



SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE
DEPARTMENT OF OTORHINOLARYNGOLOGY, HEAD AND NECK
SURGERY

EPIDEMIOLOGICAL AND CLINICAL PROFILE OF CHRONIC
SUPPURATIVE OTITIS MEDIA PATIENTS AT SAINT PAUL'S HOSPITAL
MILLENNIUM MEDICAL COLLEGE

A DESCRIPTIVE CROSS-SECTIONAL STUDY

BY: ZINABU MOLLA (MD)

A THESIS RESEARCH SUBMITTED TO THE DEPARTMENT OF
OTORHINOLARYNGOLOGY, HEAD AND NECK SURGERY, SAINT
PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE IN PARTIAL
FULFILLMENT OF THE REQUIREMENTS FOR THE CERTIFICATE OF
SPECIALITY IN OTORHINOLARYNGOLOGY, HEAD AND NECK
SURGERY

JUNE, 2019

ADDIS ABABA, ETHIOPIA



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Advisors' Approval Sheet

This is to certify that the thesis entitled **Epidemiological and Clinical Profile of Chronic Suppurative Otitis Media Patients at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia** is submitted in partial fulfillment of the requirements for the degree of MSc with specialization in **Otorhinolaryngology, Head and Neck Surgery** to the Graduate Program of Saint Paul's Hospital Millennium Medical College and has been carried out by **Dr.Zinabu Molla**, ID No: **MGSRE/006/08** under my supervision. Therefore, I recommend that the student has fulfilled the requirements and hence hereby can submit the thesis to the Department.

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Name of Co advisor	Signature	Date

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Acronyms and Abbreviations

ASOM	Acute Suppurative otitis media
CI	Confidence Interval
CSOM	Chronic suppurative otitis media
CT	Computerized tomography
CHL	Conductive hearing loss
DC	Data collectors
Dr.	Doctor
ENT	Ear Nose and Throat
ET	Eustachian Tube
ETB	Ethiopian Birr
EAC	External Auditory Canal
E. coli	<i>Escherichia coli</i>
FB	Foreign body
GERD	Gastroesophageal reflux Disease
HIV	Human Immunodeficiency Virus
MHL	Mixed hearing loss
MRI	Magnetic resonance imaging
MRSA	Methicillin-Resistant Staphylococcus Aureus
OM	Otitis Media
OME	Otitis media with effusion
OPD	Outpatient department
ORL-HNS	Otorhinolaryngology, Head and Neck Surgery
PI	Principal investigator
SES	Socioeconomic Status
SNHL	Sensorineural hearing loss
SPHMMC	Saint Paul's Hospital Millennium Medical College
SPSS	Statistical Package for Social Sciences
St	Statistician
TM	Tympanic membrane
URI	Upper Respiratory Tract Infection
WHO	World Health Organization

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Abstract

Background: Chronic suppurative otitis media (CSOM) remains one of the most common childhood chronic infectious diseases worldwide, affecting diverse racial and cultural groups both in developing and industrialized countries. It involves considerable morbidity and can cause extra- and intra-cranial complications if not diagnosed and treated at earliest.

Objectives: To describe the epidemiological and clinical profile of chronic suppurative otitis media patients at Saint Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa, Ethiopia.

Methods: All the patients who meet the inclusion criteria were included in the study. And informed consent was taken from all the patients with ear discharge from otitis media, having 02 weeks or more duration of unilateral or bilateral ear discharge, and who attended the Ear, Nose and Throat (ENT) outpatient department clinics of SPHMMC. Data was collected in three months period from February 1st, 2019 through April 30th, 2019 using a structured questionnaire and the results were added their proforma and analyzed.

