PREVALENCE AND FACTORS ASSOCIATED WITH CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AMONG ADULT PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

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By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Otorhinolaryngology at

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CERTIFICATION

The undersigned certifies that, they have read and hereby recommend for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled: **''Prevalence and factors associated with chronic suppurative otitis media complications among adult patients at Muhimbili National Hospital''** in partial fulfillment of the requirements for the degree of Master of medicine in Internal Medicine at Muhimbili University of Health and Allied Sciences.

_____

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Date: _____

_____

Dr. Jimmy Ernest

(Co-Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **Julius Casmiry Kessy,** declare that this dissertation is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: _____ Date_____

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My research supervisors, Drs. Aveline Kahinga and Jimmy Ernest, have my sincere gratitude for their constant support and encouragement throughout this work.

I express my gratitude to the patients with chronic suppurative otitis media and the medical personnel of the otorhinolaryngology department at Muhimbili National Hospital. Because they were patient and nice, they participated in our study and helped out.

I owe a lot to my family and friends for their everlasting support and never-ending belief in me.

DEDICATION

I dedicate this work to my supervisors, my family and all patients suffering from chronic suppurative otitis media.

ABSTRACT

Background: Chronic suppurative otitis media (CSOM) is still a problem in developing countries affecting both pediatric and adult patients. However rare the disease is, complications both extra cranial and intracranial may arise. The factors that seem to fuel the progression of CSOM to its complications also appear to have an impact on patients' quality of life, hence existence of the risk factors linked to CSOM complications can be addressed early to prevent the consequences of the disease.

Aim: To determine the prevalence of chronic suppurative otitis media and the factors associated with its complications among adult patients at Muhimbili National Hospital.

Methodology: A hospital based cross-sectional study was employed to collect data from patients with CSOM. Data was collected through the use of a data collecting tool, which included; demographic information about the patients, clinical characteristics and information about CSOM complications that were identified during imaging investigations in addition to physical examination results. The analysis of the data was done with Statistical Package for Social Sciences (SPSS) version 23. Whereas categorical variables were summarized by percentage, continuous variables were summarized by median and interquartile range. To investigate the relationship between the factors under investigation and complicated CSOM, logistic regression was used. The statistical significance was established at $p<0.05$.

Results: A total of 52 patients with CSOM were recruited, male to female ratio was 1:1, median (IR) age was 39 (22) years. The prevalence of complicated CSOM was found to be 51.9%. Extracranial complications were found in all patients with complicated CSOM and 19% of the patients had also intracranial complications. Higher proportion of complicated CSOM was found in male patients (61.5%), those with atticoantral type of CSOM (100%) and those who used local remedies to the diseased ear (72.7%). Binary logistic regression analysis showed that use of local remedies to the diseased ear was an independent factor for a complicated CSOM.

Conclusion:

The prevalence of complicated CSOM in our setting was 51.9% and most patients had extracranial complications. The use of local remedies was found to be an independent factor contributing to the development of complications from CSOM and thus necessitating advocacy for proper healthcare seeking behaviour and education in our society.

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LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency disease
AOM	Acute otitis media
COM	Chronic otitis media
CSOM	Chronic suppurative otitis media
CT SCAN	Computed Tomography scan
EAC	External auditory canal
FN	Facial nerve
HIV	Human Immunodeficiency virus
HRCT	High resolution CT scan
MMED	Masters of medicine Degree
MNH	Muhimbili National Hospital
MS	Microsoft
MUHAS	Muhimbili University of health and Allied Sciences
ORL	Otorhinolaryngology
PI	Primary Investigator
S Aureus	*Staphylococcus aureus*
SPSS	Statistical Package for Social Sciences
URTI	Upper respiratory tract infection
WHO	World Health organization
OPD	Outpatient department

DEFINITION OF TERMS

Otorhinolaryngology is a surgical specialty dealing with subspecialties on management of diseases of the ear, nose, larynx and head and neck region(1)

Otoscopy is the clinical procedure involving physical examination of the outer and middle ear with or without employing the use of otoscope (2).

Chronic suppurative otitis media (CSOM) is middle ear cleft infection that is characterized by a history of a persistent or recurrent otorrhea of at least 2 weeks duration through a perforated tympanic membrane (3).

Otorrhea is the drainage from the ear through the external auditory canal that is a result of inflammation or trauma in either the outer or middle ear(4)

Labyrinthitis is the inflammation of the inner ear that can either be due to infectious or non-infectious origin(5).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The ear is a paired organ serving two purposes which is hearing and balance, they are located in both sides of the head in the temporal bones. It is divided into an outer, middle and inner ear, whereas the outer and middle ear are both air containing spaces, the inner ear is a fluid containing space. Both the outer and middle ear function to conduct sound to elicit fluid vibration in the inner ear for electrical impulse generation to be transferred to the brain as well as balance impulses for interpretation. The middle ear is also known as tympanic cavity while the inner ear is also known as the labyrinth. The outer ear is made up of the auricle/pinna, external auditory canal and the outer aspect of the tympanic cavity. The middle ear contains three bones that are malleus, incus and stapes together with the two muscle that are stapedius and tensor tympani muscles and it is bounded medially with the inner ear. The inner ear houses the cochlea for hearing and semicircular canals together with the vestibule for balance (6,7).

The middle ear cavity is composed of the tympanic cavity, Eustachian or pharyngotympanic tube and mastoid cavity (Figure 1). Tympanic cavity forms the bulk space than the rest and it communicates anteriorly with the nasopharynx through the Eustachian tube and posteriorly by the mastoid cavity through aditus ad antrum (Figure 2) (8).Middle ear is an air containing cavity that is separated from the external ear by a tympanic membrane and from the inner ear by an oval and round window apart from the bony structure (9).

Tympanic membrane is divided into pars tensa (3 layered) occupying the biggest portion and a small pars flaccida (2 layered) at the superior aspect, where the difference is a middle fibrous layer that provides strength to the membrane (8). Middle ear cavity is responsible for transmission of sound vibration from the tympanic membrane through the ear ossicles to the oval window in order to cause vibration of fluid in the inner ear for transduction to occur.

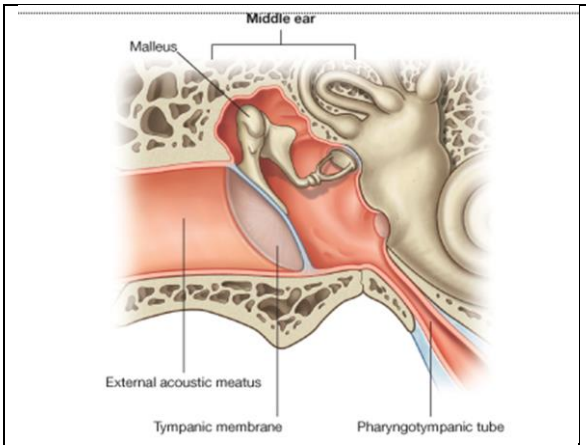


Figure 1: Middle ear cavity (10)

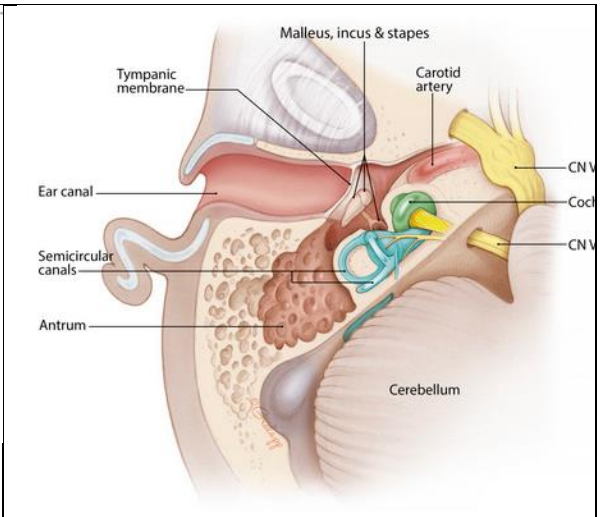


Figure 2: Anatomical relation of the middle ear (11)

Chronic suppurative otitis media (CSOM) is defined as a middle ear cleft infection that is characterized by a history of a persistent or recurrent otorrhea of at least 2 weeks duration through a perforated tympanic membrane (3). This disease is secondary to bacterial infection in the middle ear cleft that result in a chronic inflammatory process in that middle ear cleft. Studies have shown that it is a polymicrobial disease in nature however the predominant bacteria are; S Aureus, Pseudomonas species and Klebsiella species (12–15).

