A PILOT STUDY TO ASSESS THE EFFICACY OF ANTIBIOTIC PROPHYLAXIS IN CLEAN OTOLOGIC SURGERIES

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT

OF THE RULES AND REGULATIONS FOR THE **M.S (BRANCH -IV)**

OTORHINOLARYNGOLOGY EXAMINATION OF

THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY

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CONTENTS

CERTIFICATE

This is to certify that the work presented in this dissertation in partial fulfillment of the Degree of **M.S Branch IV (ENT**) Examination of the **Tamil Nadu Dr. MGR Medical University, Chennai**, entitled **"A pilot study to assess the efficacy of antibiotic prophylaxis in clean otologic surgeries"** is the bonafide work of **Dr. LATHA MARY T.S**, post graduate student of M.S (ENT). It was carried out and prepared under my overall guidance and supervision in the Department of Otorhinolaryngology & Speech and Hearing, Christian Medical College, Vellore.

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This is to certify that the work presented in this dissertation, in partial fulfillment of the Degree of **MS Branch IV (ENT)** examination of **The Tamil Nadu Dr. M.G.R. Medical university, Chennai** entitled **""A pilot study to assess the efficacy of antibiotic prophylaxis in clean otologic surgeries"** is the bonafide original work of **Dr. LATHA MARY T.S,** post graduate student in MS (ENT). Department of Otorhinolaryngology and Speech and Hearing, Christian Medical College & Hospital, Vellore.

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ABSTRACT:

1. Name of the title: A study to evaluate the efficacy of antibiotic prophylaxis in the outcome of surgeries for tubotympanic type of chronic suppurative otitis media.

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Key Words: Antibiotic prophylaxis, Clean otologic surgeries, wound infection

5. Aim of the study: A study to evaluate the efficacy of antibiotic prophylaxis in the outcome of surgeries for CSOM tubotympanic type, namely post operative wound infection and graft status.

6. Introduction :Post operative surgical site infection and hospital acquired infections are a lingering problem as widespread antibiotic therapy has resulted in the emergence of bacteria resistant to antibiotics. The use of prophylactic antibiotics for surgeries has evolved over the last 20 years. Improvements in the timing of initial administration, the appropriate choice of antibiotic agents and shorter durations of administration have made its use valuable in reducing post operative wound infections. All the studies on antibiotic prophylaxis in otologic surgeries have been done in Western setups and there is no published data from the Indian subcontinent , where a course of antibiotics are given even in clean surgeries. As the climatic conditions and the general standard of living

in a developing country like India differs from those in the West, this pilot study was undertaken to assess the outcome of antibiotic prophylaxis in an Indian set up. Cefuroxime was the drug used in this study because of its activity against both Gram positive and Gram negative bacteria and increased resistance to beta lactamases

7. Methods: 50 patients with CSOM -tubotympanic disease, were included in the study. Intraoperatively, one dose of iv Cefuroxime 750 mg was given half an hour before the incision and no oral or systemic antibiotics given post operatively. The patients underwent either tympanoplasty alone or combined with cortical mastoidectomy. If the surgery lasted for more than three hours, the patient would receive a second dose of Cefuroxime 750 mg after six hours. The duration of surgery was calculated from the time of the incision to the placement of the last suture. The wound was examined on the second and the seventh post operative days for infection. Antibiotic ear drops were prescribed and the patient was asked to report in a month to assess the condition of the ear.

8. Results : Out of the 50 patients, only one developed a wound infection and one patient developed acute otitis media following an upper respiratory infection.

   Out of the 24 patients who came for follow up, the grafts of 19 patients had taken up well and 5 patients had residual perforations.

9. Conclusions : The infection rate obtained in this study, following the use of antibiotic prophylaxis in clean otologic surgeries, which is 4% ,is well within the range accepted by the US Centers for Disease Control and Prevention for clean surgeries, which is upto 5%. This study has proved that antibiotic prophylaxis using Cefuroxime axetil as a perioperative dose, is adequate in limiting post operative wound infection in surgeries for non discharging tubotympanic type of chronic suppurative otitis media.

INTRODUCTION

Wound infection has always increased morbidity and mortality following surgical procedures and hindered advances in various surgeries. By the middle of the nineteenth century, following the works of Ignaz Semmelweis and Joseph Lister in the introduction of antisepsis in surgery, infection rates and mortality in surgical patients were markedly reduced.[1] The work of Holmes, Pasteur and Kocher in infectious diseases as well as the improvements in operating room environment and discipline established by Halsted continued to prove the "aseptic and antiseptic" theory to be the first effective measure in preventing infections in surgical patients.[2]

Introduction of antibiotic therapy in the middle of the twentieth century as a new adjunctive method to treat and prevent surgical infections was considered the hope for final elimination of infections. However, post operative wound infection and hospital acquired infections continued as widespread antibiotic therapy resulted in emergence of bacteria resistant to antibiotics. [2]

The prevalence of antibiotic resistance in any population is related to the proportion of the population that receives antibiotics and also the total antibiotic exposure. [3] Therefore, restricted use of antibiotics has to be employed, more so in clean surgical procedures.

The use of antibiotics only as prophylaxis in surgery has mainly evolved over the last 20 years. Improvements in the timing of initial administration, the appropriate choice of antibiotic agents and shorter durations of administration have defined more clearly the value of this technique in reducing post operative wound infections. [4]

There is a definite protocol for antibiotic prophylaxis in head and neck surgeries but there is no uniform consensus in the use of antibiotic prophylaxis in otologic surgeries.

Moreover, the studies that are available on antibiotic prophylaxis in otologic surgeries have been done in Western setups. Regarding this, there is no published data from the Indian subcontinent and it is a common practice to give a course of oral antibiotics starting on the pre operative day and to continue the drug for a period of seven to ten days in most of the otologic surgeries. As the climatic conditions and the general standard of living in a developing country like India differs from those in the West, this pilot study was undertaken to assess the outcome of antibiotic prophylaxis in an Indian set up.

Cefuroxime was the drug used for antibiotic prophylaxis in this study because of its activity against both Gram positive and Gram negative bacteria and its resistance to beta lactamases.

AIM

A study to evaluate the efficacy of antibiotic prophylaxis in the outcome of surgeries for tubotympanic type of chronic suppurative otitis media.

OBJECTIVES

1. To assess the efficacy of perioperative use of intravenous Cefuroxime as antibiotic prophylaxis to control post operative wound infection in clean otologic surgeries namely surgeries for tubotympanic type of chronic suppurative otitis media.

2. To study the effect of antibiotic prophylaxis on the post operative graft status.

REVIEW OF LITERATURE

SURGICAL SITE INFECTIONS (SSI) :

In 1964, the US National Research Council Group (NRC) devised a system of classification of operative wounds based on the degree of microbial contamination. [5] Wounds are classified as clean, clean contaminated, contaminated and dirty. By classifying them, one can assess the potential for development of post-operative infections.

In 1992, the Surgical Wound Infection Task Force of the US Center for Disease Control and Prevention (CDC) revised its definition of 'wound infection', based on the recommendations by Horan et al [6] , into 'surgical site infection' and infection of a traumatic wound. Surgical site infections were further divided into three groups - superficial ,deep incisional and organ-space surgical site infections.

According to Horan et al [6], superficial incisional surgical site infections must meet the following criteria :

a. They should occur within thirty days of the procedure

b. They should involve only the skin or subcutaneous tissue of the incision.

c. They should also include at least one of the following criteria:

i) purulent drainage, with or without laboratory confirmation, from the superficial incision

ii) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

iii) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling , redness or heat

iv) diagnosis of superficial incisional surgical site infection by the surgeon or attending physician

Minimal inflammation and discharge confined to the points of suture penetration should not be considered infected. Wound dehiscence or ischemic necrosis of the wound edges requiring local care also were not included as wound infections.

Most surgical site infections are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery .[7,8]

Clean surgeries usually imply an elective case without contamination from the lumen of the respiratory, alimentary, and gastrointestinal tracts. There is no associated inflammation or break in aseptic technique. They may be closed primarily and are associated with an infection rate of 1-5 % [2]. A good proportion of otologic surgeries are considered to be clean surgeries.[9]

The microbiology of SSI is related to the bacterial flora present in the exposed anatomic area of a particular procedure and has not changed during the last 30 years as shown by the National Nosocomial Infection Surveillance

System (NNIS)[2] established by the Centers for Disease Control and Prevention (CDC). This study has shown that Staphylococcus aureus remains the most common pathogen of SSI followed by coagulase negative Staphylococcus, Enterococcus and Eschericia coli.

The number of bacteria necessary to infect tissue is estimated to be 100,000 organisms per gram of tissue. [2] Host factors and local wound factors also play a role in determining the need for antibiotic therapy.

Microorganisms causing surgical site infections can be either exogenous or endogenous. [2] Exogenous organisms come from the operating team or from the environment around the surgical site such as the operation theatre, equipment, air and water. Endogenous microorganisms come either from the bacteria present in the patient at the surgical site or from the bacteria present at a different location (for example, a remote site infection or nasal colonization).

Bacteria can be introduced into a wound at the time of surgery if sterile technique is broken, or they can be introduced through airborne transmission of desquamated skin cells, aerosolized water droplets, or dust particles. A resultant wound infection may be more likely in patients who have Staphylococcus aureus colonization due to other cutaneous conditions or in patients or members of the surgical staff who are a nasal carrier of Staphylococcus aureus. Infecting organisms are often part of the resident florae of the skin or nearby mucous membranes. Staphylococcus aureus is most commonly isolated in cutaneous wound infections. Occasionally, other

gram-negative organisms and Candida albicans can be isolated. These infections may be associated with poor hand washing and improper wound care techniques.[10]

Postoperative infections can occur as a result of poor surgical technique, inadequate postoperative wound care and poor hygiene. For example, an improperly designed flap or a wound closed under too much tension may lead to ischemia, which can increase the risk of infection. Excessive suture material in a wound may increase this risk. Postoperative hematoma formation and devitalized tissue from excessive cautery during surgery provide environments conducive for wound infection.[10]

Surgical wounds can heal by primary intention, delayed primary intention or by secondary intention. Most heal by primary intention, where the wound edges are brought together and then held in place by mechanical means (adhesive strips, staples or sutures), allowing the wound time to heal and develop enough strength to withstand stress without support. The goal of surgery is to achieve healing by such means with minimal edema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation.[4]

FACTORS AFFECTING WOUND HEALING:

Once wounding has occurred, the surgeon has control over several factors concerning the wound itself that may reduce susceptibility to infection. The duration of surgery is one factor that influences the wound infection rate. Procedures that take longer than two hours [11] are associated with higher infection rates. This may be related to desiccation or maceration of the wound edges, an increase in the number of bacteria that accumulate within the wound and decreased temperature and hypovolemia leading to peripheral vasoconstriction and therefore, poorly perfused skin.