Results: A total of 186 CSOM patients were included in the study and no sex preponderance was seen with age ranging from 07 months to 77 years. Most patients, 72.0% of them were below the age of 30 years and 82.8% of the patients stayed at urban areas and students accounted for 30.1% of the patients. As to the first time visit of patients, 12.5% of the rural residents and 9.0% of the urban residents visited traditional healers. More than half of the patients (52.0%) visited non ENT specialist during their first visit. Hearing loss complaint was reported in 83.3% of the patients. Tubotympanic type tympanic membrane perforation was the commonest (76.0%) and 95.0% of the patients had subtotal perforation. Three quarter (76.0%) of the patients had conductive hearing loss and moderate degree of hearing loss was the most common (51.0%).

Conclusion and Recommendation: Among the CSOM cases, the younger segment of the population is the most affected. And the patients presented with long history of the disease, with median [IQR] duration of ear discharge of 11 [11±18] years and ranging from 01 month to 60 years. Thus, it is important to spread awareness among people for discharging ear for its early diagnosis and management. Sensorineural component of hearing loss was common in CSOM patients which affects their surgical out come on hearing. Thus, patients should be strictly counseled on the outcomes before surgery.

Keywords: Chronic suppurative otitis media, discharge, epidemiology of otitis media

Chapter One: INTRODUCTION

1.1 Background

Chronic Suppurative Otitis Media (CSOM) is chronic inflammation of the middle ear cleft (Eustachian tube, middle ear, and mastoid cavity) which presents with recurrent ear discharge or Otorrhea through a tympanic membrane perforation [1]. The World Health Organization (WHO) definition for CSOM requires only two weeks of Otorrhea [1].

Otitis media (OM) is a major health problem and occurs with a high incidence and prevalence in both developed and developing countries [2, 3]. It may be acute, chronic or recurrent. It can be suppurative or non-suppurative: Acute suppurative otitis media (ASOM) is a common childhood illness and can progress to chronic supportive otitis media (CSOM) [4].

Studies in United States, United Kingdom, Japan, India, Ghana, Sierra-Leone, Zambia, Kenia and Nigeria revealed some group of organisms that have been recorded in CSOM. The common causative organism may be aerobic (e.g. *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Proteus mirabilis*, *Klebsiella* species) or anaerobic (e.g. *Bacteroides*, *Peptostreptococcus*, *Propionibacterium*) [5, 6, 7, 8,] or mixed organisms.

The disease may begin in childhood [9] or as a complication of untreated or inadequately treated acute suppurative otitis media [10] or may be chronic from onset [11]. The bacteria may gain entry to the middle ear through a chronic perforation [1]. Children tend to have higher predisposition to ear infection than adults because anatomy of the eustachian tube in children permits easier access of organism through the nasopharynx [12].

Persistent or chronic types of the disease can lead to substantial hearing loss and negatively affect learning ability and educational accomplishment. ASOM is diagnosed in patients with acute onset, existence of middle ear effusion, physical sign of middle ear inflammation, and symptoms such as pain, irritability, or fever. ASOM is commonly a complication of Eustachian tube dysfunction that happens during a viral upper respiratory tract infection (URI).

The aims of managing the chronic discharging ear are early detection and timely, appropriate intervention to eradicate the disease permanently or to reduce its effects (i.e., ear discharge, hearing loss, and other complications) if eradication is not possible. It's therefore so imperative to know the epidemiologic distribution and the early clinical manifestation of the disease to address its consequences and to help in designing future otitis media prevention and control strategies in the country.

1.2 Statement of the problem

Otitis media is a serious healthcare concern worldwide, not only because of the distress it causes to the patient and their family but also because of the substantial economic burden it imposes on the health care system. CSOM is one of the common ear infections which are more reported from rural population and lower socio economic status group [13, 14]. It is a chronic infection of middle ear which can lead to deafness and even death if poorly treated or left untreated.

Poorly treated or untreated CSOM can lead to many complications like mastoiditis, facial nerve paralysis, labyrinthitis, irreversible hearing loss, meningitis, extradural abscess, subdural abscess and brain abscesses. It constitutes a major cause of hearing disability in developing countries and subsequently has a profound effect on language development, academic performance and psychosocial interaction.