Despite the improvement in the aspect of medical care and public health, CSOM is still a common disease especially in the developing countries and certain high risk populations in the developed countries (16). The magnitude of CSOM is high in pediatric population as compared to adult population (17). The prevalence of CSOM is estimated to be 65 to 330 million persons worldwide (18). CSOM is the preventable major cause of hearing loss among other forms of otitis media (19).

Two major causes of CSOM, firstly is due to incomplete recovery from an acute otitis media because of either inadequacy or incomplete treatment, secondly is due to infection in the middle ear from the outer ear through a perforated tympanic membrane that occurred spontaneously, post ear trauma or following surgical procedure such as tympanostomy tube placement (20).

CSOM is classified into two types, tubotympanic type where there is no cholesteatoma formation that commonly occur in the pars tensa and atticoantral type where there is cholesteatoma formation and commonly occur either in the pars flaccida or marginally perforated tympanic membrane (21). Cholesteatoma is the presence of keratinized squamous epithelium in the middle ear cleft that was supposed to be lined by respiratory epithelium, it has the tendency of eroding the bones in the middle ear such as the ear ossicles, scutum, tegmen and medial wall of the cavity (22,23).



Figure 3: TM perforation-Tubotympanic type (24)



Figure 4: Attic cholesteatoma(24)

Evaluation of CSOM depends on history and otoscopic examination preceded with aural toilet in case of pus in the external auditory canal (EAC) and temporal bone high resolution computed tomography (HRCT) scan to assess the extent of the disease and complications of the disease (22,25–27).Baseline investigations such as full blood picture (FBP) and serological tests such as Human Immune-deficiency Virus (HIV) are also crucial.

Complications arising from CSOM refers to extension of the infection outside the mucosal lining of the middle ear cleft (28). The complications can be mainly due to bone erosion around vital regions as a result of disease progression such as around the facial nerve, labyrinth and the dura (29).They can also arise from bone dehiscence around vital structures such as the facial nerve bony dehiscence.

Complications of CSOM are mainly divided into two broad groups that are intracranial and extracranial complications. Extracranial complications are further divided into intratemporal and extratemporal complications. Intratemporal complications include mastoiditis, facial nerve paralysis, labyrinthitis, labryrinthine fistula, petrositis whereas extratemporal complication include Bezold, Luc's, zygomatic, Citelli and subperiosteal mastoid abscess. Intracranial complications include meningitis, epidural abscess, subdural abscess, brain abscess and lateral sinus thrombophlebitis(30–36,79).

Several factors have been implicated in the development of complicated CSOM both demographic and clinical factors. Complicated CSOM has been found more in patients with no or primary education level, those who do not have; health insurance or employment, those who have; the tendency of using local/home based remedies to the diseased ear, immunosuppressing conditions such as HIV/AIDS, Diabetes mellitus etc., atticoantral type of CSOM(16,17,37–43,82,86)

Treatment modalities for CSOM are medical and surgery, the employed medical treatment for CSOM is the key step in the tubotympanic type and involve ear cleaning, avoidance of water entering into the middle ear and topical quinolones preferably ciprofloxacin ear drops (20,21,44).Surgery such as tympanomastoidectomy has a significance role of removing the diseases tissue and creating a safe ear with or without improving deficit in the hearing status

of the ear (21). Surgery is indicated in CSOM that is unresponsive to medical therapy, CSOM with cholesteatoma formation and CSOM with complication/s (22,45,46).

1.2 Problem Statement

The prevalence of CSOM with its complications is still evident especially in developing countries. (27, 28). A number of factors may contribute to the occurrence of CSOM complications, such as lower socioeconomic status, immune-compromising state such as HIV, diabetes mellitus, use of local/herbal medications to the discharging ear, prolonged duration of ear discharge before seeking medical attention (15,33,40,41,47–49,49,50) and atticoantral the type of CSOM due to its propensity to the development of cholesteatoma that has a tendency of eroding surrounding bones. (34).

However, little is known about the prevalence of complications of CSOM and the factors implicated for the progression of the disease into its complications in our setting.

This study will shed light on the current magnitude of the complications of CSOM and the factors for the development of its complications.

1.3 Rationale

The findings from this study will alert health care providers on the need to put more emphasis on modifiable risk factors for CSOM complications that will aid in preventive measures against development of the complications. It will involve provision of health care education to the patients that will result in overall improvement of patient health.

The findings will also be used as stepping stone towards further research on CSOM such as appropriate management strategies both to the discharging ear and its complications.

The findings may also help the ministry of health and policy makers to develop preventive strategies including community campaigns on health seeking practices in patients with ear discharge so as to prevent complications that may arise.

1.4 Main research question

What is the prevalence and factors associated with chronic suppurative otitis media complications among patients at Muhimbili National Hospital?

1.5 Specific research questions

1. What is the prevalence of complicated chronic suppurative otitis media among adult patients with chronic suppurative otitis media at Muhimbili National Hospital?
2. What are the types of complications among adult patients with complicated chronic suppurative otitis media at Muhimbili National Hospital
3. What are the factors associated with development of chronic suppurative otitis media complications?

1.6 Objectives

1.6.1 Broad Objective

To determine the prevalence and factors associated with chronic suppurative otitis media complications among patients at Muhimbili National Hospital

1.6.2 Specific Objectives

1. To determine the prevalence of complicated chronic suppurative otitis media among adult patients with chronic suppurative otitis media at Muhimbili National Hospital
2. To determine the types of complications among adult patients with chronic suppurative otitis media at Muhimbili National Hospital
3. To determine factors associated with development of chronic suppurative otitis media complications

1.7 Conceptual Framework

The figure below indicates the framework of CSOM for the outcomes of two categories of complications that may arise from CSOM. It shows the relationship between the risk factors for the development of the complications.