The ear, like all other parts of the aerodigestive tract in which otolaryngologists operate, is colonized with bacteria . But, colonization does not necessarily translate into or relate to wound infection. Furthermore, wound infection is not caused by colonizing bacteria. [12] In addition, the emergence of resistant strains can be a greater threat for surgical success. Even a single infection can have catastrophic consequences. Aseptic technique and attention to correct surgical technique contribute greatly in controlling the innoculation of microbes and prevention of bacterial proliferation resulting in infection.

Fewer bacteria are required to produce an infection in the presence of necrotic tissue, foreign bodies, hematomas, seromas and poor tissue perfusion. Although infection cannot occur without any bacterial burden or contamination, the presence of bacteria in a wound does not inevitably result in an infection. [11] Factors such as sex, age, occupation and exposure to

soaps, disinfectants, medications and ultraviolet light can modify the types and number of bacteria on the skin. The climatic conditions affect bacterial flora and variation in temperature and humidity may increase bacterial counts. [10] Although good surgical preparation can eliminate transient flora and reduce resident flora to a minimum, complete sterilization of the skin is impossible. Approximately 20% of resident flora[10] remains in the pilosebaceous units after antiseptic scrubbing.

The level of bacterial burden is a significant risk factor, but modern surgical techniques and the use of prophylactic antibiotics have reduced this risk.[13] Wound infection results when a critical number of bacteria are present in the wound at the time of skin closure. Several factors determine the size of this critical innoculum and these include the virulence of the bacteria, presence of devitalized or poorly vascularized tissue, the presence of a foreign body and the status of the host. Anti microbial agents directed against the invading microorganisms may reduce the number of viable bacteria below the critical level and thus prevent infection.

ANTIBIOTIC PROPHYLAXIS:

Upto 90% of clean surgical wounds [14] are contaminated by potentially pathogenic bacteria at the time of wound closure. Prophylaxis is an attempt to attack organisms before they have a chance to induce infection.

Antimicrobial prophylaxis has been proposed to augment host mechanisms and control the size of the innoculation so that host defense mechanisms can cope. It is also clear that mere wound colonization by potentially pathogenic bacteria does not always result in post operative wound infection. The decision of whether or not to give peri-operative antibiotics is usually based on individual cases.

The most extensive use of chemoprophylaxis is to prevent wound infections after various surgeries. Several well controlled clinical studies support the use of prophylactic antimicrobial agents in certain surgical procedures. The first such demonstration was by Bernard and Cole (1964) who showed [15] the effectiveness of prophylactic antibiotics in patients undergoing operations involving the stomach, bowel and pancreas.

Antimicrobial prophylaxis should be directed against the most likely infecting organism, not all organisms present . [9] In chronic otitis media, despite the presence of gram negative species, gram positive species, especially Staphylococcus, are the usual cause of wound infection. Therefore, an antibiotic with broad spectrum activity can be chosen as prophylaxis.

When an anti microbial agent is indicated, the goal is to choose a drug which is selectively active for the most likely infecting organism and which has the least potential to be toxic or cause allergic reactions.[9]

The effectiveness of antibiotic therapy is dependent upon the time at which the drug is administered, the route of administration and the agent used.[9] Using an animal model, Burke found that antibiotics were most

effective when given before the bacteria enters the blood or tissue and have no effect if given 3 hours after inoculation occurs. [16] This study was corroborated by Classen et al who found surgical wound infection rates in clean and clean contaminated cases to be 1.4% when antibiotics were given within three hours of surgical incision and 3.3% if antibiotics were given later.

Several factors are important for the effective and judicious use of antibiotics. [17]

First, antimicrobial activity must be present at the wound site at the time of its closure. This has led to the recommendation that the drug must be given preoperatively and perhaps, intraoperatively.

Second, the antibiotic must be active against the most likely contaminating microorganisms. This has prompted the wide use of first generation cephalosporins [17] in this form of chemo prophylaxis.

Third, there is mounting evidence that the continued use of drugs after the surgical procedure is unwarranted and potentially harmful. There are no data to suggest that the incidence of wound infections is lower if antimicrobial treatment is continued after the day of surgery (Rowlands et al. 1982). Use beyond 24 hours is not only unnnecessary, but leads to the development of more resistant flora and superinfections caused by antibiotic resistant strains [17]

Many antimicrobials require a single dose given within 30 minutes of skin incision [9] to provide adequate tissue concentration throughout the operation. Additional doses during the procedure are advisable if surgery is

prolonged (ie, greater than 4 hours), major blood loss occurs, or an antimicrobial with a short half-life is used.

The dose of an antibiotic required for prophylaxis is the same as would be used therapeutically.[9] Intravenous administration of antibiotic prophylaxis immediately before or after induction of anaesthesia is the most reliable method for ensuring effective serum antibiotic concentrations at the time of surgery.

This produces therapeutic levels of the antibiotic agents at the operative site in any seromas and hematomas that may develop. Antibiotics started as late as 1 to 2 hours [2] after bacterial contamination are markedly less effective and it is completely without value to start prophylactic antibiotics after the wound is closed. A single dose, depending on the drug used and length of operation is often sufficient.

The aim of prophylaxis [18] is to augment host defense mechanisms at the time of bacterial invasion, thereby decreasing the size of the inoculum. Previous surgery (i.e, scarring) and radiation injury decrease host defenses. Likewise, certain medical conditions, such as diabetes mellitus or HIV, predispose the patient to infection because of diminished host response.

Choosing an antibiotic for prophylaxis is multifactorial [19] and should be based on the following: the type of operation, kinetics and toxicity of the drug, microbiologic characteristics of the operative site and antibiotic sensitivities specific to the particular hospital environment .

In operations in which hollow viscous or mucosa is not violated, antimicrobial prophylaxis needs to cover only gram-positive skin flora [17], primarily Staphylococcus epidermidis and Staphylococcus aureus. In operations that feature postoperative infections with aerobic and anaerobic flora, an antibiotic regimen effective against this broad spectrum of pathogens should be used.

The regimen chosen should be compatible with findings from the hospital's infection control wound surveillance report. [17] This regimen is especially important in hospitals with high incidence of infection with methicillin-resistant organisms (eg, Methicillin resistant Staphylococcus aureus [MRSA] and Staphylococcus epidermidis [MRSE]) or with newly vancomycin-resistant organisms.

If a number of drugs appear equally acceptable for prophylaxis, the agent least likely to be used for definitive therapy in postoperative wound infection should be chosen. [9] This strategy should minimize the selection of organisms resistant to valuable therapeutic agents.

The aim of rationalizing the use of antibiotic prophylaxis is to reduce the inappropriate use of antibiotics thus minimizing the consequences of misuse.

The clinical signs of a wound infection include edema, erythema, warmth and purulence, which usually appear 4-8 days after a procedure. Infection should be considered when these signs are noted at the time of suture removal or if a patient calls and describes them. While some postoperative erythema and edema is not uncommon in a normally healing

wound, these signs should improve with time. Worsening erythema with edema and especially warmth with purulence suggest infection. Reactivity to the suture material or allergic or irritant contact dermatitis due to a wound dressing or topical antibiotic can mimic these signs.[10]

BACTERIOLOGY OF THE MIDDLE EAR CLEFT : [20]

In the healthy state, it is normal to find a permanent population of bacteria and/or fungi inhabiting various body surfaces. The types of organisms that make up this normal flora vary from one body site to another. This flora has two roles in the maintenance of health—a host defense mechanism and a nutritional function of vitamin production. In the immunocompromised patient, these organisms can become pathogenic if growth occurs outside of their normal habitat.

A wide range of organisms, both aerobic and anerobic, can be isolated from cases of chronic suppurative otitis media. The proportions of different organisms isolated vary from study to study, but Pseudomonas aeruginosa and Proteus most frequently dominate. Staphylococcus aureus and Eschericia coli are also frequently isolated. The predominance of Gram negative aerobes indicates that the source of infection is not the nasopharynx,[20] which does not contain these organisms. Anerobes and aerobes are usually found together and it has been suggested that this is because the aerobic organisms create an environment in which the anerobes can grow in mixed infections by lowering the local oxygen concentration. The

anerobic isolates, associated with a malodorous otorrhoea, include Peptostreptococcus and Bacteroides species.

Staphylococcus:

The genus staphylococcus comprises 30 species, many of which have only recently been defined or associated with human infection. [21]

Staphylococci are divided into coagulase positive and coagulase negative strains. Coagulase positive staphylococci are Staphylococcus aureus and are the most common pathogens associated with wound infections and incisions not subject to endogenous contamination. Staphylococci are Gram positive, spherical cocci which divide in three dimensions and resemble a bunch of grapes. Except for one anerobic sub species, they are aerobes and facultative anerobes. They grow in high concentrations (9%) of sodium chloride and this together with the production of catalase distinguishes them from other genera of cocci such as Streptococcus, Micrococcus and Enterococcus. On blood agar, staphylococci grow as fairly large pigmented colonies, which range in colour from white through creamy yellow to lemon yellow. For routine clinical purposes, a positive coagulase reaction is sufficient to identify an isolate as Staphylococcus aureus. Staphylococcus DNAase and phosphatase have the same significance as coagulase. Further identification of coagulase negative staphylococci is by an array of biochemical reactions and susceptibility or resistance to novobiocin or polymyxin B.

Staphylococcus aureus produces many biologically active substances like exfolatin, hemolysins, toxic shock syndrome toxin and enterotoxins. Majority produce beta - lactamases which inactivates many of the penicillins. At the Methodist Medical Center, Dallas, 97% of all strains of Staphylococcus aureus isolated were penicillin resistant. They are beta lactamase producers and are susceptible to methicillin and isoxazolyl penicillins.

Coagulase negative staphylococci:

For many years, coagulase negative staphylococci were considered contaminants and skin flora incapable of causing serious disease. But, now they are the commonest organisms recovered in nosocomial bacteremia and are frequently associated with clinically significant infections of intravascular devices. Staphylococcus epidermidis is a very common inhabitant of the skin. Staphylococcus auricularis is especially found as normal flora in the external ear. The antimicrobial susceptibility pattern of Staphylococcus epidermidis and other coagulase negative staphylococci is similar to that of methicillin resistant Staphylococcus aureus.

Streptococcus:

The streptococcal species include Beta-hemolytic streptococci (especially group A or Streptococcus pyogenes), Streptococcus pneumoniae and other alpha – hemolytic streptococci. These species were initially sensitive to Penicillin G and almost all other beta-lactam antibiotics. Penicillin

resistant Streptococcus pneumoniae are now found in most urban communities. Alpha-hemolytic streptococci or viridans streptococci rarely are significant pathogens in a surgical setting. They are commonly found on mucous membranes and skin. They are almost never found as the sole cause of significant surgical infections [2].

