Study Protocol

Study of Clinical Profile and Comparison of Various Dimensions of Chronic Otitis Media Among the Adult and Paediatric Population from Rural Area

ABSTRACT

BACKGROUND: The term Chronic Suppurative Otitis Media (CSOM) is characterized as "chro nic middle ear and mastoid cavity inflammation, which occurs through tympanic membrane perforation with recurrent ear discharge or otorrhoea . Though there are many similarities between adult and paediatric CSOM in terms of disease progression and pathological changes, there are certain notable differences stemming from temporal bone anatomy and extent of pneumatization, the immaturity of Eustachian Tube in terms of its function and variable progression of disease. Paediatric temporal bone being more pneumatized makes the disease to spread more extensively. Childhood cholesteatoma has much greater rates of residual and recurrence disease than seen in adults. This study is aimed to compare various dimensions of CSOM among the paediatric and adult age group in rural population.

METHODS: This cross sectional comparative study is scheduled during the period from November 2020 to November 2023 in ENT Department of AVBRH, Wardha. Total 50 patients with chronic Otitis Media in the paediatric and adult age group will be enrolled. Baseline investigations will be performed for all patients and compared.

EXPECTED RESULT: Clinical profile and behavior of chronic otitis media in adult and paediatric population in rural area will be outlined with emphasis on middle ear changes, grade and extent of retraction pockets and cholesteatoma respectively. Pneumatization of the temporal bone and audiological status will be reported.

CONCLUSION: Differentiating characteristics of chronic otitis media in adult and paediatric population with specified features will be concluded.

KEY WORDS: Suppurative, Chronic Otitis Media, Cholesteatoma, Mastoid pneumatization, Squamosal and Mucosal COM.

INTRODUCTION:

The term Chronic Suppurative Otitis Media (CSOM) is characterized as "chronic middle ear a nd mastoid cavity inflammation, which occurs through tympanic membrane perforation with recurrent ear discharge or otorrhoea ". [1] Chronic inflammation and changes in middle ear cleft are not necessarily associated with non-intact eardrum. The term Chronic Otitis Media (COM) is therefore a better term to encompass the varied pathology seen because of chronic middle ear infection. COM can certainly be precipitated by an acute infection with or without tympanic membrane perforation and may occur without episodes of acute otitis media. [1]

COM typically starts as a sudden tympanic perforation due to an acute middle ear infection, known as acute otitis media (AOM), or as a series of less severe types of otitis media in infancy, with a peak occurrence at 2 years of age (e.g. secretory OM). [2] Inadequate treatment with antibiotics, repeated infections of the upper respiratory

tract, nasal diseases, and poor living conditions with poor access to medical care lead to the progression of AOMs into COMs. [2] Factors contributing to the pathogenesis of COM include age, upper respiratory tract infections, hypertrophied adenoids, immune deficiency, general health scores, childcare attendance, environmental factors, household smokers, housing conditions, genetic predisposition, and inadequate/unavailable health care. [3] COM can be classified into 2 types: ***Mucosal*** and ***Squamosal COM .***

Mucosal COM is characterized by perforation in pars tensa and further classified as *active* when perforation is associated with inflammation of middle ear mucosa and mucopurulent discharge and *Inactive* when perforation sans inflammation and discharge.

Squamosal COM is associated with changes in attic part of middle ear or in posterior superior quadrant. It is *inactive* when there are retraction pockets in pars tensa or pars flaccida without cholesteatoma and discharge. It is *active* when there is presence of cholesteatoma in pars tensa or pars flaccida. This COM is attended by bone erosion, granulation tissue, purulent offensive discharge and more associated with conductive hearing loss (CHL). [4]

Though there are many similarities between adult and paediatric COM in terms of disease progression and pathological changes, there are certain notable differences stemming from temporal bone anatomy and extent of pneumatization, the immaturity of Eustachian Tube in terms of its function and variable progression of disease. Paediatric temporal bone being more pneumatized makes the disease to spread more extensively. Childhood cholesteatoma has much greater rates of residual and recurrence disease than seen in adults. Ossicular erosion is also more common in children. Immature eustachian tube function in children is also a leading cause for frequent middle ear disorders, therefore chances of late recurrence after surgical removal of disease is extremely high in children. One of the most obvious differences between children and adult patients is their ability to tolerate interventions and procedures. [5]

The purpose of this study is to compare the clinical profile and behavior of COM in adult and paediatric population in rural area with emphasis on middle ear changes, grade and extent of retraction pockets and cholesteatoma respectively and pneumatization of the temporal bone and audiological status.