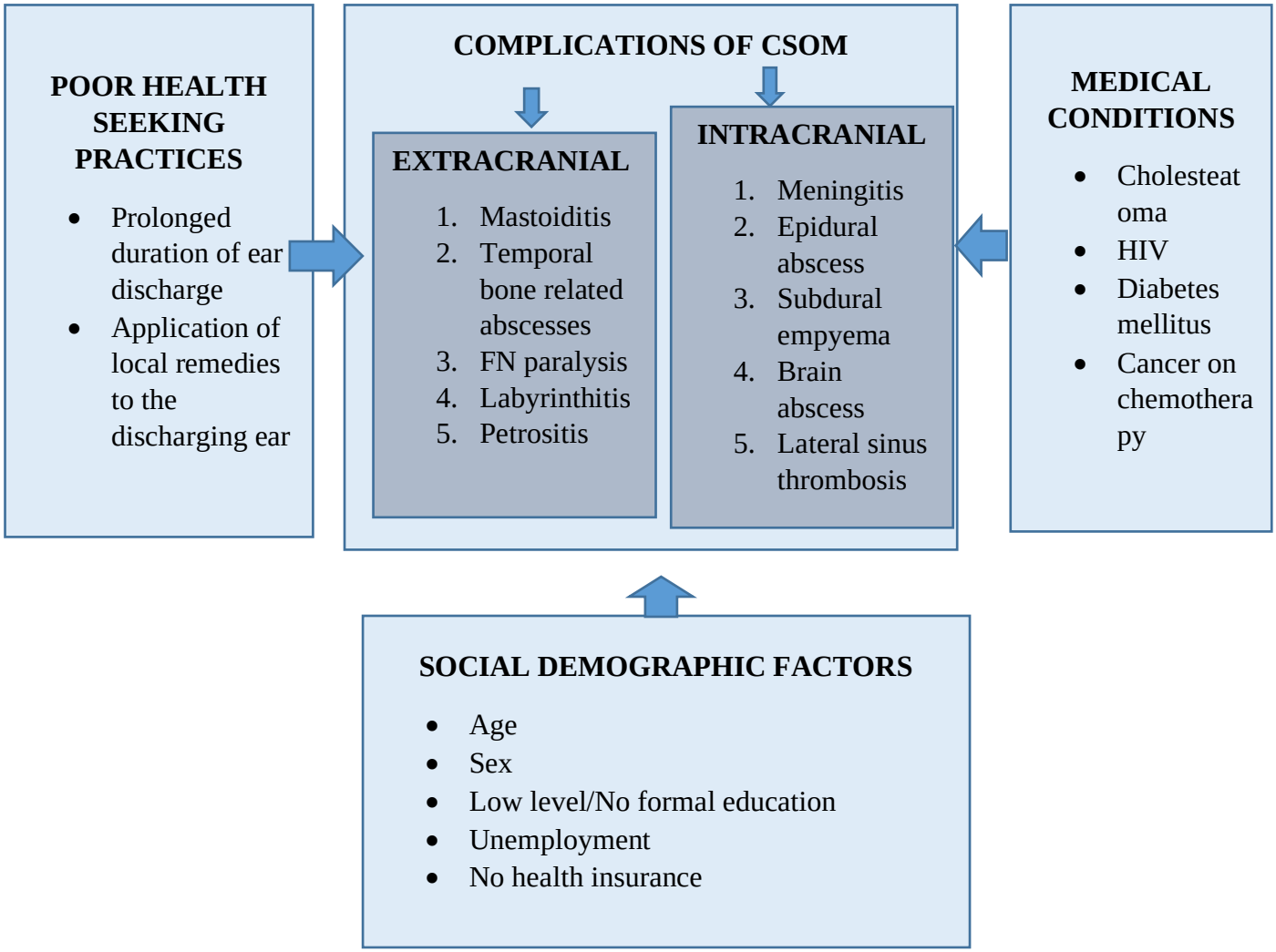


Figure 5: Conceptual framework

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Prevalence of complications of CSOM

Mostafa et all conducted a retrospective study on patients with chronic suppurative otitis media in Egypt and found a prevalence of complications of CSOM being 12.54% from a tertiary university hospital (51).

A study done in India on CSOM with complications, intracranial complications were more prevalent as compared to extra cranial ones with the prevalence of 0.17% and 0.13% respectively (29). That study also found out 4 patients from a group with extra cranial complications and 3 patients from a group with intracranial complication had more than one complication.

The most common extra cranial complication in pediatrics was acute mastoiditis, while in adults in order of decreasing frequency the findings were subperiosteal abscess, labyrinthitis and facial nerve paralysis, while brain abscess commonly in the temporal lobe and cerebellum together with meningitis were the most common intracranial complications (29).

A retrospective review on clinical records of patients with Otitis media attended in a tertiary hospital in Nepal from 2015 to 2020 showed a 0.06% and 5.6% incidence of complications among patients who had CSOM without cholesteatoma and with cholesteatoma respectively. Among 164 patients with complications, 80 %, 18% and 9% had extra cranial complications, intracranial complications and both two groups of complications respectively.

The most common extra cranial complications were mastoid complications ranging from mastoiditis, sub periosteal abscess and mastoid fistula, it was followed by facial nerve paralysis whereas the least one being labyrinthine fistula noted exclusively in CSOM with cholesteatoma patients.

All intracranial complications where brain abscess was the leading one followed by meningitis were found in patients who had CSOM with cholesteatoma. Extra cranial complications were identified more than intracranial complications, and 9% of patients had

more than two complications with coexistence mainly of facial nerve paralysis and mastoiditis (28).

From one tertiary referral university hospital in Turkey a 10-year study was done on assessing retrospectively patients with CSOM where the prevalence of complications was 2.6 % among 4630 patients. In those patients 47.1% and 30.6% had extra cranial and intracranial complications respectively, whereas 22.3% of patients had multiple complications.

Among patients with extra cranial complications mastoid abscess was the most prevalent one with 28.3% occurrence that was followed by labyrinthitis, facial nerve paralysis and Bezold's abscess. Lateral sinus thrombophlebitis was the most common complication followed by presigmoid sinus abscess, meningitis, brain abscess and extradural abscess (52).

2.2 Social demographic factors associated with CSOM complications

Several studies that have being conducted on assessing the prevalence of CSOM on different age groups had different ranges at the time of data collection to present with complications (12,42). Among adults the age group commonly affected with complications of CSOM in Turkey tertiary university hospital was found in the age group 21- 30 years with the least age group being in the range of 51-60 years. Complications were found to be common among pediatric age group of 5-10 years. It correlated with another study in India that found out among adult patients of CSOM, complications the commonest age group to experience them were in the age range of 21-30 years (29).

This young adult age group to be affected by complications of CSOM was also found in a Brazilian study that postulated its possibility of occurrence as a result of ear infections with cholesteatoma that occurred in childhood and took years to result into fulminant complications(53) . This finding was different from a Korean study where patients of 60 years and above where found to have higher prevalence of COM (54).There is slightly male predominance on the prevalence of CSOM in several studies (12,15,52).Some studies showed a 3:1 Male to female ratio for patients who had CSOM with complications (30,47)

As in several studies, most patients with CSOM and its related complications were unemployed, small scale farmers as well as with low level of education or those with no formal education (15,41,47).

Studies have shown patients who are health insured tend to seek medical help as soon as they became sick, on the other hand patients with no health insurance have a tendency of seeking medical help once the disease presents with severe signs and symptoms after using over the counter medication or cheap traditional therapy. This tendency has been shown to have an impact in the treatment outcome of the patient that may result into complications of the underlying pathology(55).

2.3 Medical conditions associated with CSOM complications

Cholesteatoma

This type of CSOM is regarded as an unsafe one due to its association with cholesteatoma formation. The worrying feature about cholesteatoma is its tendency to erode bone, and when it occurs in proximity to crucial structures results into frank complications such as facial nerve paralysis as a result of fallopian canal erosion (30,33). Intracranial complications were found in 83.3% of patients (35) while in the other study it was 79% of patients who had Atticoantral type of CSOM with cholesteatoma(34) .

Underlying immunosuppressive conditions

HIV was found to be one of the predictors that were associated with development of complications and poor treatment outcome in patients with CSOM. HIV positive patients were 4.3 times to have CSOM complications than HIV negative patients (41,50). Among the immunosuppressive conditions to be highly associated with CSOM and its complications, HIV was the leading one in an Indonesian study(56).

Diabetes mellitus has been shown to be associated with increased prevalence of CSOM that can result into manifestation of its complications(57).

Cancer patients and those receiving immunosuppressive drugs were having more odds of CSOM with a more likely risk of developing its complications as compared to patients with no immunosuppressive condition (56).