Aerobic and Facultative Gram- Negative Rods:

A great variety of gram-negative rods are associated with surgical infections. Most fall into the family Enterobacteriaceae. They are all facultative anerobic bacteria and include the familiar genera Escherichia, Proteus and Klebsiella. These three genera (also called easy gram-negative rods) [2] are considered together because they are relatively common in mixed surgical infections and because they are relatively sensitive to a broad variety of antibiotics, especially second generation cephalosporins.

Gram-Negative Bacilli:

The gram-negative rods are a large group of bacteria, many of which are part of the normal flora in the intestinal tract. Pseudomonas is a strictly aerobic gram negative rod. Pseudomonas aeruginosa is primarily an opportunistic pathogen that causes infections in seriously ill, immunocompromised people. It is associated with 10-20% of nosocomial infections. In spite of this fact, many head and neck infections caused by

Pseudomonas are community acquired. It is a common causative agent in chronic otitis media with otorrhea.

Antibiotic resistance:

Antibiotic resistance is an escalating problem whose implications include increased costs of care, hospital visits and morbidity.

Resistance has been broadly divided into two forms: [2]

1. intrinsic resistance, in which a specific species is inherently resistant to a specific antibiotic
2. acquired resistance, in which a change of the genetic composition of the bacteria occurs. This acquired resistance can be the result of intrinsic changes within the native genetic material of the pathogen or can be transferred from another species.

Factors contributing to the spread of resistance include: [17]

a) mutations in common bacterial resistance genes that have extended their spectrum of resistance

b) exchange of genetic information among bacteria

c) increase in selective pressures in hospitals, institutional settings and in the community. Selective pressures refer to environmental conditions which enhance the spread of bacterial clones that develop antibiotic resistance. By eradicating susceptible strains, antibiotic use favours resistant bacteria to emerge.

AETIO PATHOGENESIS OF OTITIS MEDIA:

There is a close correlation between patients with chronic otitis media and socioeconomic groups, the lower groups having a higher incidence. It probably relates to the general health, diet and overcrowding in the home. The disease starts in childhood and is therefore, common in that age group. It is the sequelae of otitis media following which there is a persistent perforation of the tympanic membrane. Ascending infections via the eustachian tube, infection from tonsils, adenoids and infected sinuses may be responsible for persistent or recurring otorrhoea. A persistent perforation permits repeated infections from the external ear. Tubotympanic disease remains localized to the mucosa , most often the antero inferior part of the middle ear cleft. The process of healing or destruction can take place depending on the virulence of organisms and the immunity of the patient. Thus, acute exacerbations are not uncommon.

Effects of tympanic membrane perforations on hearing[22]

There is diminished surface area of the tympanic membrane on which sound pressure is exerted, resulting in dampened ossicular chain movement. The larger the perforation, the greater the loss of surface area on which sound pressure can act, with the additional factor that sound pressure entering the middle ear through the perforation can act on the surface of the tympanic membrane against the sound pressure on the outer surface. In addition, the site of the perforation influences the degree of hearing loss; the posterior

perforations produce more severe hearing losses. A second effect of a simple perforation on hearing results from sound reaching the round window directly without the dampening and phase changing effect of an intact tympanic membrane.

Advantages of perforation closure:

The middle ear is isolated from the external environment and prevents contamination by exposure to pathogens introduced via the external auditory canal. Repeated exposure to pathogens can lead to recurrent, acute otitis media with consequent permanent alteration of the middle ear and its sound-transmitting mechanism. Closure of a tympanic membrane perforation restores the vibratory area of the membrane and affords round window protection, thus improving hearing and decreasing tinnitus.

Surgeries for chronic suppurative otitis media- tubotympanic type are based on the potential benefits to the patients in terms of the following:

a. Prevention of recurrent discharge
b. Hearing improvement
c. the ability to swim without the fear of aural discharge
d. to fit a hearing aid

Types of surgical procedures for CSOM tubotympanic type: [23]

1. Tympanoplasty : It is an operation performed to eradicate disease in the middle ear and to reconstruct the hearing mechanism, can be combined with mastoid surgery, with or without tympanic membrane grafting.
2. Myringoplasty : It is an operation performed to repair or reconstruct the tympanic membrane. Unlike tympanoplasty, it does not imply removal of disease from the middle ear.
3. Ossiculoplasty : It is an operation performed to repair or reconstruct the ossicular chain.
4. Cortical mastoidectomy: It is an operation performed to remove disease from the mastoid antrum and air cell system (when present) and the aditus ad antrum, with preservation of an intact posterior bony external auditory canal wall, without disturbing the existing middle ear contents.

SURGICAL PROCEDURE:[24]

Preparation of the surgical field is compulsive to limit wound colonization by normal skin contaminants. This preparation must account for the copious irrigation used in mastoid surgeries and limit the contamination of the field by capillary action from the surrounding non sterile areas.

In the theatre, sufficient hair is removed to permit isolation of the surgical field. For a post auricular incision, the area prepared extends to one inch around the auricle. No preparation is required for transcanal approaches. After proper cleansing, the ear being operated is draped.

Infiltration of the post auricular skin and ear canal is done. For this 1:2,00,000 2% Xylocaine : adrenaline is used. A time of 10 to 12 minutes is given after infiltration for maximum hemostatic effect.

The tympanomeatal incision allows access to the middle ear for exploration and ossicular reconstruction. This approach was originally described by Lempert and later popularized by Rosen for use in stapes surgeries.

With 12 o'clock being superior, the incision begins at 6 o'clock (a millimeter or so from the inferior annulus), gently curves to just medial to the speculum lip (8 mm to 1 cm) at 9 o'clock, back down to about 2 mm and ends above the lateral process of the malleus. A sickle knife elevates the annulus from the tympanic sulcus and the middle ear is entered. Suctioning of the flap or the tympanic membrane should be avoided as it risks devascularisation and perforation. The chorda tympani nerve is identified and gently reflected. The chorda tympani nerve that is obstructing or is traumatized should be transected as taste liability is thus reduced. The scutum (posterosuperior canal wall) can be curetted or microdrilled to expose the posterosuperior quadrant, as for stapes surgery. Curetting must reveal the entire oval window, entire stapedius tendon and facial nerve to be considered adequate.

Post auricular incision:

This incision popularized by Wilde, provides good exposure of the mastoid and its process as well as the hidden anterior sulcus of the external auditory canal. The skin incision follows the post auricular crease and begins at the top of the auricle at least 1 cm posterior to the fold, not in it. It extends behind the ear and ends over the mastoid tip. In children less than 2 years, the incision is more horizontal to avoid injury to the facial nerve.

An endaural incision can also be used. It allows better view of the ossicular chain. An anteriorly based flap is created by dissecting between the skin and superficial soft tissue overlying the mastoid. The superficial areolar tissue overlying the temporalis muscle is very loose and easily accessible by gently pulling the ear laterally. Sharp or blunt dissection accesses the temporalis fascia for harvesting graft material. Should this be unnecessary, the dissection is simply carried to the margin of the postero superior canal.

Soft tissue overlying the mastoid is incised in a “T” shape and elevated to expose the bone. The horizontal incision is carried to bone along the linea temporalis and then an inferior limb is created, which bisects the superior limb and extends inferiorly over the mastoid tip. The periosteum is elevated from the lateral surface of the mastoid superiorly, posteriorly and anteriorly. Anterior elevation should not elevate the external auditory canal wall skin so as not to risk stenosis. The spine of Henle is a good anterior limit. The mastoid process should be completely exposed as should the root of zygoma. The ear, periosteal flap with temporalis muscle, and tip soft tissue are held in

the desired position with self retaining retractors. Excessive force is to be avoided.

The key to successful mastoid surgery is good exposure and early identification of the relevant anatomy. Using a large cutting burr (6 to 7 mm) and continuous suction irrigation, the cortex should be removed from the entire lateral surface, from the temporal line above to the mastoid tip below and from the posterior osseous meatal wall in front to the probable extent of pneumatisation behind as seen on the radiograph. The initial burr stroke is usually along the temporal line, continuing superiorly until the middle fossa dura is identified.

An orderly systematic removal of cell tracts saves time and ensures complete exenteration of all accessible cells. After the cortex is opened, the air cells below the cortex are exenterated, using the middle fossa dura medially and the posterior bony canal wall as anatomic landmarks. The surgical depth is not increased until the more superficial layer is opened as widely as possible for the given extent of pneumatisation. As the depth is increased, additional landmarks are identified. Posteriorly, the sigmoid sinus is identified. It can be followed inferiorly into the mastoid tip. The tip cells are removed. The digastric ridge is then defined. The stylomastoid foramen with the facial nerve lies at the anterior end of this ridge, and by staying close to the sigmoid inferiorly, the burr is kept posterior to the location of the vertical portion of the facial nerve.

The air cells in the sinodural angle are opened until the tegmen plate meets the sigmoid sinus plate at a sharp angle. The antrum is visualized at this time. The most common error in locating the antrum is to seek it too far below the temporal line. Opening the mastoid as far anteriorly above the bony canal into the zygomatic root will help avoid this error. Small pneumatic cells medial to the antrum down to the hard bony posterior and superior semicircular canals are removed. The posterior end of the lateral semicircular canal is carefully defined to avoid injury to or dislocation of the incus. The landmarks for the vertical portion of facial nerve are defined. The anterior bony wall between the posterior end of the lateral semicircular canal and anterior digastric ridge is gently drilled with a diamond burr, stroking the burr horizontally in the direction of the facial nerve.

In the completed simple mastoid cavity, the osseous superior and posterior meatal wall is intact, the tegmen and sinus plates are defined but intact and the cell tracts have been followed to their termination from the antrum inferiorly to the tip, posteriorly to the junction of sinus plate and cortex, superiorly to the junction of tegmen plate and cortex, anteriorly to the limit of pneumatisation in the posterior root of zygoma, and medially to the superior and posterior osseous semicircular canals.

The posterior tympanomeatal flap is elevated. The undersurface of the tympanic membrane remnant or tympanic annulus and manubrium of the malleus are denuded of squamous epithelium and mucosa. The temporalis fascia graft is then trimmed to size and placed medial to the tympanic

membrane remnant and extending posteriorly over the posterior canal wall. This is the underlay technique. Small pieces of gelfoam soaked in antibiotic drops can be placed in the middle ear and gel foam with antibiotic ointment placed over the graft. The canal flaps are repositioned. The post auricular incision is closed in two layers with Vicryl sutures. A mastoid dressing is applied.

