (MRSA). The antifungal action of acetic acid extends to *Candida* and *Aspergillus* species, which are known to cause otomycosis, a secondary complication in CSOM patients." [65]

The antimicrobial efficacy of acetic acid is concentration-dependent. 2% acetic acid solution is highly recommended in reducing bacterial load in infected tissues. The acid disrupts microbial cell membranes and interferes with metabolic processes, leading to bacterial and fungal cell death. Its broad-spectrum activity makes it an excellent alternative to conventional antibiotics, especially in cases of antibiotic-resistant infections.[67]

Mechanism of Action Against Pathogenic Microorganisms

Acetic acid exerts its antimicrobial effects through several mechanisms:

1. **Disruption of Cell Membranes**: Acetic acid penetrates bacterial and fungal cell walls, altering membrane permeability. The disruption of the cell membrane leads to leakage of essential intracellular components, ultimately resulting in cell death.[67]
2. **Intracellular Acidification**: Once inside the cell, acetic acid dissociates into hydrogen ions (H+) and acetate ions (CH3COO-). The increase in intracellular hydrogen ions lowers the pH, disrupting enzymatic functions and metabolic pathways. This acidification inhibits cellular processes, DNA replication and synthesis of proteins.[68]
3. **Interference with Metabolic Pathways**: Acetic acid affects the citric acid cycle (Krebs cycle) and glycolysis, two vital energy-generating pathways in bacteria. The acid impairs ATP production, leading to reduced bacterial viability and cell death.[65]
4. **Oxidative Stress Induction**: Studies suggest that acetic acid induces oxidative stress in bacteria by increasing reactive oxygen species (ROS) levels. Elevated ROS leads to damage of proteins, lipids, and nucleic acids, further contributing to bacterial death.[66]
5. **Biofilm Disruption**: One of the significant challenges in CSOM treatment is the presence of biofilms, which protect bacteria from antibiotics and the host immune system. Acetic acid disrupts these biofilms by breaking down the extracellular polymeric substances (EPS) that hold bacterial communities together. This action makes bacteria more susceptible to clearance and enhances the efficacy of other antimicrobial agents.[67]

Impact on pH Balance and Microbial Biofilms

The ear canal maintains a slightly acidic pH (approximately 4.5 to 5.5), which serves as a natural defense mechanism against microbial colonization. However, in CSOM, prolonged infection, inflammation, and biofilm formation can lead to pH imbalances, creating an environment conducive to bacterial and fungal growth. The use of acetic acid helps restore the acidic environment, thereby inhibiting pathogen proliferation.[68]

1. **Restoration of Acidic pH**: Acetic acid lowers pH of infected ear canal, creating unfavorable conditions for pathogenic microorganisms. Most bacterial and fungal species thrive in neutral or slightly alkaline environments (pH 6.5–7.5). The acidification induced by acetic acid suppresses microbial growth and enhances the action of other antimicrobial agents.[69]

2. **Inhibition of Biofilm Formation**: Biofilms are structured bacterial communities covered in a self-produced matrix, which provides resistance to antibiotics and host immune defenses. Acetic acid disrupts the integrity of these biofilms, reducing bacterial adherence to the epithelial surface and increasing susceptibility to treatment.[66]

3. **Synergistic Effects with Other Antimicrobials**: Acetic acid can enhance the efficacy of other topical antimicrobials by increasing bacterial permeability and reducing biofilm resistance. This synergy is particularly useful in cases of multidrug-resistant infections where conventional antibiotics alone may be ineffective.[67]

4. **Prevention of Recurrence**: The ability of acetic acid to disrupt biofilms and maintain an acidic pH reduces the likelihood of recurrent infections, a common issue in CSOM management. By eliminating biofilms and restoring ear canal homeostasis, acetic acid contributes to long-term infection control.[68,69]

2.5 Rationale for 1.5% Acetic Acid Concentration

Acetic acid is widely recognized for its antimicrobial, antifungal, and wound-healing properties. The selection of an appropriate concentration is crucial to achieving therapeutic efficacy while minimizing cytotoxic effects. Among various concentrations used in clinical and laboratory settings, 1.5% acetic acid has emerged as an optimal choice for several applications. This document explores the rationale behind selecting a 1.5% concentration level, considering factors such as antimicrobial efficacy, cytotoxicity, stability, and practical applicability in medical treatments.[70]

Background on Acetic Acid as a Therapeutic Agent

Acetic acid, a weak organic acid, has been employed for its antibacterial and antifungal properties, particularly in wound care, otic infections, and urinary tract infections. Its mechanism of action involves disrupting microbial cell membranes, altering pH levels, and inhibiting biofilm formation. However, while higher concentrations provide stronger antimicrobial activity, they can also lead to tissue irritation, damage, and increased cytotoxicity. Conversely, lower concentrations may not be sufficiently effective in eradicating pathogenic microorganisms. Thus, determining the optimal concentration is essential for maximizing benefits while minimizing adverse effects.[71]

Selection of 1.5% Acetic Acid: Key Considerations

1. Antimicrobial Efficacy

One of the primary reasons for selecting a 1.5% acetic acid concentration is its proven effectiveness against a wide range of bacterial and fungal pathogens. Studies indicate that acetic acid concentrations between 0.5% and 2% demonstrate significant antibacterial activity, particularly against resistant strains such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Escherichia coli*.[72]

- Research has shown that 1.5% acetic acid effectively eradicates *Pseudomonas aeruginosa*, a common pathogen in wound infections, without the need for prolonged exposure.[73]
- It also inhibits fungal species such as *Candida albicans*, making it a viable option for antifungal treatments.
- Compared to lower concentrations (0.5–1%), the 1.5% solution provides enhanced microbial eradication without a substantial increase in toxicity.[74]

2. Cytotoxicity and Tissue Compatibility

While acetic acid is effective in killing microbes, excessive concentrations can damage human tissues. A balance must be struck between antimicrobial effectiveness and host tissue safety.[75,76]

- Studies indicate that concentrations above 2% can cause significant cytotoxicity to fibroblasts and keratinocytes, which are essential for wound healing.
- A 1.5% concentration has been found to reduce bacterial load without significantly harming healthy tissue.
- It promotes wound healing by eliminating bacterial infections while allowing fibroblast proliferation and epithelialization.

3. pH Modulation and Biofilm Disruption

The acidic environment created by acetic acid plays a crucial role in preventing microbial colonization and biofilm formation.[77-79]

- A 1.5% solution maintains an optimal acidic pH (approximately 3–4), which inhibits bacterial growth.
- It effectively disrupts biofilms, a major contributor to chronic wound infections, without causing excessive irritation.
- Unlike weaker concentrations that may not sufficiently alter the pH to inhibit biofilm-associated bacteria, 1.5% strikes a balance in disrupting microbial adherence.

4. Stability and Practical Application

In addition to its therapeutic effects, the stability and usability of 1.5% acetic acid make it a practical choice in clinical settings.[79-81]

- The solution remains stable over extended periods, ensuring consistent efficacy when stored properly.
- It is easy to prepare and administer, making it suitable for both healthcare settings and home-based treatments.
- Compared to higher concentrations, it has a lower risk of causing excessive discomfort or irritation to patients during topical application.

Applications of 1.5% Acetic Acid

1. Wound Care

1.5% acetic acid is widely used in the management of chronic wounds, burns, and infected ulcers. It helps in:[81-83]

- Reducing bacterial colonization and preventing wound infection progression.
- Enhancing wound healing by controlling inflammation and facilitating tissue regeneration.
- Providing a cost-effective alternative to antibiotics in wound management.

2. Otic Infections (Ear Infections)[84]

The solution is commonly employed in the treatment of otitis externa, particularly for infections caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

- It helps in eliminating bacterial growth and preventing recurrent infections.
- The concentration is well-tolerated by the ear canal tissues, making it an effective and safe option for treatment.

Comparative Analysis with Other Concentrations[80-83]

- **0.5%–1.0% Acetic Acid**: While still effective against some pathogens, these concentrations may require prolonged exposure to achieve similar antimicrobial effects. They are often preferred for milder cases where minimal tissue irritation is a concern.

- **2.0% Acetic Acid and Above**: Higher concentrations exhibit enhanced antimicrobial activity but pose a greater risk of cytotoxicity. Prolonged use at these levels can lead to tissue damage, making them less ideal for long-term application.

- **1.5% Acetic Acid**: This concentration provides a balance between antimicrobial efficacy and tissue safety, making it the preferred choice in various therapeutic applications.

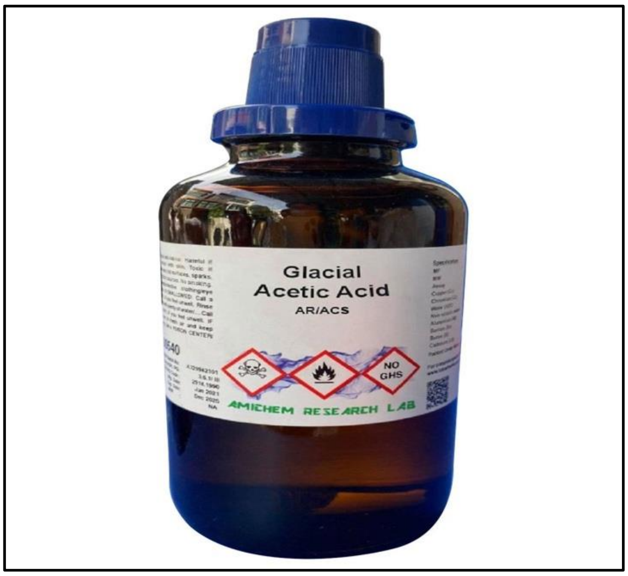


Figure 3: Acetic Acid

PAST STUDIES

"Choi HG et al (2010) Methicillin-resistant Staphylococcus aureus (MRSA) and its treatment effectiveness in chronic suppurative otitis media (CSOM) were investigated in this study. The authors conducted a bacteriological analysis of 577 patients with CSOM, revealing that MRSA was the most common pathogen, found in 28.1% of cases. Other prevalent bacteria included methicillin-susceptible *Staphylococcus aureus* (20.4%) and *Pseudomonas aeruginosa* (18.6%). The study explored three treatment modalities: aural toileting and irrigation with dilute acetic acid or Burow's solution, intravenous teicoplanin, and intravenous vancomycin. The findings demonstrated that aural irrigation successfully achieved dry ears in 79.5% of cases within an average of 19 days, compared to 78.9% with teicoplanin (16 days) and 80% with vancomycin (15.2 days). The study concluded that frequent and appropriate aural irrigation could be an effective non-antibiotic method for managing MRSA-related CSOM. The emergence of antibiotic resistance was a significant concern, and the authors emphasized the need for alternative treatment strategies to reduce dependence on systemic antibiotics." [84]