RATIONALE:

There is an urgent need to establish successful therapeutic strategies against COM with the advent of antibiotic resistance, antibiotic ototoxicity and the possible consequences of surgery. This warrant acknowledging the similarities and differences in the clinical profile and disease progression among paediatric and adult age group which will benefit in designing promising therapeutic modalities against the disease and hence mitigating the associated morbidities.

AIM

To compare various dimensions of COM among the paediatric and adult age group in rural population.

OBJECTIVES

1) To study clinical profile of COM in pediatric and adult age group in rural area.
2) To analyze and compare the site and size of perforation of tympanic membrane in mucosal COM in pediatric and adult age group in rural area.
3) To study, grade and compare the type of retraction pocket in peadiatric and adult age group in rural area.
4) To study and compare extent of cholesteatoma in pediatric and adult age group in rural area.
5) To compare the pneumatization pattern of temporal bone in pediatric and adult age group in rural area.
6) To study and compare the audiological status in COM in pediatric and adult age group in rural area.

MATERIAL AND METHOD

Type of the study:

Observational cross-sectional study

STUDY DESIGN:

Study setting:

A cross sectional and comparative study will be carried out in ENT Department AVBRH Sawangi, Wardha during the period from November 2020 to November 2023. All the selected patients with sample size 50, of COM in the paediatric age group (0-14years) and adult age group (15-60 years) with squamosal COM (active or inactive) and mucosal COM (active, quiescent, or inactive) will be considered in this study. Patients will be comprehensively and diligently examined as per the proforma meant for the study and baseline investigations will be done.

Study setup

All the paediatric and adult patients with COM visiting outpatient department [OPD], Inpatient department [IPD] of ENT in AVBRH will be studied**.**

Sample size

50 Patients. (50 Ears)

1. 25 patients- adult population
2. 25 patients- pediatric population

Sample size formula with desired error of margin:

$n= Z\left(\frac{\alpha}{2}\right) 2*p*(1-p)/d$ [6]

where,

$Z\left(\frac{\alpha}{2}\right)$ is the level of significance at 5% i.e 95% confidence interval=1.96

p= prevalence of COM= 1.4%=0.014

D= desired error of margin =5%=0.05

$N= \{(1.96)^2*0.014*(1- 0.014)\}/0.05^2$

=21.21

=25 patients needed in each group

PARTICIPANTS:

Inclusion criteria:

- All patients between the age group of 0-14 years as paediatric population
- All patients between the age group of 15-60 years as adult population
- Any gender
- Patients with active or inactive squamosal COM with cholesteatoma and retraction pocket respectively.
- Patients with mucosal COM active, quiescent, or inactive

Exclusion criteria:

- Patients with congenital SNHL.
- Patients with known immunodeficiency disorder.
- Patients with craniofacial anomalies.
- Patients with granulomatous disorder of temporal bone.

METHODOLOGY:

Study procedure:

All the selected patients of COM in the paediatric and adult age group and satisfying the -inclusion criteria will be considered and accrued in this study. We plan to look at a sample size of 50 patients (50 Ears). Patients will be comprehensively and diligently examined as per the proforma enclosed and baseline investigations will be done.
Those patients included in this study will be evaluated as follows:

- Comprehensive clinical examination of ear, nose and throat.
- Complete blood count.
- Specific investigations like examination of ear under microscope (EUM) to know more about perforation tympanic membrane, cholesteatoma, and retraction pockets.
- Pure tone audiometry and impedance audiometry will be done for assessment and grading of hearing impairment.
- CT scan to look for pneumatization of mastoid, volume of mastoid air cells, nature and extent of disease spread, ossicular chain integrity, associated abnormalities of temporal bone along with any other incidental findings will be noted.
- A predesigned proforma will be used to record the relevant information thus obtained by clinical examination, specific investigations, and surgical exploration. Photographic documentation will be done wherever necessary.

IEC: Clearance from the Ethical Committee will be obtained.

Statistical analysis:
Statistical analysis of the data obtained will be done by chi square test.