The term “tympanoplasty” was first coined by Wullstein in 1953 to describe surgical techniques for reconstruction of the middle ear hearing mechanism that had been impaired or destroyed by chronic ear disease. Initially, skin grafts were used to repair the tympanic membrane but they fared badly as they were bulky, continued to secrete sebum and became infected and necrotic. In 1956, Zollner used autologous fascia lata for repair. Autologous periosteum , autologous cheek mucosa, free autologous vein graft and fat grafts have also been used, but have fallen out of favour. Most surgeons prefer to use temporalis fascia as they are easily harvested, have similar appearance to the tympanic membrane and have a low basal metabolic rate.

Tympanoplasty with or without mastoidectomy is indicated for chronic ear disease processes such as tympanic membrane perforations resulting from previous middle ear infections, atelectatic tympanic membranes, retraction pockets, cholesteatomas, tympanosclerosis and chronic otitis media with effusion or mastoid cholesterol granuloma.

A successful tympanoplasty requires a mobile tympanic membrane with or without graft, secure the sound conducting mechanism between the mobile tympanic membrane and the inner ear fluids with aeration of the mucosa lined tympanic cleft.

The five techniques of tympanoplasty according to Wullstein's classification are:

Type I : Reconstruction of the tympanic membrane only. The ossicular chain is intact and mobile.

Type II : Malleus handle absent, reconstruction of the tympanic membrane over the malleus remnant and the long process of incus.

Type III: Malleus and incus absent, reconstruction of the tympanic membrane over an intact and mobile stapes with the stapes acting as columella (myringostapediopexy).

Type IV: Mobile stapes foot plate exteriorized with reconstruction of the tympanic membrane as a round window baffle.

Type V: Stapes fixed and lateral semicircular canal fenestration is done.

Two types of grafting technique commonly used are overlay and underlay techniques. In the overlay or onlay technique, the graft is placed lateral to the perforated tympanic membrane. Thus, the middle ear space is not opened. Its disadvantages are that the graft can become lateralised and lose its contact with the ossicular chain. Intratympanic keratin pearls can form

due to inadequate removal of the squamous epithelium from the outer surface of the drum and blunting of the angle between the anterior portion of the drum and the canal wall with impairment of drum function.

In the underlay technique, the graft is placed medial to the remnant tympanic membrane and there is contact with the ossicles. In this way, the graft is more stable. The middle ear space is entered. The type of mastoid surgery dictates the tympanoplasty technique to be used.

Ossiculoplasty:

Austin's classification for ossicular discontinuity:

In 1971, Austin presented his classification of the anatomical defects found in the ossicular chain in 1151 consecutive ears with chronic suppurative otitis media at the Abraham Lincoln School of Medicine in Chicago. Isolated loss of the malleus handle (2% of ossicular defects) and isolated loss of the stapes suprastructure (1.7% of ossicular defects) were not classified because of their rarity. In all other cases, the incus was deficient either wholly or in part and four types of ossicular defects were therefore described depending on the presence or absence of the malleus handle and the presence or absence of the stapes suprastructure.

1) Modification of Austin's classification of ossicular chain defects. Incus is absent in all cases and tympanic membrane reconstruction is required in all cases. a) Malleus handle present, stapes suprastructure present requiring reconstruction of the tympanic membrane and

reconstruction of the ossicular chain from the malleus handle to the stapes head. b) malleus handle absent, stapes suprastructure present requiring reconstruction of the tympanic membrane, malleus and incus. c) malleus handle present, stapes suprastructure absent, requiring reconstruction of the tympanic membrane and reconstruction of the ossicular chain from the malleus handle to the stapes footplate d) malleus handle absent, stapes suprastructure absent requiring reconstruction of the tympanic membrane, malleus, incus and stapes suprastructure

2) Rare ossicular chain defects: e) isolated loss of the malleus handle, requiring reconstruction of the tympanic membrane and malleus, removal of the incus and its reconstruction. f) isolated loss of the stapes suprastructure requiring tympanic membrane reconstruction and stapes suprastructure reconstruction.

3) The fixed stapes: g) malleus handle present, incus and stapes fixed, requiring tympanic membrane reconstruction and when possible, removal of the stapes, sealing the oval window with a vein or tragal perichondrial autograft and reconstruction of the ossicular chain from the oval window to the malleus handle (malleolabyrinthopexy) h) malleus handle absent, incus absent, stapes fixed, requiring tympanic membrane reconstruction and malleus reconstruction and when possible, stapes removal and oval window sealing with a vein or tragal perichondrial autograft and ossicular chain reconstruction from

the oval window to the neomalleus handle.

In g) and h), an intact tympanic membrane and a healthy, ventilated middle ear space must be achieved before the fixed stapes is removed i.e the procedure must be staged.

In a) to f), the reconstruction may or may not be staged.

The self correcting process of ossiculoplasty is an evolutionary process and the small surgical steps are slowly incorporated with surgical principles. Incorporating synthetic processes within a natural or synthetic ossicle is a logical and evolutionary step in the science of ossicular reconstruction. The tympanic membrane is the major transducer of the middle ear that converts sounds to ossicular vibration. Unfortunately, the angle of attachment of the prosthesis from the umbo to the stapes is often acute for stability for efficient transfer of vibration. If artificial bone becomes the ideal synthetic material, then the natural ossicle is indeed the first choice in ossiculoplasty.

The grafts used in ossiculoplasty are ossicular bone (refashioned incus), cortical bone, cartilage and cartilage with perichondrium. The biomaterials used in ossiculoplasty are polytetrafluoroethylene (Teflon), dimethylsilicone polymer (Silastic), bioinert aluminium oxide ceramics (PORP and TORP), high density polyethylene sponge (Plastipore) and dense calcium phosphate ceramic (hydroxyapetite). The other types are incus replica prosthesis (IRP), composite allografts, etc.

Complications of surgery:

Intraoperative:

The most undesirable complication of ear surgery is injury to the facial nerve, which can occur especially when the nerve has an anomalous course or if performed by an inexperienced surgeon. The incidence of facial nerve injury during mastoid surgery varies between 0.6 to 3.7%.[25] Facial paralysis occurring during surgery or noticed immediately afterward means a probable injury or severance of the facial nerve. An exception is transitory facial paralysis caused by a local infiltrating anesthetic agent, in which case complete recovery occurs within a few hours. Prompt exploration with decompression and repair of the injured nerve is indicated within 24 hours of the surgery, before granulations and degeneration of the severed ends of the nerve make it difficult to identify. If the paralysis begins several days after the surgery, an edema of the nerve is likely, with the probability of spontaneous recovery without surgical intervention.

Injury to the sigmoid sinus, superior petrosal sinus, jugular bulb or mastoid emissary vein results in an alarming profuse venous bleeding, which is controlled by compressed absorbable gelatin sponge (Gelfoam) moistened with saline held against the bleeding point by cottonoid for at least two minutes.

Injury to the dura with cerebrospinal fluid leak is less common than the above mentioned structures but is more dangerous. Sufficient bone around the dural tear needs to be removed to expose a margin of intact dura all

around. Temporalis fascia graft is placed over the tear. Muscle should be tucked under the margin of bone to hold it in place. Gelfoam is then used to reinforce the muscle.

Post operative:

Wound hematoma, wound dehiscence and wound and/or canal infection are some of the postoperative complications.

PHARMACOLOGY OF CEPHALOSPORINS: [26]

Cephalosporins are the commonest drugs used for prophylaxis. A single dose of Cefazolin just before surgery is the preferred drug for prophylaxis for procedures in which skin flora are the likely pathogens. The cephalosporins are derived from Cephalosporium acremonium. They inhibit the third step of bacterial wall synthesis by binding to proteins on the cell membrane. Once bound, they alter the membranes permeability and inhibit protein synthesis and release autolysins. Resistance to cephalosporins is achieved by a decrease in the bacterial cell wall permeability to the antibiotics. The cephalosporins have been divided into first, second and third generation agents.

The first generation agents include Cephalothin, Cephapirin, Cephradine, and Cefazolin. They have excellent activity against Streptococcus species and methicillin susceptible Staphylococcus. They have limited gram negative activity but are active against the easy Enterobacteriaceae like

Eschericia coli, Klebsiella and Proteus mirabilis. Associated adverse effects include allergic reactions, drug eruptions, phlebitis, and diarrhoea. Large amounts of beta lactamase will inactivate Cefazolin. The rest of the first generation cephalosporins are more resistant to beta lactamase. Cefazolin, with its longer half-life, can be given every 8 hours rather than every 4 to 6 hours and maintains more reliable serum and tissue levels when used for prophylaxis than do the other members of this class.

The major second generation cephalosporins are Cefoxitin, Cefotetan and Cefuroxime. They have increased activity against the gram negative organisms. Cefoxitin and Cefotetan are more active against the anaerobes. In one study by Maier et al, Cefuroxime was found to have an advantage of better tissue penetration in the parotid gland, sinuses, and soft tissue of the neck when compared to other second generation cephalosporins. Cefuroxime also crosses the blood brain barrier to attain a high concentration in the cerebrospinal fluid.

Cefuroxime acts mainly on Gram positive cocci. It is more resistant to beta lactamases than other second generation cephalosporins. It has a half life of 1.7 hours and the drug can be given every eight hours. Concentrations in Cerebro spinal fluid are about 10% of those in plasma. Cefuroxime axetil is the 1 - acetyloxyethyl ester of Cefuroxime.

The limited data available shows that drugs such as Cefuroxime, which has a half life of 1-2 hours in normal volunteers, has a half life of 2-4 hours in patients at the time of surgery, and that effective concentrations are maintained for at least five hours after the start of surgery.[9]

The third generation cephalosporins include Cefotaxime, Ceftizoxime, Ceftriaxone, Ceftazidime and Cefoperazone. They are less active against gram positive organisms. Cefotaxime, Ceftizoxime and Ceftriaxone are called the triplets and are very resistant to beta lactamase. They also have good activity against the gram positive organisms with the exception of enterococcus species. They have good activity against gram negative organisms except Pseudomonas species. Ceftazadime has similar but less activity against the Enterobacter species when compared to the triplets. It has superior activity against Pseudomonas species. However, for serious Pseudomonas infections it should be combined with an aminoglycoside.

Adverse reactions to cephalosporins:

Hypersensitivity reactions are the most common side effects. Immediate reactions such as anaphylaxis, bronchospasm and urticaria are observed. Maculopapular rash can also occur. Hematological disturbances like bone marrow depression, gastrointestinal complaints and reversible renal impairment are also known to occur.

Despite the use of antibiotics and better surgical techniques, chronic otitis media continues to be an important health problem across the world. Widespread use of antibiotics has resulted in decreasing mortality and morbidity, but has also helped in the development of resistant bacterial strains for chronic otitis media as well.

RELATED STUDIES :

A few studies based on Western populations have evaluated the role of prophylactic antibiotics in ear surgery.