"Gupta C et al (2015) The study aimed to assess the effectiveness of acetic acid irrigation compared to topical and systemic antibiotics in CSOM. Conducted prospectively from 2011 to 2013, the study involved 100 patients diagnosed with tubotympanic-type CSOM. Participants were divided into two groups: one treated with acetic acid irrigation and the other with conventional antibiotic therapy. After three months of follow-up, the researchers observed that 84% of the acetic acid group achieved complete resolution of otorrhea, compared to only 58% in the antibiotic group. Furthermore, 26% of the acetic acid group exhibited tympanic membrane healing, whereas only 14% in the antibiotic group showed similar improvement. The failure rate was notably higher in the antibiotic group (32%) compared to 16% in the acetic acid group. These findings suggested that acetic acid irrigation is a viable and cost-effective alternative to antibiotic therapy for CSOM. The authors highlighted its accessibility, affordability, and minimal risk of antibiotic resistance as key advantages." [85]

"IOSR Journals, Singh H, Chandra H. (2015) This comparative study evaluated the efficacy of 1.5% acetic acid versus 0.3% gentamicin sulfate in the treatment of CSOM. Conducted in a tertiary care teaching hospital in North India, the study enrolled 88 patients diagnosed with safe-type CSOM. Patients were randomly assigned to two groups: Group A received topical 1.5% acetic acid, while Group B was treated with 0.3% gentamicin sulfate. Treatment success was assessed based on changes in otological symptoms scores at 14 days. The study revealed that both acetic acid and gentamicin were statistically effective in managing CSOM, with a significant reduction in otological symptoms in both groups. However, acetic acid demonstrated a faster response in resolving otorrhea and provided a more complete resolution of symptoms compared to gentamicin. The study underscored the potential of acetic acid as a primary treatment option, especially in resource-limited settings where antibiotic resistance is a growing concern."[86]

"Vishwakarma K et al (2015) A randomized, open-label study investigated the role of 1.5% acetic acid compared to 0.3% gentamicin sulfate for CSOM treatment. The study recruited 150 patients, who were divided into two groups receiving either acetic acid or gentamicin ear drops thrice daily for two weeks. Otological symptoms were evaluated weekly. At day 7, the mean reduction in symptoms score was 1.90±1.01 for the acetic acid group and 1.96±0.57 for the gentamicin group. By day 14, the scores further improved to 3.40±1.08 and 3.12±0.74, respectively. "Treatment success" was observed in 92% of patients treated with acetic acid compared to 88% in the gentamicin group. The study concluded that acetic acid was equally effective as gentamicin and was more cost-effective. The authors recommended acetic acid as an alternative for managing CSOM in clinical settings, given its affordability and non-antibiotic nature." [87]

"Youn C et al (2016) This study examined the comparative antibacterial efficacy of topical antiseptic eardrops, including 2% acetic acid, Burow's solution, vinegar-water solution, and boric acid, against *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The researchers evaluated the bactericidal effects of these solutions in vitro and determined the time required to achieve a 90% bacterial inactivation rate (D10 value). The results indicated that Burow's solution had the highest antimicrobial activity, followed by 2% acetic acid. Acetic acid was particularly effective against quinolone-resistant *Pseudomonas aeruginosa*, suggesting its potential as an alternative treatment for antibiotic-resistant CSOM infections. The authors recommended its use in clinical practice to mitigate the overuse of antibiotics." [88]

"Patel S. (2017) This study evaluated the effectiveness of acetic acid and gentamicin in CSOM patients using an otological symptoms score. The study enrolled 150 patients, who were randomized into two groups receiving either 1.5% acetic acid or 0.3% gentamicin sulfate. Follow-up assessments were conducted at days 7 and 14. The mean reduction in symptoms score at day 7 was 1.80±1.01 for the acetic acid group and 1.86±0.54 for the gentamicin group. By day 14, symptom improvement was noted in 92% of the acetic acid group compared to 84% in the gentamicin group. The study confirmed that acetic acid was as effective as gentamicin, highlighting its potential as a first-line treatment for CSOM. The authors advocated for acetic acid's wider adoption due to its lower cost and reduced risk of antibiotic resistance." [89]

"Yadav et al., 2017 discussed the efficacy, safety, and cost-effectiveness of 1.5% acetic acid compared to 0.3% gentamicin in the treatment of Chronic Suppurative Otitis Media (CSOM). The study was conducted at Teerthanker Mahaveer Medical College and Research Centre, Moradabad, India, where patients with CSOM (safe type) were recruited. The study followed a prospective observational design with a sample size including patients attending the ENT outpatient department over a period of ten months. The primary objective was to compare the resolution of otorrhea, healing of tympanic membrane perforations, and overall symptomatic relief between the two treatment groups. Patients were randomized into two groups: one receiving topical 1.5% acetic acid and the other receiving topical 0.3% gentamicin sulfate. The study evaluated the efficacy of these treatments based on clinical assessment, otoscopic findings, and symptom scoring at baseline and follow-up visits. The findings demonstrated that acetic acid was as effective as gentamicin in reducing ear discharge, alleviating symptoms, and achieving a dry ear, with a comparable success rate. Additionally, acetic acid emerged as a cost-effective alternative, particularly in settings with limited access to antibiotics. The authors concluded that acetic acid could be considered a viable treatment option for CSOM, particularly in the context of increasing antibiotic resistance and the need for cost-effective interventions." [90]

"Shenoy et al., 2017 conducted a comparative study evaluating the efficacy of vinegar wash versus culture-based oral antibiotic therapy in the treatment of active CSOM. The study was based on the premise that chronic otorrhea in CSOM presents a significant treatment challenge due to increasing antibiotic resistance and patient affordability concerns. The study recruited 120 patients with active CSOM, randomly assigning them to two treatment groups. One group received vinegar wash (diluted in a 1:1 ratio with water at pH 4) twice daily for three weeks, while the other group received oral antibiotics based on culture sensitivity results for the same duration. The researchers followed up both groups for one month to assess the resolution of ear discharge and symptomatic improvement. The study identified *Pseudomonas aeruginosa* (40%) and *Staphylococcus aureus* (25%) as the most common pathogens. Results indicated that 96.2% of *Pseudomonas* cases and 50% of *Staphylococcus* *aureus* cases resolved with vinegar wash. The overall dry ear achievement was 81.67% in the antibiotic group and 68.33% in the vinegar group. However, the difference was not statistically significant ($p>0.05$), suggesting that vinegar wash could serve as a low-cost alternative to antibiotic therapy for managing otorrhea in CSOM patients. The authors highlighted that vinegar wash has antimicrobial properties, effectively reducing bacterial load and biofilm formation, which are key contributors to chronic infection persistence.” [91]

“**Adriztina et al., 2018** explored the efficacy of boric acid as a treatment option for CSOM, with particular attention to its ototoxicity. The study provided a comprehensive review of available literature and experimental data on boric acid's role in treating CSOM. The authors pointed out that while boric acid has long been recognized for its antimicrobial and acidifying properties, its application in otology remains controversial due to concerns about potential ototoxic effects. The study reviewed data from multiple databases, including PubMed, The Cochrane Library, and SciELO, to assess the safety and effectiveness of boric acid for managing mucosal CSOM. The findings suggested that boric acid solutions effectively eradicated pathogens associated with CSOM, especially at higher concentrations. However, concerns about ototoxicity, particularly at concentrations above 4%, necessitated further investigation. The study emphasized the need for clinical trials to determine the optimal concentration of boric acid that balances efficacy and safety. The authors concluded that boric acid remains a promising alternative for treating CSOM, particularly in cases where antibiotic resistance is a concern, but its ototoxic potential warrants caution in clinical use.” [92]

“Yogi et al., 2020 compared the efficacy of topically applied acetic acid irrigation versus topical antibiotics in the medical management of tubotympanic CSOM. The study included 200 patients who were randomly assigned to two groups: one receiving acetic acid irrigation and the other receiving topical antibiotic treatment. The researchers evaluated the resolution of otorrhea, healing of tympanic membrane perforations, and overall treatment success rates. Acetic acid, a cost-effective antiseptic, was investigated due to its potential benefits in altering the pH of the external auditory canal and middle ear, thereby inhibiting bacterial growth. The study found that acetic acid irrigation resulted in a comparable resolution of otorrhea to that of antibiotic treatment, with no statistically significant differences in treatment efficacy between the groups. However, acetic acid was noted to be a more affordable and readily available alternative, making it particularly beneficial for resource-limited settings. The authors suggested that acetic acid irrigation could be incorporated into treatment protocols, especially in primary healthcare centers where antibiotic resistance and cost constraints limit the availability of more expensive antibiotic therapies.” [93]

“Artono et al., 2023 conducted an in vitro study to assess the impact of acetic acid on biofilm formation by Pseudomonas aeruginosa, a common pathogen in CSOM. The study aimed to determine whether acetic acid could inhibit or eradicate biofilms that contribute to persistent infections and treatment failures. The researchers isolated Pseudomonas aeruginosa from mastoid cavity secretions of CSOM patients and subjected them to varying concentrations of acetic acid. The findings revealed that acetic acid significantly inhibited biofilm formation at a minimum inhibitory concentration (MIC) of 0.16%, while a biofilm eradication concentration (BEC) of 0.08% was required to disrupt pre-formed biofilms. These results suggested that acetic acid could serve as an effective alternative to conventional antibiotics, particularly in cases where biofilms render standard treatments ineffective. The authors proposed that incorporating acetic acid into treatment regimens could improve CSOM management by reducing bacterial persistence and preventing recurrent infections.” [94]

“**Neelamkavi et al., 2023** investigated the effectiveness of 2% acetic acid in treating CSOM using an otological symptoms score. This prospective study enrolled 100 patients with active mucosal CSOM, who were treated with acetic acid ear drops and monitored over 30 days. Patients were assessed at intervals of 7, 14, 21, and 30 days, with treatment success defined as either clinical cure or clinical improvement based on symptom scores. The results demonstrated that 95% of patients achieved treatment success, with significant reductions in symptoms by the end of the study period. The authors concluded that 2% acetic acid is an effective, low-cost option for managing CSOM, offering a high success rate with minimal adverse effects. They emphasized the potential for acetic acid to be used as a first-line treatment, particularly in regions with high antibiotic resistance and limited healthcare resources.” [95]