Due to its many serious complications and its persistent nature, CSOM is a significant health problem at an individual, community and national levels. It constitutes a major cause of hearing disability in developing countries and subsequently has a profound effect on language development, academic performance and psychosocial interaction. It is, ultimately, a financial burden at an individual, community and national level to which Ethiopia is no exception.

Studies are showing that CSOM is known to happen after neglected or inadequately treated acute suppurative otitis media and hence it is easily preventable disease if optimally treated from the very beginning. Unfortunately, we as a nation don't have any domestic studies showing the epidemiology and real burden of the disease and our treatment strategy is not pragmatic but simply the extrapolation of western studies. And this makes it difficult to design policies and strategies to combat the disease reasonably.

It was therefore important to conduct a study focused on the epidemiology and clinical profile of patients with CSOM at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia, where such a study has not been done before and this will ultimately be used to guide the formulation of rational prevention and treatment protocols of CSOM and thus prevent the problems highlighted above that stem from CSOM.

1.3 Significance of the study

Most approaches to treatment of CSOM have been unsatisfactory owing to variations in pattern of the disease in different places of the world. This is dependent on different factors that include climatic conditions, prior use of antibiotics, and patient population [15]. There is limitation of knowledge about CSOM and its treatment among Patients and health care workers, which ultimately results in CSOM treatment failure, intra cranial and extra cranial complications.

By conducting this study, we will identify the victims of CSOM in the population by age, sex, religion, residence etc...and their medical seeking behavior for it. The real burden of the disease on the day to day living of the people can be grossly implicated after completing the study.

This study will therefore help to guide policy makers, program managers and other responsible stake holders to formulate rational prevention and treatment strategies of CSOM. It will path a way as a preliminary study to upcoming researchers and spread awareness among people for discharging ear for its early diagnosis and management to prevent the disabling complications of CSOM.

Chapter Two: LITERATURE REVIEW

2.1 Disease burden of CSOM

Up to date there is no pan national study conducted on chronic suppurative otitis media in Ethiopia. CSOM is a very common condition, affecting approximately 11% of the globe's population each year – over 700 million people. The majority of these are children, accounting for more than half of all cases. 31 million patients affected by acute otitis media will go on to develop chronic suppurative otitis media, including more than 7 million children each year. Alarming, more than 50% of those people affected by chronic suppurative otitis media may develop hearing loss, a figure close to 0.3% of the global population. All of these figures emphasize the importance of early recognition and treatment for those affected, especially given the conversion rate of acute otitis media to chronic suppurative otitis media [16].

CSOM accounts for 28 000 deaths and a Disease burden of over 2 million Disability adjusted Life Years (DALYs). Countries (developing countries) in the South-east Asia and Western Pacific regions, Africa, and several ethnic minorities in the Pacific Rim bear Over 90% of the burden [1].

The WHO estimates that, in Africa, over 2.4 million people have CSOM, accounting for almost 4% of the global CSOM burden. Using higher prevalence rates, it has been estimated that up to 25 million people in Africa have CSOM, 50% of whom may have hearing impairment [1].

CSOM most often occurs in the first 5 years of life [17]. It is common in children with craniofacial anomalies. CSOM generally has equal distribution between males and females. Socio-economic factors such as poor living conditions and overcrowding, poor hygiene and nutrition have been suggested as a basis for the widespread prevalence of chronic suppurative otitis media in the developing countries [1, 17]

2.2 Epidemiological and clinical profile of CSOM

In a case series of 123 patients by Gupta et al in 2016 on clinical and epidemiological profile of chronic suppurative otitis media (CSOM) at a tertiary care center India [18], Male preponderance was seen with age ranging from 1 year to 70 years.