Jackson et al [27] in a randomized controlled trial evaluated 3481 patients, who underwent surgeries for chronic suppurative otitis media - both safe and unsafe disease, over a 7 year period and found no statistically significant difference ($p > 0.05$) in the rate of infection between those who received antibiotics and those who did not, in pediatric and adult patients.

Govaerts et al [28] evaluated 750 patients who underwent surgeries for safe and unsafe disease in their study, one half of whom received preoperatively Inj.Cefuroxime for one day and the other half a placebo. Postoperatively, the infection rate in the antibiotic group was 3.1% and in the placebo group 4.7%. It was concluded that Cefuroxime prophylaxis protected the patient against postoperative infections by factor 1.5, which was not considered statistically significant.

In a study by Hester et al [29], of 146 patients with safe and unsafe ear disease who were included in the study, 71 patients received perioperative antibiotics upto 5 days and 75 patients a placebo. One patient developed post operative infection in the antibiotic group and 4 patients in the placebo group. This was also not considered statistically significant ($p > 0.7$).

Donaldson and Snyder[30] reviewed prophylactic antibiotics in myringoplasty in a double blinded format. Sulfa methoxazole was used. They concluded that their data did not demonstrate any influence of the success of myringoplasty by antibiotic prophylaxis.

Liu et al [31] studied 103 otologic patients in a double blinded protocol using intramuscular penicillin in 27 patients also treated with gentamicin. Success (graft take and hearing improvement) was 67% and 92% in the non antibiotic and antibiotic groups,respectively. Prophylaxis for surgery for chronic otitis media was approved.

Bagger-Sjobeck et al [32] reviewed 100 consecutive middle ear surgical cases in a well designed study employing phenoxymethyl penicillin. No statistically significant difference between the placebo and antibiotic groups for the defined criteria was noted.

Lildholdt et al [33] studied perioperative Ceftazidime in patients undergoing surgery for chronic otitis media. Statistically significant differences were found in favour of the antibiotic group.

Eschelman et al,[34] in a double blinded,controlled and randomized study of 330 patients, evaluated ampicillin and penicillin administered prophylactically against a placebo effect. Otologic cases numbered 107. They concluded that their data did not support the use of antimicrobials in otologic surgery.

Verschuur HP et al [35], in a meta-analysis, selected 11 studies , which were randomized or quasi randomized trials that studied the effects of antibiotic prophylaxis in clean and clean contaminated ear surgeries and concluded that there is no strong evidence for the large scale usage of prophylactic antibiotics in reducing postoperative complications such as wound infection, discharge from the outer canal, labyrinthitis and graft failure.

PATIENTS AND METHODS

The study was done in the ENT Department of Christian Medical College, Vellore. 50 patients with chronic suppurative otitis media-tubotympanic type, posted for surgery, were included in the study which was done during the period between October 2005 and July 2006. Each patient was examined on the pre operative day, a relevant history was taken and examination done. Once the inclusion criteria were fulfilled, the patient was included in the study. A proforma was filled and an informed consent obtained.

Inclusion criteria:

i) Patients with tubotympanic type of chronic suppurative otitis media

ii) Age between 15 and 60 years

iii) No ear discharge at the time of presentation

iv) Should not have received systemic antibiotics in the past one week

Exclusion criteria:

i) Diabetics, patients with systemic illness or on immunosuppressants

ii) Presence of an active ENT focus of infection

iii) Allergy to Penicillin or Cephalosporins

Methodology

50 patients with chronic suppurative otitis media -tubotympanic disease, were included in the study.

Intraoperatively, the surgical site was prepared with Povidone Iodine, with attention to strict asepsis. One dose of intravenous Cefuroxime 750 mg was given approximately half an hour before the incision and no oral or systemic antibiotics given post operatively. Wilde's postaural incision was used in almost all cases. According to the findings of the middle ear, the surgical procedure was done. These included Myringoplasty and Tympanoplasty alone or combined with Cortical mastoidectomy. If the surgery lasted for more than three hours, the patient would receive a second dose of Cefuroxime 750 mg after six hours. The duration of surgery was calculated from the time of the incision to the placement of the last suture.

At the end of surgery, gel foam soaked in Ciprofloxacin drops was kept in the middle ear and gel foam with Candiderma ointment (a combination of clotrimazole 1%, beclomethasone 0.025% and neomycin sulphate with a cream base 0.5%) placed over the graft and the outer ear canal was packed with BIPP pack. The wound was sutured in layers with 3-0 vicryl and a mastoid dressing applied.

The wound was examined on the second post operative day after removal of the mastoid dressing and any signs of inflammation or wound hematoma were noted. The wound was cleaned with Povidone Iodine and

Healex spray (a combination of polyvinyl polymer, benzocaine and cetrimide) applied. On the seventh post operative day, the wound was examined again and sutures and the canal pack were removed. Antibiotic ear drops were prescribed and the patient was instructed to change the outer cotton frequently. If there was significant discharge at any point of time post operatively, the patient was advised to report immediately, a culture and sensitivity of the discharge taken and appropriate antibiotic started depending on the culture report.

Features of infection which were looked for:

i) fever and/or earache

ii) redness, swelling and discharge from the postauricular wound

iii) canal discharge – pulsatile, mucopurulent or purulent

iv) redness of the outer canal and pinna

The patients, after leaving for home, were asked to correspond or report immediately, if they developed wound infection or ear discharge. They were advised to come at the end of one month to assess the condition of the ear.

RESULTS

The following were the observations made from the study . Statistical analysis was done by using SPSS version 13. Categorical variables were analysed using Chi square test.

TABLE 1 : Age and sex cross tabulation:

Age (in years)	Male	Female
15 – 20	7	6
21 – 30	11	5
31 – 40	6	8
41 – 50	2	5
Total	26	24

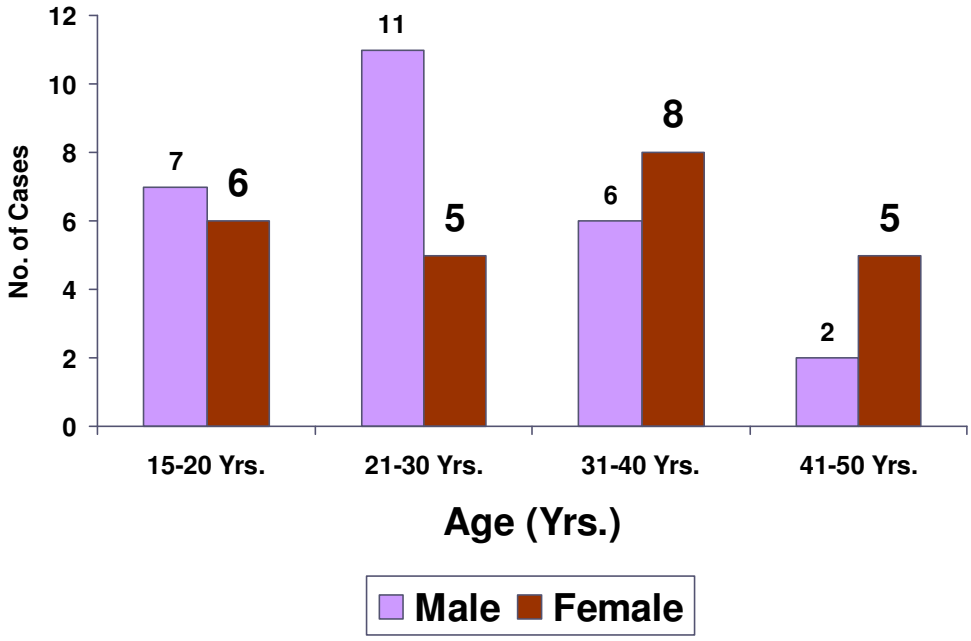
52% were males. 58% were below the age of 30 years.

TABLE 2: Place of origin:

Place	No. of Cases (n = 50)	Percentage (%)
Tamil Nadu	17	34
West Bengal	24	48
Others	9	18

66% of the patients were from states other than Tamil Nadu.

Distribution of Age and Sex



Place of origin

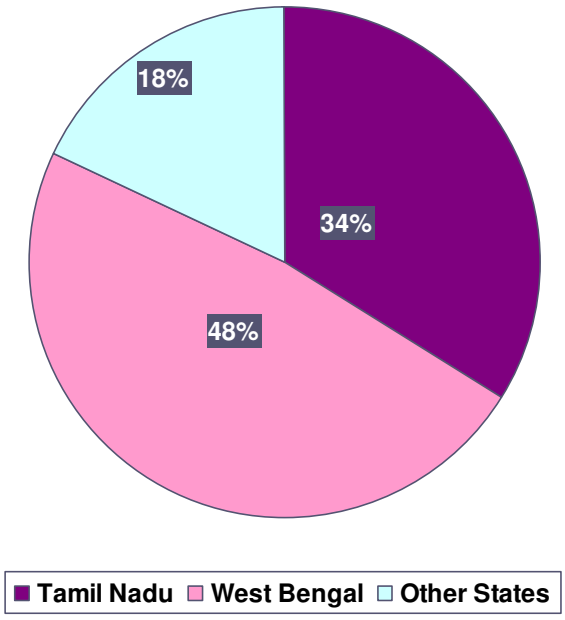


TABLE 3: Side of CSOM:

Side	No. of Cases n = 50	Percentage (%)
Right	10	20
Left	18	36
Bilateral	22	44

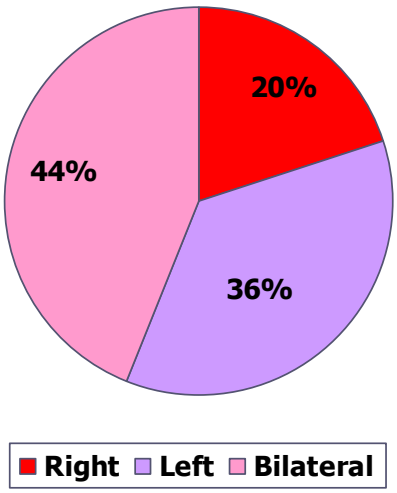
56% had unilateral disease.

TABLE 4 : Duration of CSOM:

Duration	No. of cases (n = 50)	Percentage (%)
< 1 year	11	22
1 to 5 years	5	10
6 to 10 years	1	2
> 10 years	33	66

66% of the patients had ear discharge for more than 10 years.