MATERIALS AND METHODS

METHODOLOGY

1. Study Design

This study was designed as a hospital-based, randomized controlled trial conducted in the ENT and Head & Neck Surgery department of a tertiary care hospital. The design ensured that eligible patients diagnosed with active mucosal CSOM were randomly allocated into two groups: one receiving standard medical treatment and the other receiving standard treatment plus 1.5% acetic acid ear wash. The randomized controlled design allowed for unbiased comparison of treatment efficacy between the two groups. The randomization was performed using Sequentially Numbered Opaque Sealed Envelope (SNOSE) to ensure allocation concealment. Each patient meeting inclusion criteria and consenting to participate was assigned to a group based on pre-randomized envelopes opened sequentially. Being a controlled trial, both groups underwent uniform baseline assessments, and clinical parameters were evaluated and documented at regular follow-up intervals. This design was chosen to establish whether the addition of acetic acid wash significantly enhanced symptom resolution and microbial clearance when compared to standard treatment alone. The study design incorporated weekly follow-ups for two weeks with both subjective symptom evaluation and objective clinical examination, ensuring comprehensive data collection. The design also considered potential confounders such as age, sex, symptom duration, and comorbidities by balancing these variables between groups during randomization. This parallel group design minimized selection bias and improved internal validity. By using validated clinical scales and standard microbiological techniques, the design ensured reproducibility and reliability. The final analysis compared the two groups using established statistical tests, maintaining a 95% confidence interval and 5% margin of error. Overall, the randomized controlled trial design provided a robust framework to assess the efficacy of 1.5% acetic acid ear wash in active mucosal CSOM, with rigorous efforts to minimize bias and ensure objective comparison.

2. Study Setting

The study was conducted at the ENT and Head & Neck Surgery outpatient department (OPD) of KLES Dr. Prabhakar Kore Charitable Hospital, Belagavi, a tertiary care teaching hospital in Karnataka, India. This hospital was chosen due to its high patient inflow, ensuring an adequate number of cases with active mucosal CSOM, a prevalent condition in the region. Being a tertiary care referral center, the hospital receives patients from rural, semi-urban, and urban backgrounds, thereby ensuring diverse demographic representation. The ENT department is well equipped with oto-endoscopy facilities, microbiology services for ear swab culture, and audio-vestibular diagnostic units, enabling comprehensive diagnostic workup and follow-up assessments.

The study setting provided the necessary infrastructure for detailed clinical evaluation, otoscopic and oto-endoscopic examination, tuning fork tests, and microbiological investigations. Patients presenting to the OPD with ear discharge of more than six weeks duration were screened for inclusion into the study. All clinical history documentation, diagnostic evaluations, and treatment interventions were carried out within the hospital premises, ensuring uniformity and standardization across study participants. The microbiology laboratory within the hospital processed all ear swab samples for culture and sensitivity, eliminating the need for external referrals, thereby enhancing procedural consistency. The hospital setting also allowed for ease of follow-up, as patients were accustomed to returning to the same facility for care.

Being part of a teaching hospital, the study benefited from continuous oversight by experienced faculty, postgraduate residents, and microbiologists, ensuring accurate documentation and adherence to protocol. The hospital's established ethical committee reviewed and approved the study, ensuring adherence to ethical guidelines applicable to human clinical trials. Overall, the tertiary care hospital setting provided a well-equipped, monitored, and patient-friendly environment, essential for conducting a randomized controlled trial with regular follow-up and comprehensive data collection.

3. Study Duration

The study was conducted over a period of one year, from April 1, 2023, to March 31, 2024. The 12-month duration was planned to allow sufficient time for patient recruitment, treatment, follow-up, and data analysis. The timeline included an initial two-month preparatory phase for protocol finalization, ethical clearance, and training of personnel involved in data collection and intervention delivery. Patient recruitment commenced in April 2023 and continued for nine months, allowing enough time to enroll 80 eligible participants.

Each patient, once enrolled, underwent two weeks of weekly follow-up after the initiation of treatment. This ensured short-term outcome assessment, focusing on symptom relief, microbiological clearance, and tympanic membrane status. The follow-up visits were pre-scheduled at the time of recruitment to improve adherence. The two-week follow-up period balanced the need for early outcome detection with practicality, minimizing the risk of loss to follow-up. An additional one-month buffer period at the end of recruitment allowed for delayed follow-up or catch-up visits if participants missed scheduled appointments.

The study duration was also influenced by the seasonal variation in ENT infections. Chronic suppurative otitis media cases were anticipated to be more common during certain months due to monsoon-related infections, ensuring robust recruitment. Data entry, cleaning, and preliminary analysis were conducted concurrently with follow-up visits to maintain data quality and real-time error detection.

The final month of the study was dedicated to data analysis and manuscript preparation. Statistical analysis was performed using SPSS software, comparing outcome measures between the two groups. The one-year duration provided sufficient time to enroll the required sample size while maintaining high-quality data collection and follow-up compliance, ensuring comprehensive and reliable results for the comparative efficacy analysis.

4. Participants - Inclusion and Exclusion Criteria (in points)

1. **Inclusion-Criteria:**
    - Patients diagnosed with active mucosal chronic suppurative otitis media (CSOM).
    - Age group: 18 to 65 years.
    - Patients willing to participate in the study.

2. **Exclusion-Criteria:**

- Patients with Diabetes Mellitus.
- Patients with immunocompromised status such as HIV, malignancy, or on immunosuppressive therapy.
- Patients with a history of prior ear surgery.
- Patients diagnosed with squamosal type CSOM instead of mucosal type.

5. Study Sampling

The study utilized a simple random sampling technique to ensure equal opportunity for all eligible patients to participate. After initial screening based on clinical diagnosis, all patients meeting the inclusion criteria were explained the nature and purpose of the study in their local language. Patients willing to participate were asked to sign informed consent forms.

The sampling process followed the SNOSE technique. Each envelope contained a pre-assigned group allocation—either Group 1 (Standard treatment + 1.5% Acetic Acid wash) or Group 2 (Standard treatment alone). Upon recruitment, the envelope was opened in the presence of the patient, ensuring allocation concealment.

Sampling continued until the target sample size of 80 participants was achieved. This ensured that each group would consist of 40 patients, allowing for balanced comparison of outcomes. The random allocation process minimized selection bias, ensuring that both groups were comparable in terms of baseline characteristics like age, gender, symptom duration, and severity.

The randomization process and sealed envelope method ensured that treating clinicians were blind to allocation at the time of consent, thus avoiding potential bias in counseling or baseline assessment. Simple random sampling combined with allocation concealment made the process transparent and reproducible, contributing to the internal validity of the study findings.

6. Calculation of study sample size

The sample size was calculated based on the expected difference in treatment success rates between the acetic acid group and the standard treatment group. Prior studies reported that standard treatment alone resulted in a success rate of approximately 52%, while the addition of 1.5% acetic acid wash improved outcomes to approximately 88%.

Using these estimates, the sample size was calculated using the formula for comparing two proportions:

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \cdot 2(p_1 q_1 + p_2 q_2)}{(p_1 - p_2)^2}$$

Where:

- p1=88 (Acetic acid group success rate)
- p2=52 (Standard treatment success rate)
- $z_{1-\alpha/2}$=1.96 for 95% confidence interval
- $z_{1-\beta}$=1.64 for 95% power

The calculated sample size per group was 35.5, which was rounded up to 40 to account for 10% attrition. Thus, the final sample size was set at 80 patients (40 per group). This sample size was considered sufficient to detect a clinically significant difference between the two treatment approaches with adequate statistical power.

7. Study Groups

The study involved two parallel groups for comparative analysis.

- Group 1 (Interventional Group): Received standard treatment (topical and systemic antibiotics) along with 1.5% acetic acid ear wash. The wash was administered under aseptic precautions during weekly follow-up visits.

- Group 2 (Control Group): Received standard treatment alone, without any additional acetic acid wash.

Both groups underwent baseline clinical evaluation, including detailed history, otoscopy, and oto-endoscopy. Ear swabs were collected for microbiological examination.

During follow-ups, both groups were assessed for:

- Symptom relief (discharge, pain, hearing improvement)
- Objective clinical improvement (tympanic membrane appearance)
- Microbiological clearance (culture-negative rates)

The groups were followed for a total of 2 weeks with weekly visits to evaluate short-term response. The randomization process ensured comparable baseline characteristics, and both groups were treated according to current clinical guidelines, apart from the additional acetic acid wash in the intervention arm.

8. Study Parameters

Key study parameters included both clinical and microbiological outcomes.

Primary Parameters:

- Resolution of ear discharge (clinical drying of ear)
- Improvement in tympanic membrane status (size and nature of perforation)
- Microbiological clearance (negative culture on follow-up swabs)

Secondary Parameters:

- Symptom relief (pain, itching, fullness) assessed using Visual Analogue Scale (VAS)
- Patient-reported satisfaction
- Occurrence of any adverse effects (irritation, discomfort post-acetic acid wash)

All parameters were documented at baseline, after 1 week, and after 2 weeks. Both subjective and objective parameters were recorded in pre-structured case report forms (CRFs).

9. Study Procedure

After consent and randomization, baseline data collection was performed including detailed history, otoscopy, and oto-endoscopy. Ear swabs were obtained for culture and sensitivity.

Group 1 underwent weekly acetic acid ear wash using 1.5% acetic acid applied via sterile syringe under direct otoscopic guidance. Group 2 received standard treatment (antibiotic drops + systemic antibiotics) alone.

All participants were instructed on ear hygiene and adherence to medications. Follow-up visits occurred at week 1 and week 2, during which symptoms, clinical findings, and microbiological status were reassessed.

10. Study Data Collection

Data was collected using a pre-designed case record form (CRF), capturing:

- Demographics, symptoms, clinical findings
- Culture reports (before and after treatment)
- Follow-up symptom scores (VAS), tympanic membrane appearance, and adverse events

11. Data Analysis

Data was entered into SPSS software. Descriptive statistics were applied for baseline characteristics. Comparative analysis between groups used:

- Chi-square test (categorical variables)
- Paired t-test (continuous variables within groups)
- Independent t-test (continuous variables between groups)

A p-value < 0.05 was considered significant. Results were expressed as means, percentages, and confidence intervals.

12. Ethical Considerations

The study was approved by the Institutional Ethics Committee of KLES Dr. Prabhakar Kore Charitable Hospital, Belagavi. Written informed consent was obtained from all participants, after providing detailed explanations in their preferred language. Patients were assured that participation was voluntary, and refusal would not affect their standard care.