Most patients 45(36.59 %) belong to the age group of 10–20 years. Most patients belong to poor socioeconomic status (SES class IV, V comprise more than three-fourth of patients). Most of the patients (81.30%) visited to an ENT specialist for the first time. Most of the patients belonged to rural background (65.04%). Bilateral CSOM was less frequent (only 17.07%). Safe CSOM was more common (89.43%) as compared to cases with unsafe CSOM (10.57%). Hearing complaints were present in 52.85 % cases. Mucopurulent discharge was seen in 61.8% of the cases followed by purulent discharge (37.4%) cases and mucoid discharge (0.8%). Left ear was found to be affected most (46.34%) followed by right ear (36.59%) while bilateral disease was seen in only 17.07% cases. As per size of perforation, medium-sized perforation was most common (i.e., 36.8%) followed by large 30.56%, small 18.75%, attic 6.94%; subtotal 4.17% and total 2.78%. These results were comparable with study conducted by Ilechukwu GC et al in Nigeria.

A retrospective study conducted in a tertiary care medical college hospital in India by dubey et al in 2018 [19] on clinical profile and management of patients with chronic suppurative otitis media over a period of 5 years by including 528 patients was done and it showed majority of patients were among the age group 21–30 years, 193(36.6%). 18 patients (3.4%) below 10 years of age were affected by Unsafe CSOM. 225(42.61%) cases were male and 303 (57.39%) were females. Female to male ratio was 1.34:1. 97(81%) patients had unsafe CSOM without any complications. Unsafe CSOM with complications like mastoid abscess was seen in 10% of cases, meningitis was seen in 4% of cases, cerebellar abscess was seen in 3.3% of cases, sigmoid sinus thrombosis was seen in 1.6% of cases. The results were in contrast to the ones obtained by Gupta et al with regard to the sex preponderance and the type of CSOM in the same country.

In a prospective study in Nigeria by Ilechukwu GC et al in 2006 [20], 100 children with CSOM were examined and the age range of the 100 patients recruited into this study was from 1 month (0.08 year) to 17 years (median 3 years). The mean age was 4.8 years (standard deviation 4.55). There were 53 males (53%) and 47 females (47%) with a male: female ratio of 1.13:1. Children aged between 1 month and 5 years accounted for 68/100 (68%) of the study population while 32/100 (32%) were between 6 years and 17 years. Twenty-two percent (22.0%) of the 100 patients were in the second year of life and 19.0% in their first. Twenty-five of 100 (25.0%) subjects were from the upper socio-economic class, whereas 24/100 (24.0%) and 51/100 (51.0%) subjects were from the middle and lower socio-economic classes respectively. This portends an important consideration to made due emphasis to the people with lower socio-economic classes.

A study by Deviana et al in 2016 in Indonesia [21] on 208 CSOM patients showed that 54,84% of patients were female and 45,16% of patients were male. The majority of patients were among the age group 21-30 years (24, 73%). The majority pattern of hearing loss was conductive hearing loss (59%), followed by mixed hearing loss (27%) and sensorineural hearing loss (8%). 5% of cases had normal hearing. Most of the CSOM tubotympanic type cases had moderate (34,75%) and mild conductive hearing loss (19,68%), whereas most of the CSOM atticoantral type cases had moderately-severe conductive hearing loss (22,03%). CSOM was more common in one ear/unilateral (67,2%) than both ears/bilateral (32,8%), CSOM tubotympanic type was found in 188 ears (76,11%) and CSOM atticoantral type (with cholesteatoma) was found in 59 ears (23,89%). Most type of perforation in CSOM cases was central perforation (40,08%). In CSOM tubotympanic type, most cases had central (51,6%) and subtotal (25%) perforation. In CSOM atticoantral type, most cases had total (47,46%) and attic (42,73%) perforation. These results were comparable with the study conducted by Handi PS et al in 2018 in India with regard to age and sex distribution of CSOM.

A study by Kumar, *et al.* in India [22], 50 patients aged 15-60 years with CSOM tubotympanic type showed that 92.18% of patients had conductive hearing loss and 7.82% of patients had sensorineural hearing loss. Most of the hearing losses were in range of 26-40 dB in 50% of patients and between 41 and 55 dB in 42.19% of patients. These results were comparable with the study conducted by Deviana et al in 2016 in Indonesia in the pattern of the type of hearing loss.