Side of CSOM



Duration of CSOM

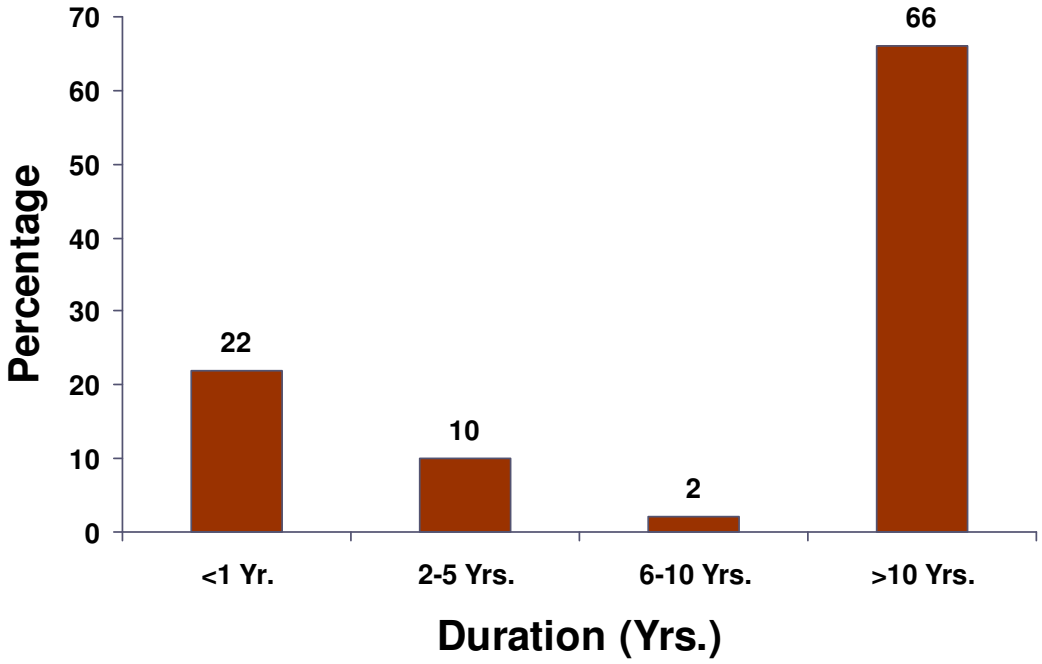


TABLE 5: Last episode of ear discharge:

Duration	No. of Cases (n = 50)	Percentage (%)
1 month	14	28
2 to 3 months	15	30
4 to 6 months	10	20
7 months to 1 year	6	12
More than 2 years	5	10

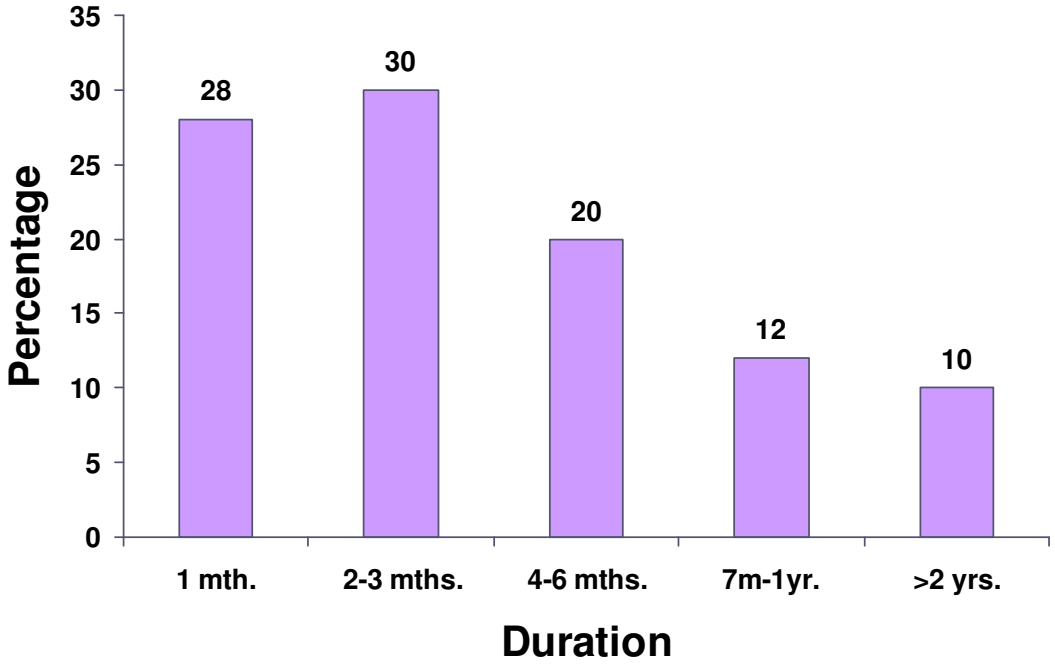
72% of the ears were dry for more than one month.

TABLE 6: Pre operative audiogram:

Hearing loss (in dB)	No. of Cases (n = 50)	Percentage (%)
Mild Conductive	11	22
Mod conductive	22	44
Severe conductive	12	24
Moderate mixed	4	8
Severe to profound	1	2

90% of the patients had varying degrees of conductive loss.

Last Episode of ear discharge



Audiogram(Pre operatively)

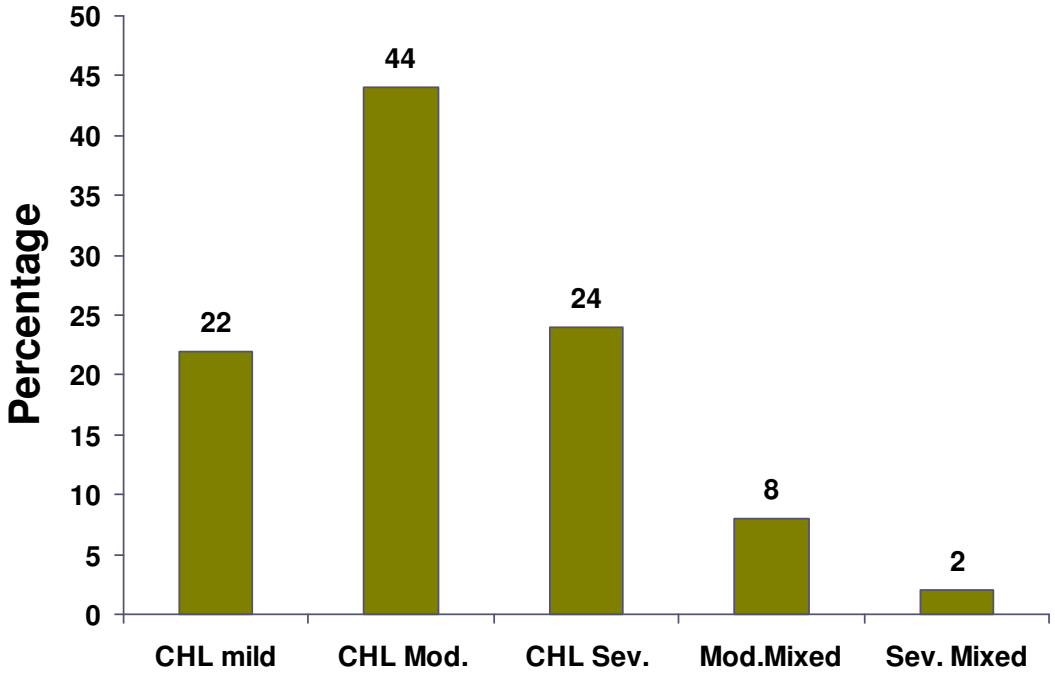


TABLE 7: Surgery done:

Type of surgery	No. of Cases (n = 50)	Percentage (%)
CMT + Type I	17	34
CMT + Type II	3	6
Tympanoplasty I	20	40
Tympanoplasty II	6	12
Myringoplasty	4	8

40% underwent Type I Tympanoplasty alone.

TABLE 8: Duration of surgery :

Duration in hours	No. of Cases (n=50)	Percentage (%)
Within 1 hour	11	22
1 – 2 hours	34	68
More than 2 hours	5	10

68% of the surgeries were within 2 hours.

Surgery Done

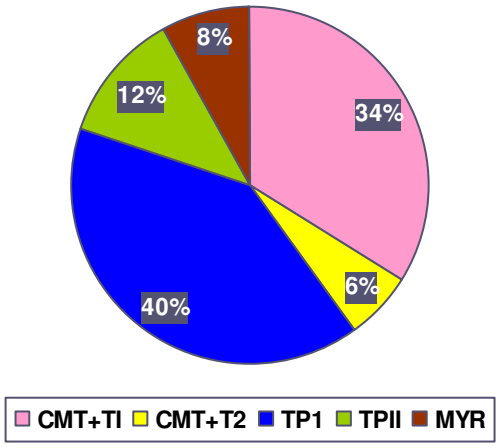


TABLE 9: Ossicular status:

	No. of Cases (n = 50)	**Percentage (%)**
Intact ossicles	41	82
Malleus eroded	4	8
Incus eroded	3	6
Malleus and incus eroded	1	2
Incus and stapes SS absent	1	2

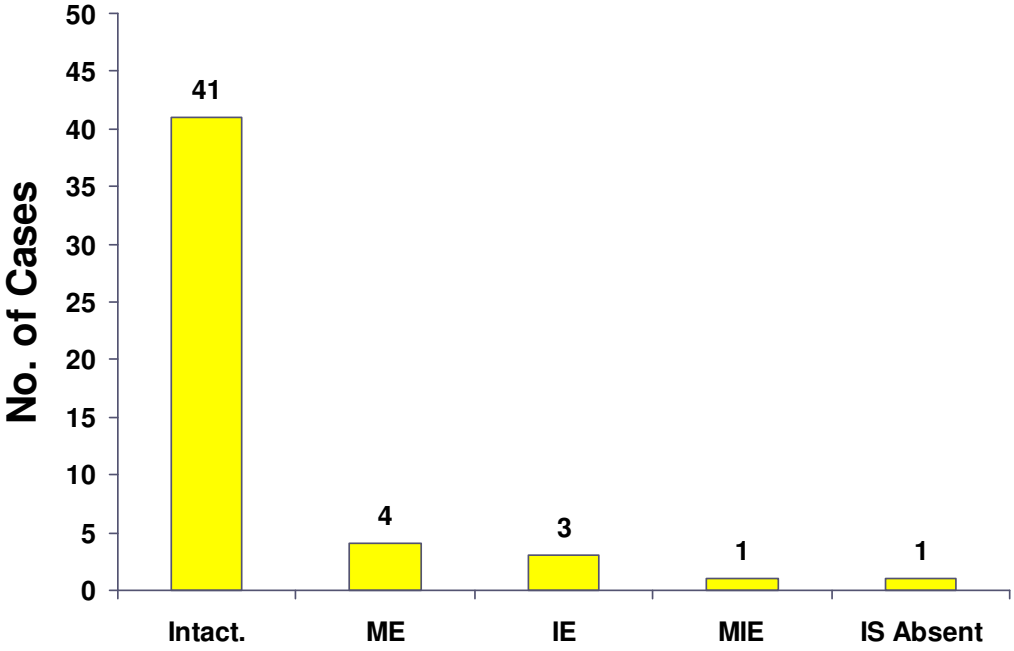
82% of ears had intact ossicles.