Patient confidentiality was maintained by anonymizing data during analysis. The acetic acid ear wash used in the intervention arm is a well-established adjunct for otitis media, ensuring minimal risk. Adverse effects like irritation were monitored, and any discomfort reported was addressed promptly.

The study adhered to Declaration of Helsinki guidelines and ICMR ethical guidelines for biomedical research. Participants were free to withdraw at any time. The primary investigator bore all costs related to additional investigations or procedures arising from study participation.

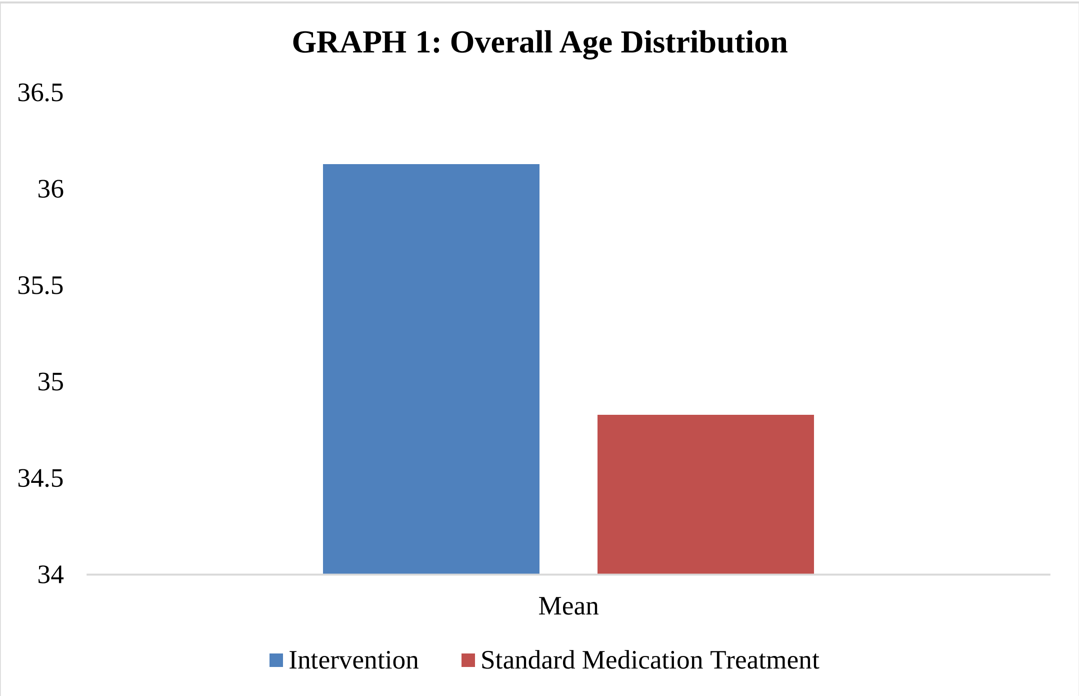
RESULTS

1. Overall Age Distribution

The study involved 80 patients with an overall mean age of 35.46 years, a standard deviation of 12.87, and an age range from 18 to 65 years. This broad age distribution indicates moderate variability among subjects and reflects a representative adult sample.

Table 1: Overall Age Distribution

AGE				
N	Mean	SD	Minimum	Maximum
80	35.46	12.87	18	65



2. Age Distribution by Group

When comparing the two treatment groups, the Intervention group (n=39) had a mean age of 36.13 years (SD=14.05; range 18–64) while the Standard Medication Treatment group (n=41) had a mean age of 34.83 years (SD=11.78; range 18–65).

Table 2: Age Distribution by Group

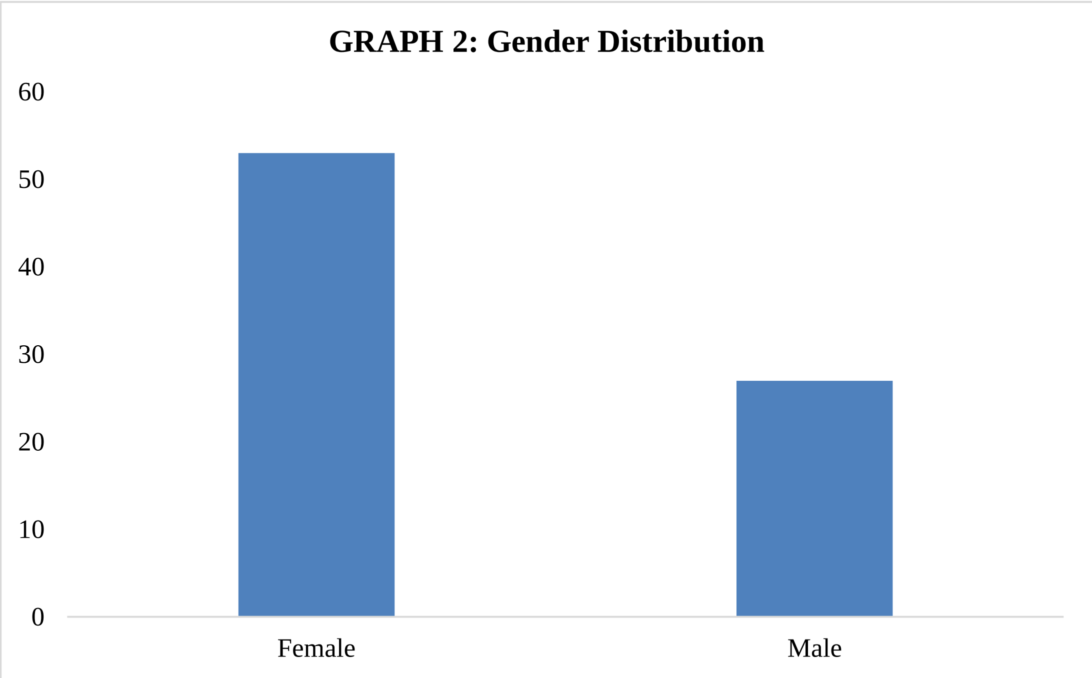
AGE by Group					
Group	N	Mean	Std Dev	Minimum	Maximum
Intervention	39	36.13	14.05	18	64
Standard Medication Treatment	41	34.83	11.78	18	65

3. Gender Distribution

Among the 80 participants, the gender distribution reveals a predominance of females, with 53 (66.25%) female and 27 (33.75%) male subjects. This skew toward female subjects may influence treatment outcomes if gender-related biological differences affect disease manifestation or response. However, the representation of both genders provides valuable insight into the study population's makeup.

Table 3: Gender Distribution

GENDER	Number	Percent
Female	53	66.25
Male	27	33.75

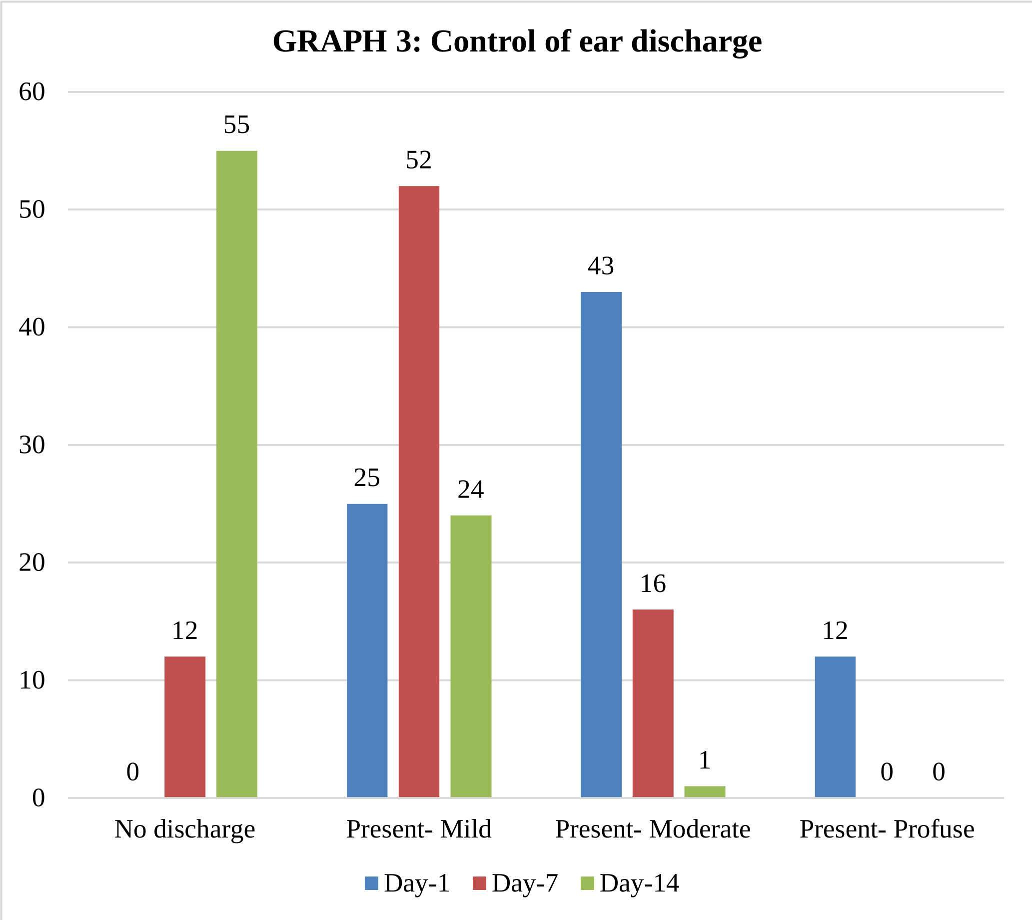


4. Control of ear discharge

Ear discharge was measured on Day-1, Day-7, and Day-14. On Day-1, no patients had an absence of discharge; 31.25% had mild, 53.75% moderate, and 15% profuse discharge. By Day-7, absent discharge appeared in 15% of patients, mild discharge increased to 65%, and moderate discharge decreased to 20% with no profuse cases. On Day-14, absent discharge rose markedly to 68.75%, mild discharge dropped to 30%, and moderate discharge nearly vanished (1.25%). These results indicate progressive improvement in ear discharge severity, suggesting that the treatment—especially the intervention—effectively reduces discharge over time.