2.4 Poor health seeking practices associated with CSOM complications

Prolonged duration of ear discharge that could be accounted mainly by ignorance, fearing cost of treatment and home/local based treatment was one of the predictors for complications development that would later on result on poor treatment outcome (41). Poor health seeking practices such as from traditional healers results in poorly managed as well as progression of chronically discharging ear that predisposes patients to overt complications (48,49) . Example of local remedies used by patients with CSOM are leaf paste, oil from animal products and water (40).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design
This was a hospital-based cross-sectional study.

3.2 Study duration
The study was conducted for a duration of 6 months, from October 2023 to February 2024.

3.3 Study area
This study was done in the department of otorhinolaryngology at Muhimbili National Hospital. Muhimbili National Hospital (MNH) is a tertiary Hospital in Tanzania which serves as a national hospital as well as teaching hospital for Muhimbili University of Health and Allied Sciences (MUHAS). The hospital is located in two campuses, the main campus is located at Upanga in Ilala district and another campus is located at Mloganzila in Ubungo district. This study was conducted at Upanga which has 1500 bed capacity and serves about 1000 outpatients a day.

The otorhinolaryngology department in Upanga has 5 units, which are rhinology, otology, head and neck surgery, audiology, together with speech and language therapy. Also, the department has two wards each serving for female and males In-patients with 24 bed capacity in each ward. Private wards are present in the same building and serve patients from different departments. Pediatric inpatients have their own ward. Each unit has an outpatient clinic for follow up patients and is categorized into general, audiology, speech and language therapy clinic.

A minimum of 1 patient and maximum of 2 patients with COM are being managed surgically each week. Following surgery they are being attended at the outpatient department (OPD). At least 15 patients (both adults and pediatrics) with CSOM are being attended monthly in ORL department.

3.4 Study population
All adult patients with CSOM who were attending ORL clinic or admitted in the wards.

3.5 Study sample
Adult patients with CSOM who met the inclusion criteria.

3.5.1 Inclusion criteria
Only consented adult patients aged 18 years and above with clinical features of CSOM at Muhimbili National Hospital. Such features were a history of recurrent or persistent ear discharge of at least 2 weeks plus otoscopic examination finding of perforated tympanic membrane(3).Those patients should have undergone imaging HRCT with/without brain upon treatment initiation at MNH

3.5.2 Exclusion criteria
Adult patients who had clinical features of CSOM but did not have radiological imaging as part of investigations and those who were on follow up following tympanoplasty with/without mastoidectomy.

3. 6 Study Variables
For the purpose of this study the following variables were used:

3.6.1 Dependent Variable
Complications of chronic suppurative otitis media

3.6.2 Independent variables
- Social demographic characteristics (Age, sex, education level, employment status, health insurance).
- Medical conditions (Cholesteatoma, HIV, Diabetes mellitus, cancer on chemotherapy).
- Poor health seeking practices (Prolonged duration of ear discharge before seeking medical help, application of local remedies to a discharging ear).

3.7 Sample Size Estimation
By using Yamane’s formula.

Yamane's formula (39,58)

n = N/ (1 + N e2)

n - Corrected sample size

N - Population size

N= 60, which was the average number of adult patients with CSOM that were attended at MNH for a duration of 6 months from a pilot study

£ - Margin of error 5% = 0.05

$$n = \frac{60}{1 + 60 \times 0.05^2}$$

n = 52

Hence the estimated minimum sample size was 52 **patients**.

3.8 Sampling techniques

Consecutive sampling technique was used to enroll patients who were seeking ORL health care at MNH-Upanga who fulfilled the inclusion criteria until the sample size was reached. These were the patients with clinical features both from history and otoscopic examination suggestive of CSOM or patients who had been diagnosed already with CSOM by other doctors at the clinic or in the ward(3). Their medical records in the clinic or files in the wards concerning investigations (such as high-resolution CT scan (HRCT) of the temporal bone) done to them was assessed for acquiring data. Study objectives was well explained and those patients who consented to participate were provided with informed consent for the study and recruited in the study.

3.9 Data Collection

3.9.1 Data Collection Tool

Data was collected using a data collection tool that contained three sections.

Section A

Section A was divided into two sub-sections

I. Demographic variables

This consisted of demographic characteristics of patients with CSOM, it included; the age, sex, educational level, employment status (whether the patient is self-employed or is employed by another person/institution was regarded as employed) and whether the patient is health insured or not.

II. Clinical characteristics

Following a history of persistent or recurrent ear discharge of at least 2 weeks a specific type of CSOM was diagnosed through otoscopy where perforation of tympanic membrane at the attic was termed atticoantral type of CSOM, while tympanic membrane perforation at the pars tensa was regarded as a tubotympanic type of CSOM(21).

Risk factors for the development of complications of CSOM in adult patients that included; Prolonged symptom duration (more than 4 weeks of active ear discharge) before seeking medical attention, use of local remedies to a discharging ear, immune compromising state like diabetes mellitus, HIV and chemotherapy. For the case of sensitive information from the patient such as HIV status, it was obtained verbally by asking the patient concerning their medical history if they had been diagnosed with HIV.

Section B

This section comprised of;

Complications of CSOM that they were broadly divided into two categories that were; intracranial and extracranial complications. This was assessed based on clinical presentation of the patient together with imaging done to the patient-HRCT of the temporal bone. Extracranial complications that were assessed were mastoiditis, temporal bone/mastoid related abscesses, facial nerve paralysis, labyrinthitis, labyrinthine fistula and petrous apicitis. Intracranial complications that were assessed were; meningitis, epidural abscess, subdural empyema, intracerebral abscess and lateral sinus thrombophelebitis.

The following assessment of the participants gave aid in diagnosing for the presence of otogenic complications of CSOM.

EXTRA CRANIAL COMPLICATIONS

1. **Mastoiditis**, was be found through assessment of the mastoid cavity in an affected ear through a HRCT temporal bone looking for opacification of the mastoid air cells (36).

2. **Mastoid/Temporal bone related abscess**
    a. **Sub periosteal abscess**, post auricular tender and fluctuant swelling in patients with CSOM (59)
    b. **Bezold abscess**; pus draining into the medial wall of the mastoid process into digastric ridge resulting into suppurative collection, clinical presentation of the patient apart from fever, otalgia, otorrhea include neck swelling and torticollis sometimes with facial nerve palsy. The presence of abscess can be revealed by CT scan at the level of the neck(60)
    c. **Lucs abscess,** a sub periosteal temporal abscess in the pre auricular region that can be seen clinically as a swelling anterior to the pinna(36)
    d. **Catelli's abscess,** pus collection in the occipital region that has trickled down through the posterior belly of digastric muscle from the mastoid tip (31)**.**

e. **Zygomatic abscess,** a temporal parietal swelling due to pus from the mastoid that has eroded the root of zygomatic process. Can be confirmed by HRCT scan that will show irregular osteolytic areas that involves the posterior portion of the right zygomatic process and zygomaticotemporal junction. Other features are erosion of the superior, lateral and anterior wall of the middle ear cavity (61).

3. **Facial nerve paralysis**, clinical onset of mouth deviation accompanied with other hemifacial paralysis features such as incomplete or inability to close the eye following a history of ear discharge. Assessment of this complication in CSOM patients with above history followed a House-Brackmann classification of facial nerve dysfunction (62).
4. **Labyrinthitis,** clinical history of worsening hearing loss that could lead to severe to profound hearing loss and tinnitus, also vestibular symptoms such as severe vertigo that can be associated with ataxia and vomiting. These symptoms vary depending on being serous or suppurative labyrinthitis (46,63,64**).**
5. **Labyrinthine fistula,** clinical history of episodic vertigo or worsening disequilibrium and worsening hearing sensorineural loss and a physical finding of positive fistula test upon tragal pressure with nystagmus pointing towards the healthy side. HRCT of

temporal bone that revealed cortical thinning or a defect/lysis on the lateral wall of bony labyrinth (65)

6. **Petrositis**, clinical history of CSOM together diplopia, facial pain especially around the orbit. This complication can be confirmed by opacification of petrous air cells sometimes with bone erosion HRCT temporal bone of a patient with CSOM (66) .