TABLE 10: Materials used for reconstruction:

	No. Of Cases (n = 50)	Percentage (%)
Temporalis fascia	44	88
Temp fascia + GI Cement	2	4
Temp fascia + Cartilage	2	4
Temp fascia + PORP	1	2
Tragal perichondrium	1	2

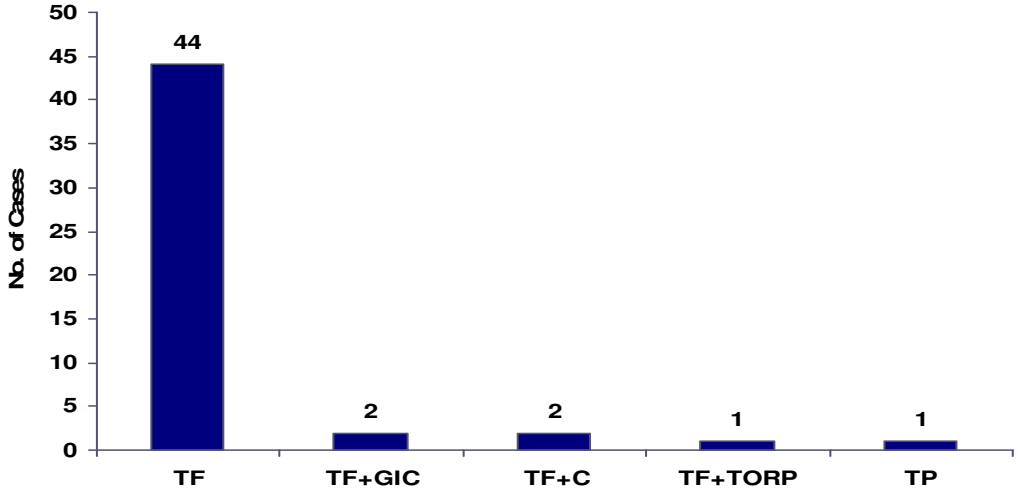
88% of the reconstruction was only with temporalis fascia grafting.

OSSICLE Status



ME=Malleus eroded; IE=Incus eroded; MIE=Malleus & incus eroded; IS Absent=incus & Stapes

Reconstruction material



TF=Temporalis Fascia; GIC=Glass Ionomer Cement; C=Cartilage; PORP-Partial Ossicular Replacement prosthesis; TP=Tragal Perichondrium

TABLE 11: Wound assessment on the first post operative day:

	No. of Cases (n = 50)	**Percentage (%)**
Healthy wounds	48	96
Allergy to Cefuroxime	0	0
Fever	0	0
Canal discharge	0	0
BIPPs allergy	2	4

96% of the wounds were healthy. None of the patients developed fever or allergy to Cefuroxime. 2 patients developed allergy to BIPP pack, which was manifested by redness around the ear and periorbital edema which settled after pack removal.

TABLE 12: Wound assessment at one week:

	No. of Cases (n = 50)	**Percentage (%)**
Healthy wound	45	90
Wound gaping	3	6
Wound infection	1	2
Canal infection	1	2

90 % of the wounds, middle ear and canals were healthy. 1 patient developed wound swelling and purulent discharge was let out on suture removal. Culture was done and Staphylococcus aureus was grown, sensitive to first line antibiotics. Out of the three patients who developed discharge in the canal, 2 were cultured which revealed no growth and 1 patient developed pulsatile discharge from the middle ear after he developed an upper respiratory infection and was started on systemic antibiotics. 3 patients developed gaping wounds, but there was no sign of infection.

Wound assessment (1 week)

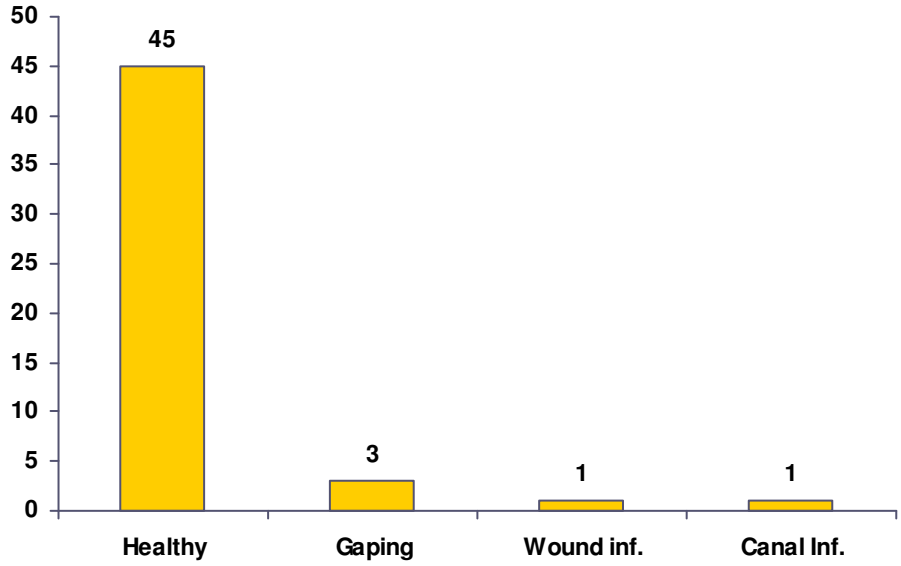


TABLE 13: Duration of surgery and

wound assessment at one week

Duration of surgery	Healthy wound	Wound infection	Canal discharge
Less than 1hour	11	0	0
1- 2 hours	30	1	3
> 2 hours	5	0	0

There was no significant association between the duration of surgery and the wound status after one week (Chi square = 1.05 p value = 0.30)

TABLE 14: Surgical site assessment after one month

Of the 50 patients, only 24 came back before the study was terminated.

Surgical site assessment	**No. of Cases (n = 24)**
Healthy	24
Unhealthy	0

100% of the postaural scars assessed after one month were healthy

TABLE 15: Graft status after one month

Graft status	**No. of Cases (n = 24)**
Graft taken up well	19
Graft failure	5

79.2% of the grafts inspected were intact .

Graft status (1 month)

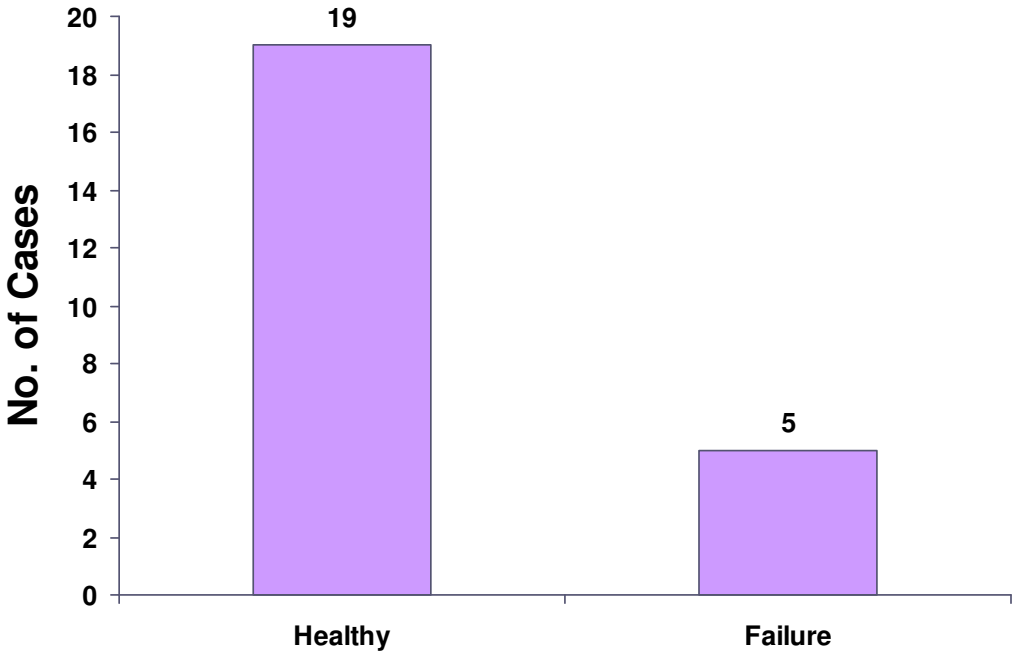


TABLE 16: Last episode of ear discharge compared with wound assessment at one week :

Last episode	Wound healthy	Wound infected	Canal discharge
Within 3 months	25	1	3
4- 6 months	10	0	0
> 6 months	11	0	0

The wound infection in 1 patient and the canal discharge in 3 patients occurred in those whose last episode was within the last 3 months.

TABLE 17: Last episode of ear discharge and graft status:

Last ear discharge	**Graft taken up**	**Graft failure**
1 month	7	2
2 to 3 months	5	2
4 to 6 months	4	1
7 months to 1 year	1	0
More than 2 years	2	0

The relationship of the last episode of ear discharge with the graft status was compared by Chi square test. It revealed no significant association.

(Chi square 1.09 p value = 0.30)

DISCUSSION

This pilot study was done in a tertiary training care center in India to look at the efficacy of antibiotic prophylaxis in preventing surgical site infections in tubotympanic type of chronic suppurative otitis media. All of the published studies on antibiotic prophylaxis have been done in Western setups.

In Govaerts' et al's study [28], the maximum number of patients were in the fourth decade. In the present study, the patients were mostly in the second and then in the third decade.

Jackson et al [27] had a female preponderance in his study (male: female ratio being 4.7: 5.3). Our study showed a male preponderance (M:F = 2.6: 2.4).

In Jackson's study [27], draining, non draining and cholesteatomatous ears were studied but in the present study, only non discharging ears were included.

In the study by Govaerts' et al [28] , 40% of patients underwent Type I tympanoplasty with or without mastoidectomy, whereas in the present study, 74% of the patients underwent similar surgeries.

The average duration of surgery in Govaerts' study [28] was 2.1 hours compared to 2 hours in our study.

In all the patients operated upon by Hester et al [29], the middle ear had gel foam soaked in Colistin drops and the ear canal was packed with an antibiotic ointment, bacitracin. We used Ciprofloxacin soaked gelfoam in the

middle ear and gel foam with Candiderma ointment on the graft and BIPPs pack (Bismuth Iodoform paraffin paste) in the external canal.

In Jackson et al's study [27] on 3481 patients, with the use of antibiotic prophylaxis, the rate of wound infection was 1.2% and canal infection 3.4% (totally 4.6%) and in Hester's [29] study, the rate of wound infection was 2%. In Govaerts' [28] study, the rate of postoperative infection was 3.9% in patients who underwent tympanoplasty alone whereas in the present study, the wound infection rate was 4% which were in one patient (2%) who underwent Cortical mastoidectomy with Type I Tympanoplasty and in another one (2%) who had only Type I Tympanoplasty.