Table 4: Control of ear discharge

Ear Discharge	Day-1		Day-7		Day-14	
	Number	Percent	Number	Percent	Number	Percent
Present- Profuse	12	15	0	0	0	0
Present- Moderate	43	53.75	16	20	1	1.25
Present- Mild	25	31.25	52	65	24	30
No discharge	0	0	12	15	55	68.75

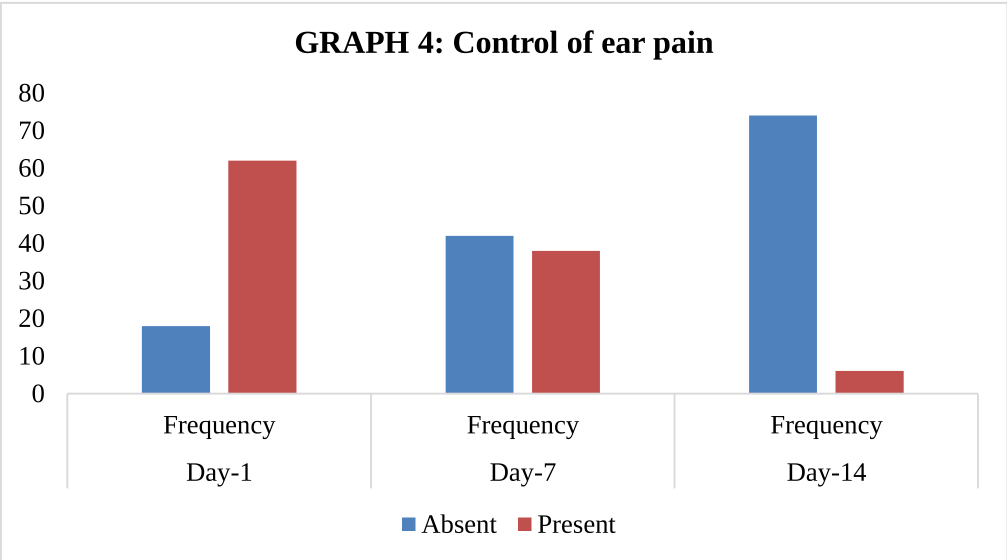

GRAPH 3: Control of ear discharge
60
50
40
30
20
10
0
55
52
43
25
24
16
12
12
1
0
0
0
No discharge
Present- Mild
Present- Moderate
Present- Profuse
Day-1
Day-7
Day-14

5. Control of ear pain

Ear pain was evaluated at three time points. On Day-1, 22.5% of patients reported no pain while 77.5% experienced pain. By Day-7, the percentage of patients without pain increased to 52.5%, with pain present in 47.5% of cases. On Day-14, a substantial improvement was observed with 92.5% of patients pain-free and only 7.5% reporting pain. This consistent reduction over time suggests that the treatment is effective in alleviating ear pain. The early reduction observed by Day-7 and the near-complete resolution by Day-14 underscore the clinical benefit of the treatment in improving patient comfort and reducing symptomatic distress.

Table 5: Control of ear pain

EAR PAIN	Day-1		Day-7		Day-14	
	Number	Percent	Number	Percent	Number	Percent
Absent	18	22.5	42	52.5	74	92.5
Present	62	77.5	38	47.5	6	7.5

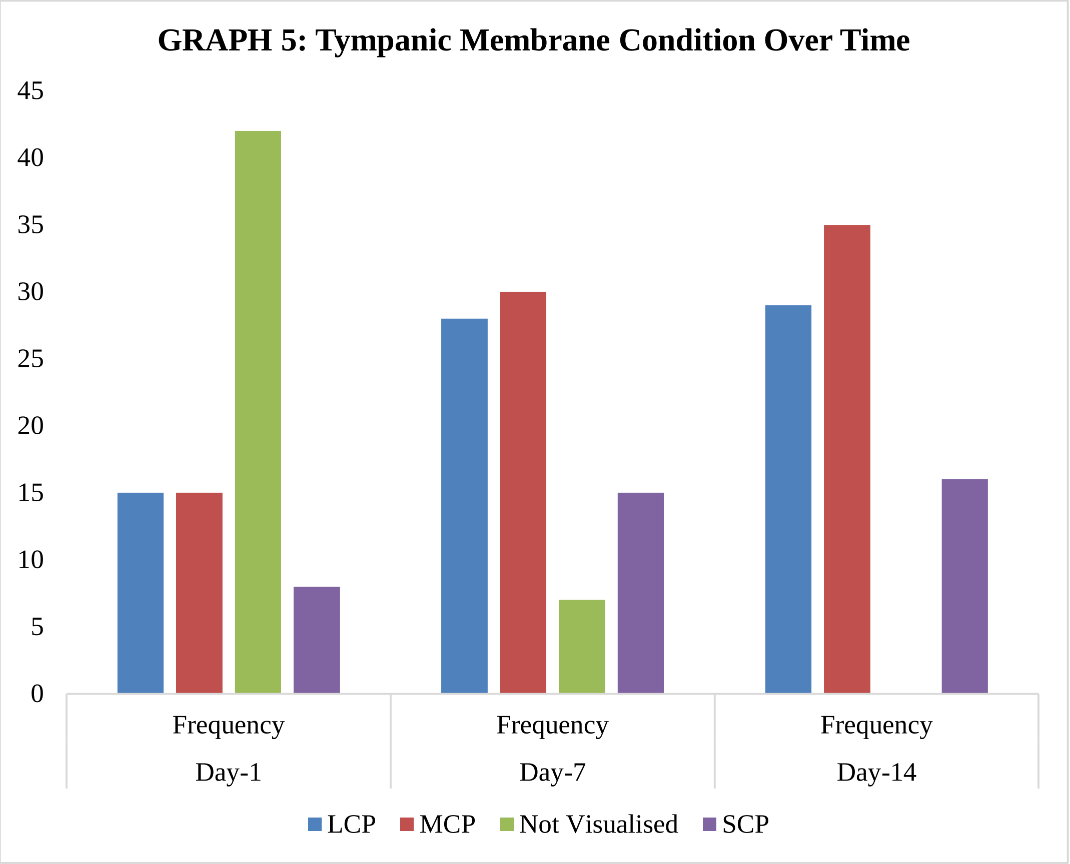


6. Tympanic Membrane Condition Over Time

Tympanic membrane status was classified as LCP, MCP, SCP or Not Visualised. On Day-1, 18.75% were LCP, 18.75% MCP, 10% SCP and 52.5% not visualised. At Day-7, LCP and MCP increased to 35% and 37.5%, respectively, with not visualised due to persistent discharge despite repeated dry mopping and suctioning, cases dropping to 8.75% and SCP rising to 18.75%. By Day-14, LCP and MCP further improved (36.25% and 43.75%, respectively), with complete resolution of non-visualisation and SCP at 20%. This indicates marked improvement in membrane clarity, suggesting that the treatment accelerates healing and enhances visualization of the tympanic membrane over time.

Table 6: Tympanic Membrane Condition Over Time

Tympanic membrane	Day-1		Day-7		Day-14	
	Number	Percent	Number	Percent	Number	Percent
LCP	15	18.75	28	35	29	36.25
MCP	15	18.75	30	37.5	35	43.75
Not Visualised (even after repeated dry mopping and suctioning)	42	52.5	7	8.75	0	0
SCP	8	10	15	18.75	16	20

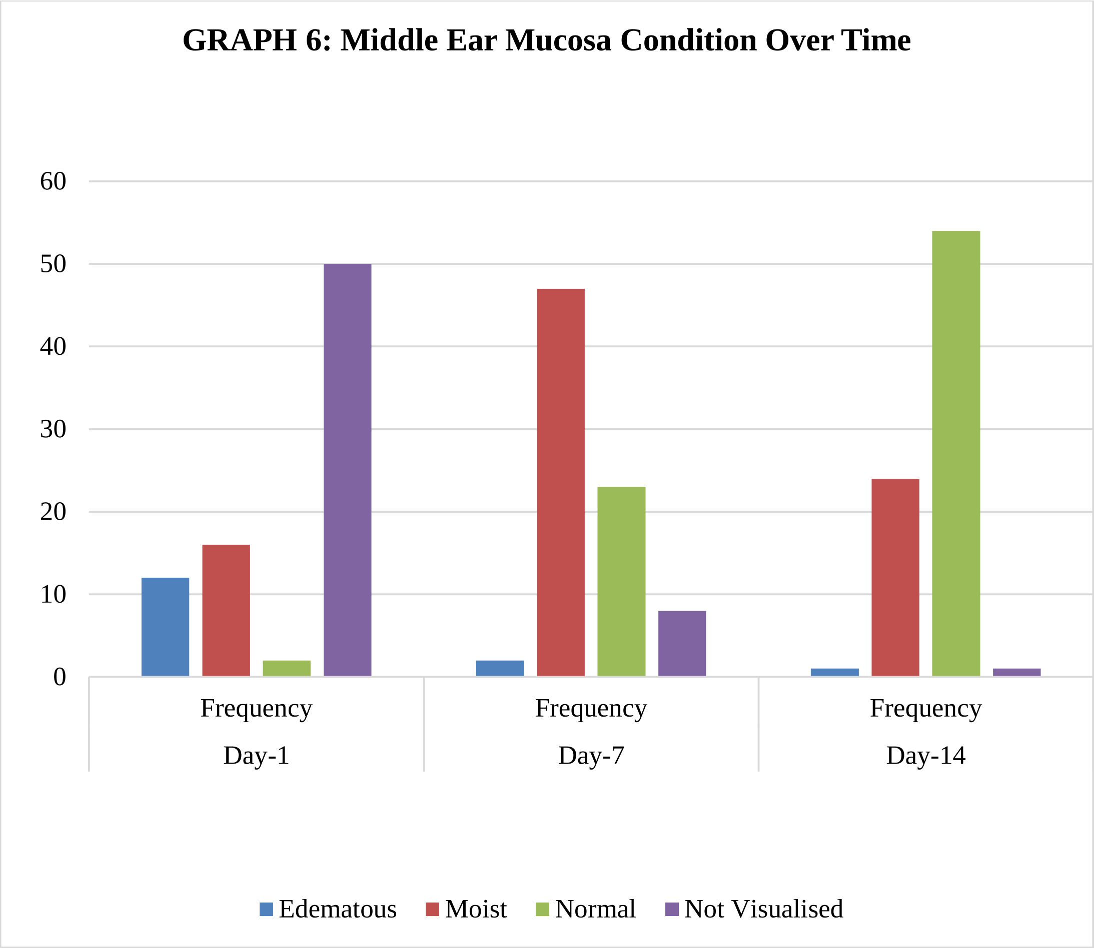

GRAPH 5: Tympanic Membrane Condition Over Time
45
40
35
30
25
20
15
10
5
0
Frequency
Day-1
Frequency
Day-7
Frequency
Day-14
LCP
MCP
Not Visualised
SCP

7. Middle Ear Mucosa Condition Over Time

Middle ear mucosa was evaluated and categorized as edematous, moist, normal, or not visualised. On Day-1, 15% were edematous, 20% moist, 2.5% normal, and 62.5% not visualised. By Day-7, edematous mucosa decreased to 2.5%, moist increased to 58.75%, normal improved to 28.75%, and not visualised cases dropped to 10%. On Day-14, further improvements were seen with edematous at 1.25%, moist at 30%, normal rising significantly to 67.5%, and not visualised nearly resolving at 1.25%. This progressive improvement demonstrates a strong treatment effect on mucosal healing and clarity over time.