INTRACRANIAL COMPLICATIONS

These complications were suspected in patients with fever, persistent headache, general body malaise, vomiting, photophobia, diplopia, blurring of vision, convulsion, neck rigidity, dysmetria, dysdiadochokinesia, aphasia etc.

1. **Meningitis**, a clinical triad of fever, nuchal rigidity, altered mental status or headache and other physical findings that are Kernig and Brudzinski signs after being done, other supporting features such as convulsion, photophobia and cranial nerve palsies were also enquired. (67).
2. **Epidural abscess,** CT scan that showed an extraxial biconvex shaped isodense or hypodense lesion with peripheral enhancement that usually do not cross the midline (68)**.**
3. **Subdural empyema,** CT scan that showed crescentic extraaxial hypodense collection with prominent, sharply etched medial rim enhancement (69)**.**
4. **Brain abscess**, CT scan that showed an outer hypodense and inner hyperdense rim (double rim sign) in the brain parenchyma commonly in the temporal lobe or cerebellum (70)
5. **Lateral sinus thrombophlebitis,** clinical history of severe headache, ear pain, picket fence fever and signs that are papilloedema and Griesinger's sign (which is tenderness and edema over the mastoid) prompted more towards its diagnosis. Radiological feature in the HRCT included a delta sign of perisinus dural enhancement and a filling defect of the lateral sinus (71,72)**.**
6.

3.9.2 Data Collection Tool Pre Testing

The data collection tool was at first pretested in a small group of adult patients with CSOM attending OPD/inpatient in order to ensure validity and consistency of the study. It was done in two weeks' time prior to the start of this study and was done in a similar manner as the main study. The tool was reviewed by ORL surgeon, and the opinions were collected. Adjustments and calibration of the data tool was done accordingly.

3.10 Data Management and Statistical Analysis

Data obtained in this study was analyzed using SPSS version 23. Continuous variables were summarized by median and standard deviations, while categorical data were summarized by percentage. Chi-square test was used for assessing association for categorical variables. Multivariate logistic regression analysis was used to determine the factors associated with development of complicated CSOM.

Determining prevalence of complicated CSOM

It was obtained by running frequency of adult people with complicated CSOM among all adult patients with CSOM.

Determining social demographic characteristics associated with complicated CSOM

It was obtained by running frequencies of age, sex, education level, employment status and health insurance among patients with CSOM. Association between social demographic factors and complicated CSOM was determined, a P value <0.05 was taken as statistically significant.

Determining clinical characteristics associated with complicated CSOM

This was obtained by running the frequencies of diabetes mellitus, HIV, cholesteatoma, duration of ear discharge before seeking medical therapy and using local remedies to a diseased ear among patients with CSOM. Association between clinical characteristics and complicated CSOM was determined, a P value <0.05 will be taken as statistically significant.

3.11 Ethical clearance

Ethical clearance was provided by the Muhimbili University of Health and Allied Sciences' Research and Publications Committee. The permission to conduct this research was given by the Research, Training and Consultancy Unit of the Muhimbili National Hospital.

Participants were provided with a formal written informed consent, in Kiswahili. Participants' confidentiality was maintained using codes and not names on the data collection tool and all filled research forms.

3.12 Limitation

Limitation

The study's short study duration and small sample size of CSOM patients made it difficult to gather sufficient information to link the complicated CSOM to plausible potential risk factors identified by other researches.

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic characteristics of the study participants

The study included 52 patients with CSOM, the youngest was 20 years old while the oldest was 76 years old. The median age was 39 (IQR 22) years, with the predominant age group being 30-39 years (26.5%), half of the patients (50%) were males with M: F being 1:1. Majority of the patients had primary school education (44.2%) and more than half of the patients had employment (63.5%) and health insurance (57.7%). Table 1

Table 1: Socio-demographic characteristics of study participants

Variables	SEX		Total
	Male	Female	
	n (%)	n (%)	n (%)
Age category (years)			
20-29	5 (41.7)	7 (58.3)	12 (23.1)
30-39	9 (64.3)	5 (35.7)	14 (26.9)
40-49	3 (37.5)	5 (62.5)	8 (15.4)
50-59	5 (55.6)	4 (44.4)	9 (17.3)
60+	4 (44.4)	5 (55.6)	9 (17.3)
Education level			
Primary school	9 (39.1)	14 (60.9)	23 (44.2)
Secondary school	10 (58.8)	7 (41.2)	16 (32.7)
College/University	7 (58.3)	5 (41.7)	12 (23.1)
Occupation			
Employment	17 (51.5)	16 (48.5)	33 (63.5)
No employment	5 (33.3)	10 (66.7)	15 (28.8)
Retired	4 (100)	0 (0)	4 (8.2)
Health Insurance			
Yes	16 (53.3)	14 (46.7)	30 (57.7)
No	10 (45.5)	12 (54.5)	22 (42.3)
TOTAL	26 (50)	26 (50)	52 (100)

4.3 Prevalence of complicated CSOM among adult patients with CSOM

The prevalence of complicated CSOM was found in 27 (51.9%) patients among 52 patients who had CSOM.

4.4 Types of complications among adult patients with CSOM

All 27 patients with complicated CSOM had extracranial complications, whereas (19%) had an additional of intracranial complication/s.

4.4.1 Extracranial complications

Mastoiditis was found in all 27 patients (100%), followed by facial nerve paralysis (22.2%) and labyrinthitis (11.1%). Figure 6

4.4.2 Intracranial complications

Meningitis (11.1%) and lateral sinus thrombophlebitis (11.1%) were the commonest complications. Figure 6