Scope:
Comprehensive and co relative study.
It may influence positively surgical approach to this entity

Limitation:
Sample size.

Implication:

1) This study may help in designing and developing protocol.
2) This study may bring precision in intervention.

EXPECTED OUTCOMES:

A total of 50 patients of COM in the paediatric and adult age group and satisfying the inclusion criteria- paediatric patients in a age group of 0-14 years, adult patients in the age group of 15-60 years, both genders, patients with active or inactive squamosal COM with cholesteatoma and retraction pocket and patients with mucosal COM active, quiescent, or inactive will be considered and accrued in this study. The patients included in this study will be evaluated for their clinical findings of ear, nose and throat. Specific investigations like examination of ear under microscope (EUM) to know more about perforation tympanic membrane, cholesteatoma, and retraction pockets. Pure tone audiometry and impedance audiometry will be done for assessment and grading of hearing impairment. CT scan to look for pneumatization of mastoid, volume of mastoid air cells, nature and extent of disease spread, ossicular chain integrity, associated abnormalities of temporal bone along with any other incidental findings will be noted.

DISCUSSION:

Chronic otitis media (COM) is a middle ear space inflammation that results in permanent cha nges in the tympanic membrane, including atelectasis, dimer formation, perforation, tympan osclerosis, retraction pocket growth, or cholesteatoma, in the long term or more frequently. [7] The bacteriology of COM is diverse and includes both aerobes and anaerobes and the predominant organisms recovered are Pseudomonas aeruginosa, S. aureus, Klebsiella pneumonia, and Bacteroides species. [8]

The structural and functional obstruction of the Eustachian Tube (ET) seems to be fundamental to all types of Otitis Media pathogenesis. ET anatomical obstruction is caused by inflammation of the mucosa of the eustachian tube or by extrinsic tumor compression or large adenoids. More prevalent in the winter months is otitis media, which represents the incidence of upper respiratory tract infections. For children with cleft palate, otitis media is used almost uniformly. [9] Compared with adults, the shorter, straighter and broader ET structure seen in children can also result in impaired ET opening function. Poor mastoid pneumatization is also found to be associated with COM. Temporal bone pneumatization plays an important role in etiology, behavior, course, and outcome of COM. The mastoid region's degree of pneumatization can be divided into three parts:

1) Sclerotic mastoid (absent pneumatization),
2) Diploic mastoid partial(pneumatization),
3) Pneumatic mastoid (complete pneumatization).

The non-pneumatized areas are the bone marrow (in the diploic mastoid) and the dense bone (in the sclerotic mastoid).[10] Cholesteatomas are retraction pockets or cysts lined with epithelium of squamous cells and filled with keratin debris that occurs inside the temporal bone pneumatized spaces. They are commonly associated with marginal perforations and have a tendency for formation, bone loss, and chronic infection.COM with cholesteatoma is therefore treated as a "unsafe" ear that needs surgical intervention. [11] Post-operative middle ear retraction occurs in tympanoplasty with mastoidectomy much more than

tympanoplasty without mastoidectomy. Some of the related studies were reviewed [12,13]. A few articles have been reported in GBD study [14-17]. Jain et. al. reported on role of eustachian dysfunction and primary sclerotic mastoid pneumatisation pattern in aetiology of squamous chronic otitis media [18]. Methwani and Deshmukh reported about Type I Tympanoplasty with or without mastoidectomy in tubotympanic type of chronic suppurative otitis media patients[19]. Singh et. al. studied the correlation of pre-operative findings with intra-operative ossicular status in patients with chronic otitis media [20]. Other related studies were reviewed[21-23].

In order to find a link between preoperative HRCT and intraoperative findings in patients with attic antral disease, Sirigiri RR et al conducted a review. Their studies showed varying degrees of sensitivity and sensitivity to various aspects of the illness. They conclude that while HRCT offers good visualization of the main areas, the wholesome reliability of it is prevented by elevated levels of false positive and false negative.[25-27]

CONCLUSION:

The purpose of this study is to help the clinician have a better insight on the similarities and differences regarding the clinical profile and behavior of COM in adult and paediatric population in rural area with significance on middle ear changes, grade and extent of retraction pockets and cholesteatoma respectively and pneumatization of the temporal bone and audiological status.

Conflict of Interest-None

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