Table 7: Middle Ear Mucosa Condition Over Time

Middle ear mucosa	Day-1		Day-7		Day-14	
	Number	Percent	Number	Percent	Number	Percent
Edematous	12	15	2	2.5	1	1.25
Moist	16	20	47	58.75	24	30
Normal	2	2.5	23	28.75	54	67.5
Not Visualised	50	62.5	8	10	1	1.25


GRAPH 6: Middle Ear Mucosa Condition Over Time
60
50
40
30
20
10
0
Frequency
Day-1
Frequency
Day-7
Frequency
Day-14
Edematous
Moist
Normal
Not Visualised

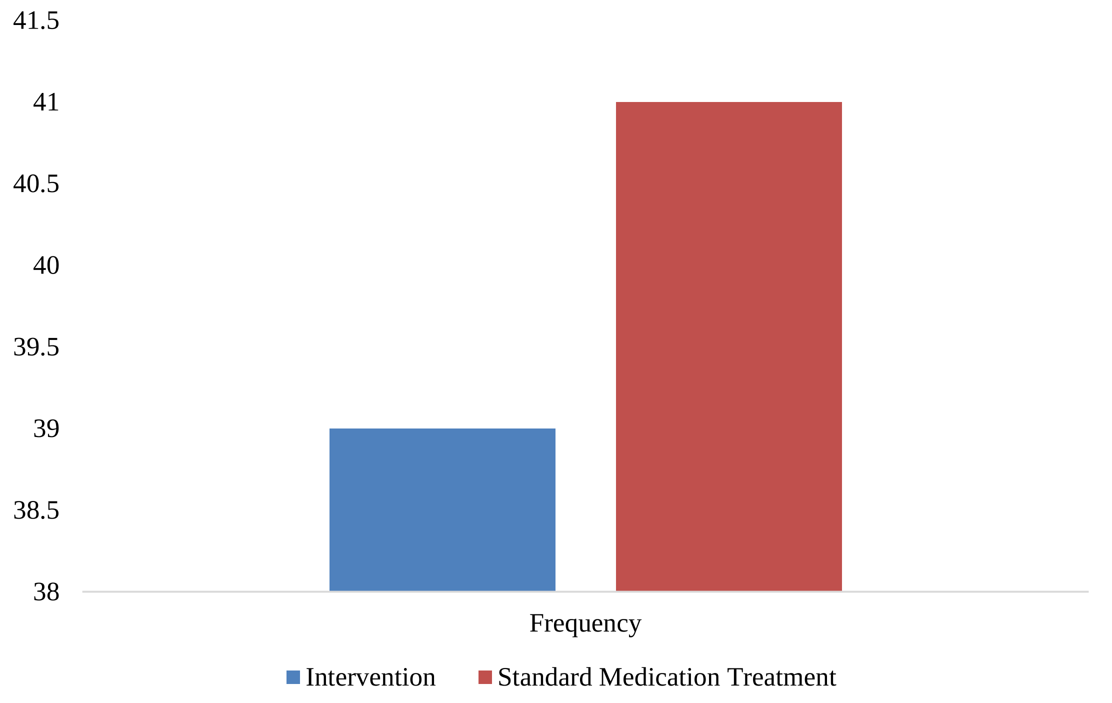
8. Group Distribution Analysis

The near-equal distribution between intervention (48.75%) and standard medication (51.25%) groups confirms effective randomization, minimizing bias and ensuring reliable comparisons. This balanced allocation strengthens internal validity, supporting robust clinical conclusions.

Table 8: Group Distribution Analysis

Group	Number	Percent
Intervention	39	48.75
Standard Medication Treatment	41	51.25

GRAPH 7: Group Distribution Analysis



DISCUSSION

Mucosal, Chronic Suppurative Otitis Media (CSOM) is a persistent inflammatory condition of the middle ear, characterized by recurrent otorrhea through a perforated tympanic membrane. Globally, CSOM presents a significant public health burden, especially in low- and middle-income countries, where it contributes notably to hearing impairment, chronic morbidity, and compromised quality of life. The persistent inflammation and infection associated with CSOM can result in serious complications if inadequately managed.

Standard medical treatment typically involves topical and systemic antibiotics; however, increasing antibiotic resistance and recurrence rates necessitate exploring adjunctive therapies. Acetic acid, with its acidic pH, has emerged as a beneficial adjunctive agent due to its antimicrobial properties, effective in suppressing bacterial growth, restoring ear canal pH, and reducing the frequency of infection-related complications. Furthermore, acetic acid's availability, cost-effectiveness, and ease of administration make it an attractive therapeutic option to enhance the effectiveness of standard medical management in patients with active mucosal CSOM.

The primary aim of this study was to evaluate the clinical efficacy of adding a 1.5% acetic acid ear wash to the standard medical treatment for patients with active mucosal CSOM. By integrating this non-antibiotic intervention into conventional treatment protocols, the study sought to determine whether acetic acid irrigation could enhance patient outcomes, with respect to the rapid resolution of ear discharge, reduction in ear pain, and improvement in the overall condition of the tympanic membrane and middle ear mucosa, viz. reduction in congestion, edema of the tympanic membrane and reduction in the size of the perforation. The significance of this investigation lies in its potential to provide a cost-effective, accessible alternative that could reduce the reliance on systemic antibiotics—a critical consideration in an era of rising antibiotic resistance. Moreover, the study was designed to capture both immediate and progressive clinical improvements through detailed assessments at multiple time points, thereby offering a comprehensive understanding of the treatment's impact over time.

The overall age distribution in our study provides a critical foundation for assessing treatment efficacy in a representative CSOM population. In our sample of 80 participants, the mean age was 35.46 years (SD = 12.87), with ages ranging from 18 to 65 years. This spread indicates moderate variability and suggests that our cohort reflects the adult demographic commonly affected by chronic suppurative otitis media. A broad age range is essential, as age can influence both the natural history of CSOM and the host response to interventions such as the 1.5% acetic acid ear wash. In comparison, Choi et al. (2010)[84] analyzed 577 CSOM patients and reported that the affected individuals predominantly fell within a similar adult age bracket. Gupta et al. (2015) [85] also observed a mean age in the mid-thirties in their study of tubotympanic CSOM patients, thereby reinforcing that our demographic profile is consistent with previous literature.

In our study, 66.25% (53/80) of the participants were female, while 33.75% (27/80) were male. This predominance of female subjects is consistent with observations in prior research on chronic suppurative otitis media. For instance, Choi et al. (2010) [84] and Gupta et al. (2015) [85] both reported a similar female predominance in their patient populations, suggesting that CSOM may affect females slightly more or that there is a higher likelihood of seeking treatment among women.

The implications of our gender distribution are twofold. First, it provides an opportunity to evaluate whether the 1.5% acetic acid ear wash is equally effective across genders or if there are differential outcomes that could warrant subgroup analysis. Second, the similarity in gender ratios with previous studies reinforces the external validity of our findings. When demographic parameters align with established literature, it enhances the generalizability of our conclusions and supports the notion that our study results are applicable to a typical CSOM population.

Ear discharge is one of the most critical clinical parameters in CSOM, reflecting both the severity of infection and the response to treatment. At baseline (Day 1), our study showed that none of the 80 patients exhibited an absence of ear discharge; rather, 31.25% had mild discharge, 53.75% moderate, and 15% profuse. Such findings underscore the significant inflammatory burden present at the outset. With the administration of the 1.5% acetic acid ear wash, by Day 7, there was a notable shift: 15% of patients achieved complete resolution of discharge, mild discharge increased to 65%, and moderate discharge decreased to 20%, with no cases of profuse discharge observed. By Day 14, the therapeutic effect became even more pronounced; 68.75% of patients had no discharge, only 30% exhibited mild discharge, and a minimal 1.25% continued to have moderate discharge.

These improvements are clinically significant and align with findings from previous studies. Choi et al. (2010)[84] reported that aural irrigation with diluted acetic acid resulted in dry ears in 79.5% of cases within an average of 19 days. Similarly, Gupta et al. (2015)[85] demonstrated that acetic acid irrigation led to complete resolution of otorrhea in 84% of patients compared to 58% in the antibiotic group. In our study, the progression to nearly 70% at Day 14—with significant p-values

($p = 0.0004$ on Day 7 and $p < 0.0001$ on Day 14)—reinforces the potent antimicrobial and cleansing properties of acetic acid irrigation.[84,85,87,89].

In our study, the assessment of ear pain revealed a striking trend. On Day 1, only 22.5% of patients reported no ear pain, while 77.5% experienced pain—a reflection of the intense inflammatory process at work. With the initiation of the 1.5% acetic acid ear wash alongside standard therapy, a significant improvement was noted. By Day 7, the proportion of pain-free patients rose to 52.5%, and by Day 14, an impressive 92.5% of patients were pain-free, leaving a mere 7.5% with residual pain.

This progressive reduction in ear pain is not only clinically important but also indicative of the rapid anti-inflammatory effects of acetic acid. The early alleviation of pain, particularly the significant improvement observed by Day 7 ($p = 0.0133$), is comparable to findings in previous studies, Patel et al (2017)[89] reported that patients treated with acetic acid experienced notable reductions in otological symptoms, including pain, within the first week of treatment.

The condition of the tympanic membrane (TM) serves as a crucial indicator of the underlying inflammatory process and the effectiveness of therapeutic interventions in CSOM. In our study, the baseline assessment (Day 1) revealed that only 18.75% of patients exhibited a Large central perforation (LCP) , 18.75% a medium central perforation (MCP),10% demonstrated a small central (SCP), while a substantial 52.5% of TMs were not visualized . These findings reflect significant inflammation and poor visualization due to exudative processes. With the incorporation of the 1.5% acetic acid ear wash, improvements were observed over time. Early p-value comparisons in our study (0.0142 on Day 1 and 0.0390 on Day 7) further support the rapid benefits of acetic acid in restoring TM integrity, although the differences became statistically non-significant by Day 14 ($p = 0.8654$)

These dynamic changes in TM appearance are in line with previous research. Singh and Chandra (2015)[86] demonstrated that topical acetic acid not only improved TM visualization but also expedited the resolution of inflammation compared to 0.3% gentamicin sulfate. Similarly, Youn et al. (2016)[88] reported that acetic acid significantly reduced bacterial biofilm formation, thereby enhancing TM clarity and overall appearance in CSOM patients. In conclusion, the progressive improvement in TM condition observed in our study substantiates the efficacy of acetic acid irrigation in reducing inflammation and promoting healing, reinforcing its potential as a valuable adjunct in the management of CSOM[86,88].