In most of the published data available on graft status, the surgeries were performed by a single or two experienced surgeons, whereas in this study the surgeries were done by different surgeons, including trainees. Jackson et al[27] recorded a graft failure rate of 1.2%. In our study, 20% of the grafts failed and this may be due to the less number of patients who were followed up before the completion of the study and due to the reason that surgeries were done by surgeons with varied experiences. 24 out of 50 patients were followed up before the completion of the study and we received no correspondence from any of the other patients stating any postoperative complications.

The organisms causing infection in Jackson's study [27] were mainly Staphylococcus aureus followed by Pseudomonas, Gram negative isolates and anerobes which were rare. In Govaerts' study [28] , Staphylococcus aureus

(1%), followed by Staphylococcus epidermidis (0.1%), Pseudomonas aeruginosa (0.6%) and Proteus mirabilis (0.4%) were the organisms causing the infection and in the present study, the microbe causing wound infection was Staphylococcus aureus.

According to the US Centers for Disease Control and Prevention [2], a wound infection rate of upto 5% for clean surgeries is considered acceptable. In the present study, we found the postaural wound infection rate to be 2% and canal infection rate to be 2%,(a total of 4%) which falls within this range.

This suggests that prolonged antibiotic therapy is not essential in clean otologic surgeries and it is not a substitute for meticulous aseptic technique. The study therefore proves that prophylaxis is adequate to prevent wound infection in otologic surgeries that are considered to be clean surgeries, like surgeries done on non discharging ears.

SUMMARY

1. The infection rate obtained in this study, following the use of antibiotic prophylaxis in clean otologic surgeries, which is 4% ,is well within the range accepted by the US Centers for Disease Control[2] and Prevention for clean surgeries, which is upto 5%.
2. From this study, it may be concluded that the use of antibiotic prophylaxis is adequate to prevent wound infection in clean otologic surgeries like tubotympanic type of chronic suppurative otitis media . (non discharging ears)
3. The evidence and the literature review clearly lays down the directions for the legitimate use of antibiotics. This practice also prevents the emergence of resistant strains of bacteria.

LIMITATIONS

1. As the prevalence of chronic suppurative otitis media varies between 1.3% and 10.6% [36,37] in children in developing countries and the wound infections in clean otologic surgeries is infrequent, this study needs to be done in a larger number of patients to confirm the above findings.

2. The number of patients lost to follow up is high. This is due to the fact that majority of the patients enrolled in the study came mainly from the northern states and due to financial constraints were yet to come for follow up visits.

CONCLUSION

This study has proved that antibiotic prophylaxis using Cefuroxime axetil perioperatively is adequate in limiting post operative wound infection in surgeries for non discharging tubotympanic type of chronic suppurative otitis media.

FUTURE OF THE STUDY

Further studies may be done to compare the usage of antibiotic prophylaxis versus no antibiotics in clean otologic surgeries.

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APPENDIX

Proforma:

TO ASSESS THE EFFICACY OF ANTIBIOTIC PROPHYLAXIS IN OUTCOME OF SURGERY FOR CSOM TUBOTYMPANIC DISEASE

---

1. Name:

2. Hospital no:

3. Age: (in years)

4. Sex: 1.male 2.female

5. Address:

6. CSOM - 1.Right 2.Left 3.Bilateral

7. Duration of ear discharge:

8. Last episode of ear discharge:

9. Pre op audiogram

10. Size of the perforation 1. small 2. moderate 3. large 4. subtotal

11. Surgery done :1. Cortical mastoidectomy

    2. Tympanoplasty

       a) type I b)type II

    3. Myringoplasty

12. Ossicular status :1.Handle of Malleus a.intact b.necrosed

    2.Incus long process a.intact b.necrosed

    3. Lenticular process a.intact b. necrosed

    4. stapes suprastructure a.intact b. necrosed

    5. ossicular status not assessed

    6. restricted mobility

13. Material used for Reconstruction-1) Temporalis fascia 2) Cartilage 3) PORP 4) Bone chip 5) GIC

14. Duration of surgery: 1) <1hr 2) 1-2 3) >2 hours

15. Post operative wound evaluation on the second post operative day

    1. Healthy 2. Infected

    a. Fever : Yes/ no

    b. Wound collection : Yes/ no

    c. Wound discharge :Yes / No

    d. Discharge in canal : Yes/ No

    e. Drug reaction: Yes/ No

16. Post operative wound evaluation on the seventh post operative day

    1. Healthy 2. Infected

    a. Fever : Yes/ no

    b. Wound collection : Yes/ no

    c. Wound discharge :Yes / No

    d. Discharge in canal : Yes/ No

    e. Drug reaction: Yes/ No

17. Pus for c/s : Yes / no

18. Treatment given :1) Antibiotics used 2) no antibiotics

19. Post op graft status assessed after 1 month : a)graft taken up b)graft failure c) data unavailable

    Scar assessment a)healthy b) unhealthy

20. Post op audiogram

CONSENT FORM :

INFORMED CONSENT

I, Mr/Mrs _____ , Son/daughter of_____, Hospital No. _____, have been explained in my vernacular that a study is being done to assess the need of antibiotics in ear surgeries . I am given to understand that the use of antibiotics is not necessary always in ear operations and I may get only one dose before surgery . I declare that I was not forced into making this decision to partake in the study and am in a clear state of mind when I made this decision. Thereby, I give my full consent for taking part in the study

Signature and full name of Doctor

Signature and full name of patient/ guardian

Date

Vellore

S.NO	age	Hospital no	sex	place	side of Csom	duration	last attack	Drug group	preop audio	size of perfo	surgery	length of su	oss status	material
1	2	736300c	1	2	3	5	4	1	2	4	3	2	1	1
2	2	741939c	2	2	2	5	4	1	2	4	1	3	1	1
3	2	724569c	2	3	2	1	1	1	1	2	3	2	1	1
4	2	658939c	1	3	3	5	3	1	2	4	4	2	2	1
5	3	730377c	2	3	2	1	1	1	1	2	3	1	1	1
6	3	730800c	1	2	3	1	2	1	2	4	3	2	1	1
7	3	737461c	1	2	3	1	2	1	2	2	3	2	1	1
8	3	744959c	1	2	1	1	1	1	2	2	5	1	1	1
9	1	743903c	1	2	1	5	3	1	3	3	3	2	6	6
10	3	676819c	2	2	3	1	1	1	2	2	1	3	1	1
11	1	735821c	2	3	3	1	2	1	3	3	2	2	3	2
12	1	735380c	2	1	3	2	1	1	2	4	1	2	1	1
13	4	747078c	2	3	1	5	5	1	3	2	4	1	3	3
14	3	757074c	2	1	2	5	2	1	1	2	3	2	1	1
15	3	755871c	2	1	2	1	2	1	3	4	3	2	1	1
16	3	752629c	1	1	2	1	1	1	3	2	1	3	1	1
17	2	768048c	2	2	3	5	1	1	2	3	1	3	1	1
18	1	674320c	2	1	1	5	1	1	2	2	3	2	1	1
19	1	731201c	2	1	1	5	2	1	2	2	3	2	1	1
20	1	770056c	1	1	2	4	1	1	3	3	1	3	1	1
21	2	761123c	1	3	2	5	5	1	3	3	2	2	3	2
22	2	990950a	1	3	2	5	1	1	8	2	1	2	1	1
23	3	706006c	2	2	1	5	4	1	3	4	3	2	5	1
24	1	778752c	1	3	2	5	4	1	9	3	5	2	7	1
25	4	731071c	2	1	3	5	2	1	3	2	5	1	7	1
26	3	511216c	2	1	1	2	3	1	2	2	3	2	1	1
27	1	500048c	1	1	3	5	2	1	2	3	1	2	1	1
28	1	788430c	1	2	3	5	2	1	1	4	1	2	1	1
29	1	758458c	1	2	3	5	5	1	2	2	2	1	1	1
30	1	782941c	1	2	3	2	2	1	2	3	1	2	5	1
31	1	731213c	2	2	1	5	2	1	2	3	3	2	1	1
32	3	854683c	1	2	2	5	2	1	1	4	2	2	2	1
33	1	853396c	1	2	3	5	4	1	3	3	3	2	5	1
34	1	630490c	2	1	3	5	1	1	1	2	1	2	1	1
35	3	785384c	1	3	1	5	3	1	8	2	3	2	1	1
36	3	779324c	2	2	3	5	3	1	8	4	4	2	2	1
37	1	845735c	1	2	2	5	3	1	2	2	1	2	1	1
38	1	780298c	1	2	3	5	3	1	1	2	3	2	1	1
39	2	816130c	2	1	2	3	2	1	8	2	5	1	7	1
40	2	843319c	1	2	2	5	5	1	3	4	4	1	4	3
41	1	825445c	2	2	2	5	1	1	2	4	1	2	8	1
42	3	820405c	2	1	2	1	1	1	1	2	3	2	1	1
43	1	687678c	2	1	3	5	2	1	3	3	3	2	1	1
44	1	314694c	1	1	3	5	2	1	1	4	2	2	2	1
45	2	857852c	2	2	3	3	1	1	1	3	1	2	1	1
46	1	740449o	1	1	1	5	4	1	2	4	3	1	1	7
47	1	788430c	1	2	3	5	3	1	2	4	1	2	1	1
48	1	790047c	1	2	2	5	5	1	2	4	3	1	1	1
49	2	792631c	1	2	3	5	3	1	2	4	3	1	1	1
50	1	728908c	2	1	2	1	3	1	1	2	3	1	1	1

wd ass 1st	Wound ass	pus c/s	graft status	postop audio	
2	1	1	5	11	
1	1	1	1	1	
1	1	1	1	10	
1	2	1	5	11	
1	1	1	1	11	
5	1	1	3	11	
1	6	1	5	11	
5	1	1	1	10	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	1	11	
1	4	1	1	10	
1	1	1	1	7	
1	1	1	1	10	
1	3	2	1	4	
1	1	1	3	3	
1	1	1	5	11	
1	1	1	5	11	
1	2	1	1	10	
1	1	1	1	2	
1	1	1	1	4	
1	1	1	3	8	
1	1	1	5	11	
1	4	1	5	11	
1	1	1	3	11	
1	1	1	2	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	1	4	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	5	11	
1	1	1	1	11	
1	1	1	5	11	
1	6	2	1	11	
1	1	1	4	11	
1	6	2	5	11	
1	1	1	5	11	
1	3	2	5	11	
1	1	1	1	11	
1	1	1	5	11	
1	4	1	5	11	
1	1	1	1	11	
1	1	1	3	11	