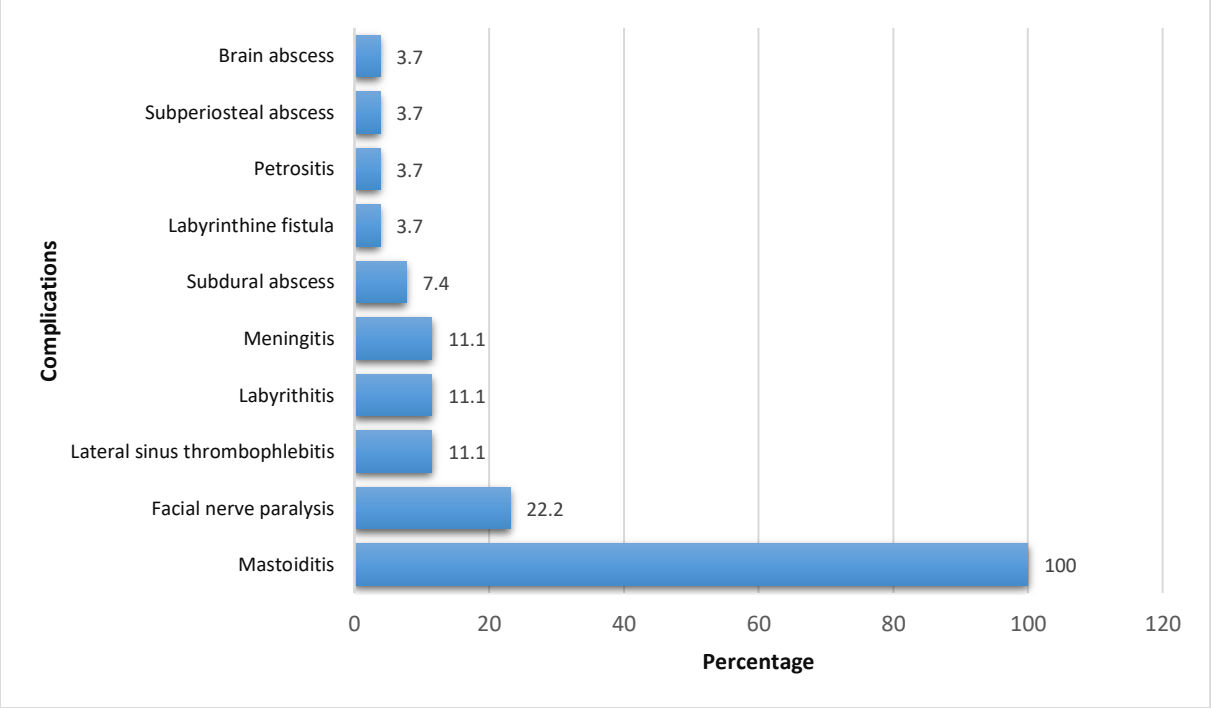


Figure 6: Proportion of each complication of CSOM

4.4.3 Distribution of complications according to the type of CSOM

Mastoiditis were more significantly observed among patients with tubotympanic type CSOM (74.1%) whereas labyrinthitis were significantly more observed among patients with atticoantral type of CSOM (100%). However, other complications were not significantly distributed between the two types of CSOM. Table 2

Table 2: Distribution of Complications according to the type of CSOM

Complications	Type of CSOM		P value
	Tubotympanic type n (%)	Atticoantral type n (%)	
Extracranial complications			
Mastoiditis	20 (74.1)	7 (25.9)	0.01
Facial nerve paralysis	4 (66.7)	2 (33.3)	0.18
Labyrinthitis	0 (0)	3 (100)	0.002
Labyrinthine fistula	0 (0)	1 (100)	1.14
Petrositis	1 (100)	0 (0)	1.00
Subperiosteal abscess	1 (100)	0 (0)	1.00
Intracranial complications			
Meningitis	3 (100)	0 (0)	1.00
Lateral sinus thrombophlebitis	3 (100)	0 (0)	1.00
Subdural abscess	2 (100)	0 (0)	1.00
Brain abscess	1 (100)	0 (0)	1.00

4.5 Factors associated with complicated CSOM

4.5.1 Sociodemographic factors among patients with complicated CSOM

The sociodemographic distribution of factors associated with complicated CSOM are presented in table 3. The results show higher proportion of complicated CSOM in patients who were 60 years and older (66.7%), male patients (61.5%), those patients who had secondary education (58.8%), retired (75%) and those who did not have health insurance (59.1%) however their distribution were not statistically significant. Table 3

Table 3: Sociodemographic factors among patients with complicated CSOM

Variables	Complicated CSOM		P value
	Yes n (%)	No n (%)	
Age category (years)			
20-29	4 (33.3)	8 (66.7)	
30-39	8 (57.1)	6 (42.9)	
40-49	4 (50.0)	4 (50.0)	0.62
50-59	5 (55.6)	4 (44.4)	
60+	6 (66.7)	3 (33.3)	
Sex			
Male	16 (61.5)	10 (38.5)	0.16
Female	11 (42.3)	15 (57.7)	
Education level			
Primary school	11 (47.8)	12 (52.2)	
Secondary school	10 (58.8)	7 (41.2)	0.78
College/ university	6 (50.0)	6 (50.0)	
Occupation			
Employment	16 (48.5)	17 (51.5)	
No employment	8 (53.3)	7 (46.7)	0.60
Retired	3 (75.0)	1 (25.0)	
Health insurance			
Yes	14 (46.7)	16 (53.3)	0.38
No	13 (59.1)	9 (40.9)	

4.5.2 Clinical characteristics among patients with complicated CSOM

The results show significant higher proportion of complicated CSOM in patients with atticoantral type (100%) and those who used local remedies to the discharging ear (72.7%). Table 4

Table 4: Clinical characteristics among patients with complicated CSOM

Variables	Complicated CSOM		P value
	Yes n (%)	No n (%)	
Type of CSOM			
Atticoantral type	7 (100.0)	0 (0.0)	
Tubotympanic type	20 (44.4)	25 (55.6)	0.01
Duration before medical therapy			
≤ 4 weeks	23 (53.5)	20 (46.5)	
> 4 weeks	4 (44.4)	5 (55.6)	0.72
Local remedies to the ear			
Yes	16 (72.7)	6 (27.3)	0.01
No	11 (36.7)	19 (63.3)	
HIV			
Yes	2 (50.0)	2 (50.0)	
No	25 (52.1)	23 (47.9)	1.00
Diabetes mellitus			
Yes	5 (71.4)	2 (28.6)	0.42
No	22 (48.9)	23 (51.1)	

4.6 Association of the factors for complicated CSOM

To identify independent factors associated with CSOM complications, binary logistic regression analysis was performed. Factors including sex, age, education, health insurance, occupation, duration before medical therapy, application of local remedies to a discharging ear, HIV and diabetes mellitus were included in the model. The model identified that patients who were using

local remedies to a discharging ear were 5.2 times more likely to develop CSOM complications as compared to those who did not use local remedies to a discharging ear. Table 5

Table 5: Logistic regression model for factors associated with complicated CSOM

Variable	Univariate		Multivariate	
	cOR (95% CI)	p value	aOR (95% CI)	p value
Age category (years)				
20-29	Ref			
30-39	0.38 (0.08-1.86)	0.23		
40-49	0.50 (0.08-3.13)	0.46		
50-59	0.40 (0.07-2.37)	0.31		
60+	0.25(0.04-1.56)	0.14		
Sex				
Male	2.18 (0.72-6.61)	0.168	2.23 (0.66-7.52)	0.196
Female	Ref			
Education				
Primary	0.91 (0.22-3.70)	0.903		
Secondary	1.4 (0.32-6.32)	0.638		
College/university	Ref			
Health insurance				
Yes	Ref	0.377		
No	1.65 (0.54-5.01)			
Occupation				
No employment	1.21 (0.36-4.12)	0.756		
Retired	3.18 (0.29-36.89)	0.336		
Employment	Ref			
Duration before medical therapy				
> 4 weeks	0.69 (0.16-2.95)	0.623		
≤ 4 weeks	Ref			
Local Remedies Use				
Yes	4.61 (1.39-15.24)	0.012	5.21 (1.48-18.35)	0.010
No	Ref			
HIV				
Yes	0.92 (0.12-7.07)	0.936		
No	Ref			
Diabetes Mellitus				
Yes	2.61 (0.46-14.9)	0.279	3.94 (0.61-25.07)	0.147
No	Ref			

CHAPTER FIVE

5.0 DISCUSSION

Our study recruited 52 adult patients of CSOM, with male to female ratio 1:1, majority of the patients were in the age group of 30 to 39 years, most patients had primary school education, health insurance and they had employment.

5.1 Prevalence of complicated CSOM

Prior to the discovery of antibiotics, CSOM complications were more evident; however, with the advancement of antibiotics and the development of microsurgical methods for CSOM treatment, these complications sharply decreased. Unfortunately, they have been shown to exist especially in the developing countries like in our study where its prevalence was found to be 51.9%, however this observation was slightly higher compared to other studies like Mostafa et al in Egypt where the prevalence was found to be 12.54% (51).