The status of the middle ear mucosa is a direct reflection of the inflammatory process in CSOM and is critical for evaluating the healing response to treatment. At baseline (Day 1), our study found that only 2.5% of patients exhibited normal mucosa, while 15% had edematous mucosa, 20% had a moist appearance, and a substantial 62.5% had mucosa that was not visualized. These findings underscore the extensive mucosal inflammation and damage present at the start of treatment. With the use of the 1.5% acetic acid ear wash, a progressive improvement was noted. The statistically significant p-values in our study ($p = 0.0037$ on Day 7 and $p < 0.0001$ on Day 14) further substantiate the rapid improvement in mucosal condition due to acetic acid irrigation. These findings are clinically significant, as restoration of normal mucosa is associated with improved hearing outcomes and a reduced risk of recurrent infection.

These improvements are in line with prior research. Yadav et al. (2017)[90] reported that 1.5% acetic acid was as effective as 0.3% gentamicin sulfate in promoting mucosal healing, with significant reductions in otorrhea and enhanced mucosal recovery. Similarly, Neelamkavi et al. (2023)[95] demonstrated that treatment with 2% acetic acid resulted in a 95% treatment success rate in active mucosal CSOM, indicating robust healing of the middle ear mucosa. In summary, our data strongly support the efficacy of acetic acid irrigation in restoring normal middle ear mucosa, thereby reducing inflammation and facilitating tissue repair. This aligns well with previous studies and highlights the potential of acetic acid as a cost-effective, non-antibiotic alternative in the management of CSOM[90].

LIMITATIONS OF THE STUDY

Our Study being a part of dissertation therefore, study period was restricted to one year. Because of this collection of larger sample size was not possible and relatively short follow-up , which may not capture long-term outcomes such as recurrence rates, sustained mucosal healing, or the potential development of resistance over time.

CONCLUSION

This study demonstrates that adding a 1.5% acetic acid ear wash to standard medical treatment significantly enhances clinical outcomes in active mucosal Chronic Suppurative Otitis Media (CSOM). Marked improvements were observed in ear discharge, pain relief, tympanic membrane condition, and condition of middle ear mucosa within 14 days. As Acetic acid wash is a simple OPD procedure, it is very cost-effective & patient compliance is excellent, it can be considered as a non-antibiotic adjunct to standard medical treatment of CSOM.

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ANNEXURES

ANNEXURE – I - INFORMED CONSENT FORM

COMPARISON OF ADDITION OF 1.5% ACETIC ACID WASH WITH STANDARD TREATMENT IN THE MEDICAL MANAGEMENT OF ACTIVE MUCOSAL CHRONIC SUPPURATIVE OTITIS MEDIA.

Name of Student/Principal Investigator: ______________

Name of Guide/Co Investigators: __________________

Introduction:

The prevalence of Chronic suppurative otitis media is high in India.

Early diagnosis and treatment of Chronic suppurative otitis media helps in restoring the hearing and preventing the complications.

Usage of oral antibiotics in management of Chronic suppurative otitis media can result in untoward side-effects.

Simple, local treatment with acetic acid is usually devoid of systemic side-effects. Very few studies have been done in India, comparing the efficacy of 1.5% acetic acid with standard treatment in the medical management of Chronic suppurative otitis media.

The present study is conducted among patients with Chronic suppurative otitis media, controls of Same age and sex in equal number attending outpatient department of ENT and HNS in KLE's Dr Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi and they will be investigated for otoscopy, oto-endoscopy, Pure tone audiometry. Your requested to participate in the study and your participation is completely Voluntary.

Explanation of procedure: If you agree to participate in this study, the relevant data will be collected as per proforma and final diagnosis will be confirmed. After getting inducted in the study, You will be examined for symptoms with otoscopy and oto-endoscopy and evaluated for hearing with Pure tone audiometry.

Withdrawal from participation in the study: Participation in this study in voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will not get any benefits by participating in this study. The data gathered will help population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication. Financial incentives: You will not receive any payment for participating in this study. Cost of investigations done during the course of study will be paid by the principal investigator. Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your personal identity will never be revealed.

Questions:

If you have any question or complaints with regard to your right as study participant you may contact : Dr Harsha Hegde, Chairperson, Ethical Committee for Human Subject's Research of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waiving of any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision of participate in the study "Comparison of addition of 1.5% acetic acid wash with standard treatment in the medical management of Active Mucosal Chronic suppurative otitis media." My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity of ask questions and that they have been answered of my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator: Signature of the investigator:

ANNEXURE II: PROFORMA

PROFORMA

COMPARISON OF ADDITION OF 1.5% ACETIC ACID WASH WITH STANDARD TREATMENT IN THE MEDICAL MANAGEMENT OF ACTIVE MUCOSAL CHRONIC SUPPURATIVE OTITIS MEDIA.

Date:

Name:

Age: OP/IP no:

Sex: Date of assessment:

Address: Date of discharge:

Occupation: Diagnosis:

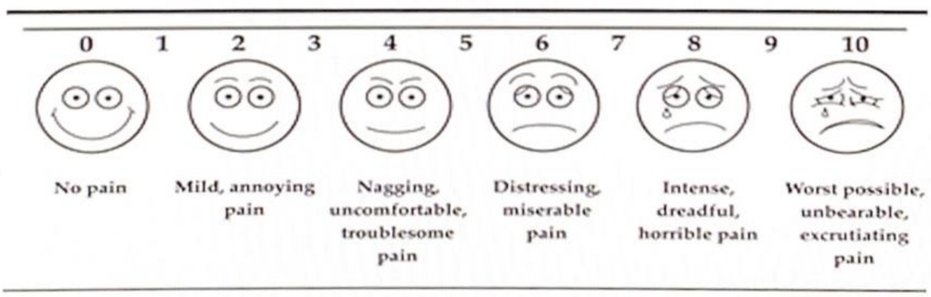
CLINICAL PROFILE:

Chief Complaint:

History of Present illness:

SYMPTOMS	BEFORE TREATMENT	AFTER TREATMENT (DAY-7)	AFTER TREATMENT (DAY-14)
EAR DISCHARGE			
EAR PAIN			

VISUAL ANALOGUE SCALE- FOR PAIN ASSESSMENT



Past History:

Personal History:

Family History:

I) General Physical Examination -

Blood Pressure:
Pulse:
Respiratory Rate:

SIGNS OF: Pallor
Icterus
Clubbing
Cyanosis
Lymphadenopathy
Edema

II) ENT Examination

1. EAR EXAMINATION:

	Right	Left
• Pinna		
• Pre auricular area		
• Post auricular area		
• External auditory canal		
• Tympanic membrane		

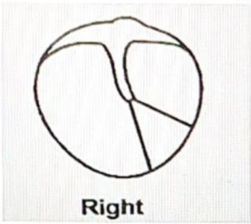
TUNING FORK TESTS:

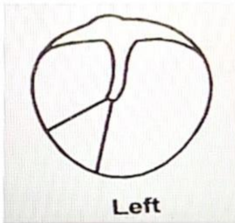
- Rinne's test 256 Hz
  512Hz
  1024Hz

- Weber's test
- Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION:

1. OTO-ENDOSCOPY EXAMINATION:





SIGNS	BEFORE TREATMENT	AFTER TREATMENT (DAY-7)	AFTER TREATMENT (DAY-14)
1. PRE-AURICULAR AREA			
2. PINNA			
3. POST-AURICULAR AREA			
4. EXTERNAL AUDITORY CANAL			
5. TYMPANIC MEMBRANE			
6. MIDDLE EAR MUCOSA			

2. **NOSE EXAMINATION**

External appearance :

- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test:

On tip elevation:

Anterior Rhinoscopy:

Posterior Rhinoscopy:

Paranasal Sinus Tenderness Examination:

3. **THROAT EXAMINATION:**

Oral cavity:

Oropharynx:

DIAGNOSIS:

INVESTIGATIONS:

ANNEXURE III: PHOTOGRAPHS

PHOTOGRAPH :1 SIMPSON AURAL SYRINGE

ANNEXURE IV: MASTER CHART

						SYMPTOMS											SIGNS-OTOENDOSCOPY										
				EAR DISCHARGE			EAR PAIN			Pre-auricular area			Pinna			Post-Auricular area			EAC			Tympanic membrane			Middle ear mucosa		
	OP no.	AGE	GENDER	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14	DAY-1	DAY-7	DAY-14
1	7090631	60	F	Present-Mild	Absent	Absent	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	SCP in AI Quadrant	SCP in AI Quadrant	SCP in AI Quadrant	Moist	Normal	Normal
2	7104265	50	F	Present-Profuse	Present-Moderate	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Normal	Not Visualised	Partially visualised	SCP in PI Quadrant	Not Visualised	Normal	Normal
3	1167750	27	F	Present-Moderate	Present-Mild	Absent	Present-2	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist & Edematous	Moist
4	3387313	40	M	Present-Mild	Absent	Absent	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Edematous	Normal	Normal
5	4612004	33	M	Present-Moderate	Present-Moderate	Present-Mild	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	MCP in AI & PI Quadrants	Not Visualised	Not visualised	Moist
6	4520801	20	M	Present-Mild	Present-Mild	Absent	Present-6	Present-5	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	Not Visualised	SCP in PI Quadrant	SCP in PI Quadrant	Not Visualised	Not visualised	Normal
7	7158614	35	F	Present-Mild	Present-Mild	Present-Mild	Present-5	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Discharge-Mild	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Moist	Moist	Moist
8	7136303	18	F	Present-Profuse	Present-Moderate	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	MCP in AS & AI Quadrant	Not Visualised	Not visualised	Moist
9	7161883	34	M	Present-Moderate	Present-Mild	Absent	Present-5	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Moist
10	7152849	37	F	Present-Moderate	Present-Mild	Absent	Present-4	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Moist & Edematous	Moist	Normal
11	4430070	65	F	Present-Moderate	Present-Mild	Present-Mild	Present-6	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	Not Visualised	SCP in PI Quadrant	SCP in PI Quadrant	Not Visualised	Normal	Normal
12	3448223	25	F	Present-Profuse	Present-Moderate	Present-Mild	Present-5	Present-4	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Moist & Edematous
13	6610066	24	F	Present-Moderate	Present-Moderate	Present-Mild	Present-4	Present-3	Present-3	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Moist & Edematous	Moist & Edematous	Moist
14	7151772	52	M	Present-Mild	Present-Mild	Present-Mild	Present-5	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Discharge-Mild	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Moist	Moist	Moist
15	7146292	32	M	Present-Moderate	Present-Mild	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in PS & PI Quadrants	MCP in PS & PI Quadrants	Not Visualised	Moist & Edematous	Moist