Similar to other studies, extracranial complications dominated by affecting 81% of the patients while 19% had both extracranial and intracranial complications. A study on complications of CSOM done in New Guinea that included 70 patients who presented with the complications of CSOM at the tertiary hospital, found out 56% of patients had exclusive extracranial complications, 11% had only intracranial complications and 33% had both(30). Dongol et al found that among 164 patients with complications of otitis media during a 5 year retrospective study (2015-2020) in Nepal 94.5% had extracranial complications(28). In another series of a 10 years study in Turkey by Yorgancalar et al identified 121 patients with complicated CSOM, majority (47.1%) of the patients had extracranial complications, however it showed difference from our study where 30.6% of the patients had intracranial complications and the least were patients with both groups of complications were they constituted 22.3% (52). Difference was also noted from another study by Osma et al. found among 93 patients with complicated CSOM 59% had intracranial complications whereas 41% had extracranial complications (73).

5.2 Complications of CSOM

The most common extracranial complication was mastoiditis that was followed by facial nerve paralysis. These findings were in keeping with studies done in Nepal by Dongol et al the most common ones were mastoid complications that was followed by facial nerve paralysis and labyrinthitis (28). Osmo et al also reported the similar results where mastoid compilations were the most common presenting in more than half of the patients (64.1%) with extracranial complications of CSOM, that was followed by facial nerve paralysis and labyrinthitis (73).

The findings from our study in a descending order of the intracranial complications were meningitis and lateral sinus thrombophlebitis in equal proportion, subdural abscess and the least was brain abscess in the ipsilateral temporal lobe. This observation was similar to the findings from Dubey et al where meningitis was the most common intracranial complication, followed by lateral sinus thrombophlebitis and the least was temporal lobe abscess in one patient (30). Osmo et al also had closely resemblance where meningitis dominated by 71.9% out of the intracranial complications among 93 patients with complicated CSOM (73).

5.3 Factors associated with complicated CSOM

Demographic characteristics

The majority of our patients with complicated CSOM were elderly, based on the age distribution, contrary to other studies where these complications were more frequently observed in the young and middle-aged adults (29,32,73). Males were more affected with complicated CSOM with M:F 1.5:1, comparable results were found in several other studies (30,73). However, unlike other studies such as by Mushi et al., our study's patient demographics did not show a statistically significant association with complicated CSOM (41).

Clinical characteristics

Type of CSOM

Similar to other studies patients with atticoantral type have been shown to have high proportion of complications due to bone erosion from the associated cholesteatoma that pave a way for the spread of infection to the surrounding vital structures(38). Patient with Atticoantral type of CSOM were more likely (100%) to present with complications in our study. Furthermore, all atticoantral CSOM patients had labyrinthitis (100%) with comparable findings to a retrospective research on chronic suppurative otitis media consequences from Turkey (52). Elsewhere most of the complications are associated with atticoantral type of CSOM however in our study its was different that could be attributed to differences in sample size.

Local remedies to the diseased ear

A major finding from our study is that a sizable portion of respondents (42%) said they have been treating their discharging ears with home or local remedies. We found out that those who applied local remedies to their discharging ears had a five-fold increased risk of developing complicated CSOM. The most often reported types of these cures included, oil derived primarily from chicken soup, leaf paste, water and marijuana leaves, some used local remedies only while others reported using both local remedies at the same times with topical medications that they were prescribed from health care facilities. This could be explained both by false attitude of the patients as well as either lack or not adhering to proper health education from healthcare providers concerning ear care in patients with CSOM ears apart from medications.

Previous studies have demonstrated this type of healthcare-seeking behavior in relation to an ear discharge, primarily from underdeveloped nations. A study that aimed to investigate the knowledge, attitudes, beliefs and practices of both affected and unaffected residents of Pokhara, Nepal, regarding CSOM and hearing impairment, found out that 42 % of the participants used home remedies as treatment for CSOM, and the remedies that they used were oil, leaf paste, water and food items (40). Okafor et al. conducted a study on chronic discharging ear in Nigeria and discovered that all patients with complicated CSOM had persistent aural discharge. This

was partially caused by partly patients' need to travel long distances and partially by the general public's belief that visiting a hospital should only be done as a last resort after trying other non-hospital treatments. (43).

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The prevalence of complicated CSOM at MNH was 51.9% that was higher as compared to studies from other parts of the world and most patients had extracranial complications. Males, patients with 60 years and older and those who did not have health insurance had more proportion of complicated CSOM. Patients with atticoantral type of CSOM and those who were using local remedies to the discharging ears had significant higher proportion of complicated CSOM. The use of local remedies commonly they used chicken oil, was found to be an independent factor contributing to the development of complications from CSOM.

6.2 Recommendations

The results from this study provide valuable insight on the necessity of promoting healthcare education to both those who experience CSOM and the society in general as poor health seeking practice has been significantly associated with complicated CSOM.

Additionally, we advise more research on CSOM with a larger sample size to gain more understanding of the scope of other factors linked to development of its complications so that early intervention can be implemented to enhance patient care.

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APPENDECIES

Appendix I: Informed Consent Form - English Version

Consent to participate in the study titled **"PREVALENCE AND FACTORS ASSOCIATED WITH CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AMONG PATIENTS AT MUHIMBILI NATIONAL HOSPITAL"**

Study number…….

Hospital registration number …… **Date**……

My Name is Dr Julius Kessy, a postgraduate student doing masters of medicine in Otorhinolaryngology (MMED-ORL) at Muhimbili University of Health and Allied Sciences. I am conducting a research study on "**Prevalence and factors associated with chronic suppurative otitis media complications among patients at Muhimbili national hospital".**

I hereby request your participation.

Purpose of the study

To determine the prevalence and factors associated with chronic suppurative otitis media complications among patients at MNH and is also a partial fulfillment for the degree of masters of medicine in ORL MUHAS.

How to participate

If you are willing and ready to participate in this study you will have to sign this consent form.

Confidentiality

Information that you will give will be kept confidential and they will be used solely for research purposes.

Costs

Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will not affect in any way to your rights to care and treatment.

Risk

No risk is expected to arise from participating in this study

Benefits

Your participation will help to determine the prevalence and factors associated with chronic suppurative otitis media complications among patients at MNH so as to improve quality of care given to these patients.

Whom to contact:

If you have any questions or concerns during the study, you may contact the following:

Principal Investigator: Dr. Julius Kessy. P.O. Box 65001 Dar es Salaam. Mobile phone: +255 754865610.

Research supervisors: Dr Aveline Kahinga. Mobile phone: +255 764 608 917 and Dr Jimmy Ernest Mobile phone: +255 686 346 515

OR

In case you need any information concerning your rights as a participant please contact

Dr. Nahiya, Director of Research Publication and Innovation (DRPI) of MUHAS, P.O. Box 65001, Dar es Salaam, Tanzania. Tel: +255-022-2152489, Fax: +255-022-2152489, Email: drp.muhas.ac.tz.

DECLARATION.

I ……. have read the contents in this form and understood. My questions have been answered and I agree to participate in this study.

Signature of a Participant----------

Phone number……

Signature of a Researcher/Research assistant…….

Appendix II: Informed consent form - Swahili version

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA TAFITI NA UCHAPISHAJI

Idhini ya kushiriki kwenye utafiti Namba ya dodoso…….

Namba ya hosipitali……. Tarehe…….

Kwa majina naitwa Dr Julius Kessy, mwanafunzi wa shahada ya uzamili ya udaktari idara ya masikio,pua na koo katika chuo kikuu cha afya na sayansi shirikishi Muhimbili.

Lengo la utafiti

Kutafuta ukubwa wa tatizo na visababishi vinavopelekea kupata madhara yatokanayo na ugonjwa wa muda mrefu wa kutoka usaha kwenye sikio katika wagonjwa wanaopata huduma katika hospitali ya taifa ya Muhimbili.