16	7140513	50	F	Present-Mild	Absent	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	SCP in AI Quadrant	SCP in AI Quadrant	SCP in AI Quadrant	Not Visualised	Normal	Normal
17	7210066	26	F	Present-Mild	Present-Mild	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Discharge-Mild	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Edematous	Edematous	Edematous
18	6788322	24	M	Present-Moderate	Present-Mild	Present-Mild	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist	Moist
19	7152849	37	F	Present-Mild	Present-Mild	Absent	Present-6	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Normal	Normal
20	6287326	41	F	Present-Profuse	Present-Moderate	Present-Mild	Present-3	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	MCP in AS & AI Quadrant	Not Visualised	Moist & Edematous	Normal
21	7152625	38	F	Present-Moderate	Present-Mild	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	MCP in PS & PI Quadrant	MCP in PS & PI Quadrants	MCP in PS & PI Quadrants	Edematous	Edematous	Normal
22	2562367	30	F	Present-Moderate	Present-Moderate	Present-Mild	Present-6	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	Not Visualised	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Not Visualised	Moist	Moist
23	7123719	34	M	Present-Moderate	Present-Moderate	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	MCP in AI & PI Quadrants	Not Visualised	Not visualised	Moist & Edematous
24	7120458	30	F	Present-Profuse	Present-Moderate	Present-Mild	Present-8	Present-6	Present-3	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	LCP in all Quadrants	Not Visualised	Not visualised	Moist
25	5201157	35	F	Present-Moderate	Present-Moderate	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	Not Visualised	Not visualised	SCP in PI Quadrant	Not Visualised	Not visualised	Moist
26	5293190	21	M	Present-Profuse	Present-Moderate	Present-Moderate	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Moderate	Not Visualised	Not visualised	MCP in AS & AI Quadrant	Not Visualised	N	Moist
27	6653016	45	M	Present-Moderate	Present-Moderate	Present-Mild	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Moist
28	7119866	19	F	Present-Moderate	Present-Moderate	Present-Mild	Present-6	Present-5	Present-2	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Moderate	Discharge-Mild	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist	Moist
29	6525879	53	M	Present-Moderate	Present-Mild	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	Not Visualised	SCP in AI Quadrant	SCP in AI Quadrant	Not Visualised	Not visualised	Moist
30	7352316	30	F	Present-Profuse	Present-Moderate	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Normal	Not Visualised	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Moist & Edematous	Moist	Normal
31	7090631	60	F	Present-Mild	Present-Mild	Absent	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	SCP in AI Quadrant	SCP in AI Quadrant	SCP in AI Quadrant	Not Visualised	Not visualised	Not Visualised
32	7144143	30	F	Present-Moderate	Present-Mild	Absent	Present-5	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in PS,PI & AI Quadrant	LCP in PS,PI & AI Quadrant	Moist	Moist	Normal
33	5187519	28	F	Present-Mild	Present-Mild	Absent	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	Not Visualised	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Not Visualised	Moist	Normal
34	7137561	24	F	Present-Profuse	Present-Mild	Present-Mild	Present-5	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Mild	Discharge-Mild	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Moist
35	7130545	33	M	Present-Profuse	Present-Moderate	Present-Mild	Present-4	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Discharge-Mild	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Moist
36	6948265	40	F	Present-Moderate	Present-Mild	Present-Mild	Present-3	Present-3	Present-2	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Moist

37	7106676	42	F	Present-Moderate	Present-Mild	Present-Mild	Present-5	Present-4	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist & Edematous	Moist
38	6710056	24	F	Present-Mild	Present-Mild	Absent	Present-5	Present-4	Present-2	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	Not Visualised	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Moist	Moist	Normal
39	7136758	33	M	Present-Mild	Present-Mild	Absent	Present-5	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist & Edematous	Moist
40	7688345	24	M	Present-Moderate	Present-Mild	Present-Mild	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Discharge-Mild	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Moist & Edematous	Moist & Edematous	Moist
41	7346502	25	M	Present-Moderate	Present-Mild	Absent	Present-5	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Normal
42	7382478	25	F	Present-Moderate	Present-Mild	Absent	Present-6	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	Subtotal Perforation	Subtotal Perforation	Not Visualised	Moist & Edematous	Normal
43	6290334	62	F	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Normal
44	3738014	29	F	Present-Mild	Absent	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	Partially visualised	MCP in PS & PI Quadrants	MCP in PS & PI Quadrants	Not Visualised	Moist	Normal
45	7250441	27	F	Present-Moderate	Present-Mild	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Edematous	Moist	Normal
46	4355172	32	M	Present-Moderate	Present-Mild	Absent	Present-2	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in PS & PI Quadrant	MCP in PS & PI Quadrants	MCP in PS & PI Quadrants	Edematous	Normal	Normal
47	7252860	18	F	Present-Moderate	Present-Mild	Absent	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Edematous	Normal	Normal
48	5311080	60	F	Present-Moderate	Present-Mild	Absent	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Edematous	Normal	Normal
49	6254210	40	F	Present-Profuse	Present-Moderate	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Moderate	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Normal
50	5474201	18	F	Present-Mild	Present-Mild	Absent	Present-5	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	SCP in PS & PI Quadrant	SCP in PS & PI Quadrant	SCP in PS & PI Quadrant	Normal	Normal	Normal
51	764251	36	F	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Normal	Normal
52	758135	49	F	Present-Mild	Absent	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Not Visualised	Normal	Normal
53	654987	57	M	Present-Mild	Absent	Absent	Present-6	Present-4	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	SCP in PI Quadrant	SCP in PI Quadrant	SCP in PI Quadrant	Normal	Normal	Normal
54	7214350	56	F	Present-Mild	Absent	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	MCP in All Quadrants	MCP in All Quadrants	MCP in All Quadrants	Edematous	Normal	Normal
55	6698374	26	F	Present-Mild	Absent	Absent	Present-2	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Moist & Edematous	Moist	Normal
56	7352617	21	M	Present-Mild	Present-Mild	Absent	Present-6	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	MCP in AI & PI Quadrant	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Moist & Edematous	Normal	Normal

57	7364940	18	F	Present-Moderate	Present-Mild	Absent	Present-3	Present-1	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Normal
58	1209829	64	F	Present-Mild	Absent	Absent	Present-4	Present-2	Present-2	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	Pin point perrforation in AI Quadrant	Pin Point in AI Quadrant	Pin point in AI Quadrant	Not Visualised	Normal	Normal
59	7241160	32	F	Present-Mild	Present-Mild	Absent	Present-5	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Not Visualised	Moist & Edematous	Normal
60	7864731	30	M	Present-Moderate	Present-Mild	Absent	Present-1	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Normal
61	3971076	39	M	Present-Mild	Absent	Absent	Present-3	Present-1	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	Not Visualised	SCP in PI Quadrant	SCP in PI Quadrant	Not Visualised	Normal	Normal
62	6231035	44	F	Present-Moderate	Present-Mild	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Moist & Edematous	Moist	Normal
63	7437014	41	M	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Moist	Moist	Normal
64	7398003	34	M	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist	Normal
65	5413947	33	F	Present-Moderate	Present-Mild	Absent	Present-6	Present-4	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in PS,PI & AI Quadrant	LCP in PS,PI & AI Quadrant	Not Visualised	Moist	Normal
66	724453	26	F	Present-Profuse	Present-Mild	Absent	Present-2	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Mild	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Edematous	Normal	Normal
67	5813524	18	F	Present-Moderate	Present-Mild	Absent	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Edematous	Normal	Normal
68	10044265	57	F	Present-Profuse	Present-Mild	Absent	Present-5	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Profuse	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist	Normal
69	10044253	31	M	Present-Moderate	Present-Mild	Absent	Present-6	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in PS & PI Quadrant	MCP in PS & PI Quadrants	MCP in PS & PI Quadrants	Edematous	Normal	Normal
70	7365118	25	F	Present-Mild	Absent	Absent	Present-4	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Edematous	Moist	Normal
71	7352463	22	F	Present-Mild	Absent	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Normal	Normal	SCP in AS Quadrant	SCP in AS Quadrant	SCP in AS Quadrant	Not Visualised	Normal	Normal
72	7095035	42	F	Present-Moderate	Present-Mild	Absent	Present-6	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	SCP in AI Quadrant	SCP in AI Quadrant	Not Visualised	Moist & Edematous	Normal
73	7153395	28	M	Present-Moderate	Present-Mild	Absent	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist	Normal
74	7239305	45	F	Present-Moderate	Present-Mild	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	LCP in all Quadrants	LCP in all Quadrants	LCP in all Quadrants	Moist & Edematous	Moist & Edematous	Normal
75	7148471	25	F	Present-Moderate	Present-Mild	Absent	Present-5	Present-3	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in all Quadrants	MCP in All Quadrants	MCP in All Quadrants	Not Visualised	Moist	Normal
76	7257214	40	M	Present-Moderate	Present-Mild	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	MCP in AS & AI Quadrant	Moist & Edematous	Moist & Edematous	Normal

77	7246110	59	M	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Not Visualised	Moist & Edematous	Normal
78	7264907	29	F	Present-Moderate	Present-Mild	Absent	Present-4	Present-2	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	LCP in all Quadrants	LCP in all Quadrants	Not Visualised	Moist & Edematous	Normal
79	7327629	18	F	Present-Mild	Present-Mild	Absent	Present-3	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Mild	Discharge-Mild	Normal	Not Visualised	MCP in AI & PI Quadrant	MCP in AI & PI Quadrants	Moist & Edematous	Moist	Normal
80	6525879	53	M	Present-Moderate	Present-Mild	Absent	Absent	Absent	Absent	N*	N*	N*	N*	N*	N*	N*	N*	N*	Discharge-Moderate	Discharge-Mild	Normal	Not Visualised	SCP in AI Quadrant	SCP in AI Quadrant	Not Visualised	Normal	Normal

N*= NORMAL