Washiriki

Endapo umeridhia au upo tayari kushiriki katika utafiti huu utahitajika kuweka sahihi ya kuidhinisha katika fomu hii.

Usiri

Taarifa utakazozititoa zitatumika kwa uangalifu mkubwa na kwa lengo la utafiti huu tu.

Gharama

Hakutakua na gharama yoyote katika ushiriki wako kwenye utafiti huu na unaruhusiwa kusitisha ushiriki wako muda wowote ule

Madhara ya utafiti

Hakutakua na madhara yoyote yanayotarajiwa kwa washiriki wa utafiti huu

Faida ya utafiti

Kushiriki kwako kutasaidia kujua ukubwa wa tatizo, kuboresha matibabu stahiki katika kuzuia madhara yatokanayo na tatizo la kutoka na usaha sikioni katika hospital ya taifa Muhimbili.

Mawasiliano

Ikitokea kuna changamoto yoyote au maswali unaweza kuwasiliana na wafuatao

Dr. Julius Kessy. Sanduku la posta 65001 Dar es Salaam. Namba ya simu: +255 754865610.

Wasimamizi wa utafiti: Dr Aveline Kahinga. namba ya simu: +255 764 608 917 pamoja na Dr Jimmy Ernest namba ya simu: +255 686 346 515

Ikitokea kuna suala lolote linalohusu mwenendo wa kimaadili wa utafiti unaweza kuwasiliana na mwenyekiti wa kamati ya tafiti na machapisho wa chuo kikuu cha afya na sayansi shirikishi Muhimbili. Dr. Nahiya sanduku la posta 65001, Dar es Salaam, Tanzania. Namba ya simu: +255-022-2152489, barua pepe: drp.muhas.ac.tz.

Nakubali kwa hiari yangu kwamba mimi……nimesoma na kuelezwa kwa undani na maswali yangu yamejibiwa kwa ufafanuzi na nimeridhia kushiriki katika utafiti huu.

Siahihi ya mshiriki ……

Namba ya simu ya mshiriki…….

Sahihi ya mtafiti mkuu au msaidizi wa utafiti ……..

Appendix 1II: Data Collection Sheet.

TITLE: PREVALENCE AND FACTORS ASSOCIATED WITH CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AMONG ADULT PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

Section A		
Patient Particulars		
Study Number		
Socio-demographic characteristics		
Age	In years	
Sex	1: Male 2: Female	
Education Level	1: No formal education 2: Primary school 3: Secondary school 4: college/university	
Employment status	1: Has employment 2: No employment 3: Retired	
Health insured	1. Yes 2. No	
Clinical characteristics of the patient		

Type of CSOM/Perforation	1: Atticoantral type 2: Tubotympanic type	
Duration of ear discharge before seeking medical attention	1.≤ 4 week 2. >4 weeks	
Traditional/local remedies to the discharging ear	1: Yes 2: No	
Cancer on chemotherapy/Immunosuppressant	1: Yes 2: No	
Diagnosed with HIV	1: Yes 2: No	
Diagnosed with diabetes mellitus	1: Yes 2: No	
Extra cranial complications of CSOM		
MASTOIDITIS (HRCT-Opacification of the mastoid air cells with/without loss of definition bony septae that define the mastoid air cells)	1: Yes 2: No	
SUBPERIOSTEAL ABSCESS (Hyperemic post auricular (mastoid region) tender and fluctuant swelling (pus))	1: Yes 2: No	
BEZOLD ABSCESS (Swelling and tenderness below the mastoid process and under the sternocleidomastoid	1: Yes 2: No	

muscle)		
LUCS ABSCESS (Preauricular tender and fluctuant facial swelling (pus))	1: Yes 2: No	
CITELLI ABSCESS (Tender fluctuant swelling (Pus collection) in the occipital region)	1: Yes 2: No	
ZYGOMATIC ABSCESS (Temporal parietal swelling Confirmed-HRCT; Irregular osteolytic areas that involves the posterior portion of the right zygomatic process and zygomaticotemporal junction)	1: Yes 2: No	
FACIAL NERVE PARALYSIS (Both incomplete eye closure and mouth deviation)	1: Yes 2: No	
LABYRINTHITIS (Severe–profoundSNHL/MHL,persistent vertigo)	1: Yes 2: No	
LABYRINTHINE FISTULA (Episodic vertigo, positive fistula test & HRCT-Cortical thinning or a defect/lysis on the lateral wall of bony labyrinth)	1: Yes 2: No	
PETROSITIS (HRCT-Opacification of petrous air cells	1: Yes 2: No	

sometimes with/without bone erosion)		
Intracranial complications of CSOM		
MENINGITIS (Fever Altered mental status Headache Convulsion Nuchal rigidity Kerning sign (≥3 features)	1: Yes (>2) 2: No	
EPIDURAL ABSCESS (CT scan - An extraxial biconvex shaped isodense or hypodense lesion with peripheral enhancement that usually do not cross the midline)	1: Yes 2: No	
SUBDURAL ABSCESS (CT scan - A crescentic extraaxial hypo dense collection with prominent, sharply etched medial rim enhancement)	1: Yes 2: No	
BRAIN ABSCESS (CT- Outer hypodense and inner hyperdense rim (double rim sign) in the brain parenchyma (intraaxial) commonly in the temporal lobe or cerebellum)	1: Temporal lobe 2: Cerebellum 3: No	

LATERAL-SINUS THROMBOPHLEBITIS HRCT: Delta sign - enhancement and filling defect of the lateral sinus (outline a triangular filling defect)	1: Yes 2: No	

Appendix IV: Ethical Clearance Letter

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1900 Date: 08/09/2023

MUHAS-REC-09-2023-1900
JULIUS KESSY
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE AND FACTORS ASSOCIATED WITH CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AMONG PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

Reference is made to the above heading,

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 08/09/2023
EXPIRATION DATE OF APPROVAL: 08/09/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this cross sectional study is to determine the prevalence and factors associated with chronic suppurative otitis media complications among patients at Muhimbili national hospital

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee



Appendix V: Introduction Letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.178/2021

18th September, 2023

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is Julius Kessy with Reg. No. HD/MUH/T.178/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Otorhinolaryngology.

As part of his studies, he will be doing an elective research titled: "**Prevalence and Factors Associated with Chronic Suppurative Otitis Media Complications Among Patients at Muhimbili National Hospital."** he is being supervised by Jimmy Ernest from MNH and Aveline Kahinga from MUHAS.

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Julius Kessy

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix VI: Permission Letter

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/523 Date: 11th October, 2023

Head Department,

- ENT
- Surgery

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Julius Kessy**
Title	**"Prevalence and Factors Associated with Chronic Suppurative Otits Media Complications Among Patients at MNH"**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Jimmy Ernest (MUHAS)
Co - Supervisor	Dr. Aveline Kahinga (MNH)
Period	11th October, 2023 to 30th March, 2024

Approval has been granted to the above mentioned student to collect data at MNH. **A final study report should be lodged with Clinical Research, Training and Consultancy Unit.** Dissemination of study findings to MNH stakeholders shall be overseen by Dr. Aveline Kahinga (MNH) Co – supervisor.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Yours Sincerely,

Dr. Jessie Mbwambo
Head of Clinical Research, Training and Consultancy Unit

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT * MUHIMBILI NATIONAL HOSPITAL * P. O. Box 65000 DAR-ES-SALAAM

c.c DSS
c.c Dr. Aveline Kahinga
c.c **Julius Kessy**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz

PREVALENCE AND FACTORS ASSOCIATED WITH CHRONIC SUPPURATIVE OTITIS MEDIA COMPLICATIONS AMONG ADULT PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

ORIGINALITY REPORT

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