A prospective study by Handi PS et al in 2018 in India [23] on Evaluation of hearing loss by pure tone audiometry in 50 chronic suppurative otitis media patients showed that 23 were male and 27 were female patients with age ranging from 10 years to 64 years. Most [17 (34%)] of these patients were in 11 to 20 age group. 41 patients (82%) were in the age range of 11 to 40 years. 23 patients had bilateral hearing loss (46 ears), 15 patients had hearing loss in left ear (15 ears) and 12 patients had hearing loss in right ear (12 ears). Most of the ears [61 ears (83%)] had mild to moderate hearing loss. Only one ear showed severe hearing loss. These results were comparable with the study conducted in India by dubey et al in 2018 with regard to age and sex distribution of CSOM.

2.3. Basics of CSOM

2.3.1. Anatomy and Physiology of middle ear cleft

The middle ear cleft is made up of the middle ear, Eustachian tube (ET), mastoid air cells and antrum [24, 25]. The middle ear cavity is an irregular air filled space that contains ossicles (malleus, incus, and stapes) which are important in sound transformation transmission, and amplification [26]. Middle ear, while offering a conductive pathway for sound transmission, functions as an impedance-matching device by coupling the low impedance of air to the high impedance of the fluid-filled cochlea [26].

The Eustachian tube is a narrow air pressure equalizing tube connecting the middle ear laterally to the nasopharynx. Its functions includes pressure regulation (ventilation) that equilibrates middle ear air pressure with atmospheric air pressure [25], protection of the middle ear from nasopharyngeal sound pressure and secretions, and clearance of secretions produced within middle ear into the nasopharynx which is provided by the mucociliary system of the ET. The mastoid bone contains air cells, antrum and additus. The middle ear cleft is related to the temporal lobe of the brain superiorly, the sigmoid sinus posteromedially, the inner ear medially, the external ear laterally, and the internal jugular vein inferiorly [24].

2.3.2 Pathogenesis and Risk factors for CSOM

The pathogenesis of CSOM is multifactorial with factors such as Eustachian tube dysfunction, genetic predisposition, and environmental factors playing a role [27]. A dysfunctional and structurally immature Eustachian tube (ET) is the most important factor in the pathogenesis of otitis media. Negative middle-ear pressure, resulting from ET dysfunction, causes an influx of bacteria and viruses from the nasopharynx when the ET opens [28]. Infants and young children are especially at risk for reflux (containing bacteria and viruses) into the middle ear from nasopharynx via the ET because their ET is short, horizontal, and ‘floppy’ [27].

The bacteria and viruses in the middle ear elicit an inflammatory response causing an acute infection. CSOM is initiated by an episode of acute infection of the middle ear that fails to resolve and result in a permanent TM perforation [29].

Children with a cleft palate or deformity of the mid-face, skull base, nose or paranasal sinuses have a statistically higher incidence of OM at all ages, especially during the first 2 years of life which is attributed to the associated ET dysfunction [30].

Bacteria can also reach the middle ear from the external ear canal through a non-intact tympanic membrane [30]. Other risk factors for CSOM include low socioeconomic status, poor housing conditions (such as congested houses with more than 10 people, indoor-cooking) infant day care attendance, supine bottle feeding, and passive smoking. The clinical risk factors include upper respiratory tract infections, allergy and Adenoid hypertrophy [1, 31].

2.3.3 Microbiology

CSOM is commonly caused by bacteria. This can either be aerobic or anaerobic, gram negative or gram positive bacteria [32, 33, 34]. The aerobic microorganisms most frequently isolated in CSOM are *Pseudomonas aeruginosa* and *Staphylococcus aureus* [1]. Commonly isolated Gram-negative organisms include organisms such as *Proteus spp*, *Klebsiella spp*, *Escherichia spp* and *Haemophilus influenza* [33, 1]. The most frequently isolated anaerobic organisms are *Bacteroides spp* [34, 15,]. Fungal organisms that include *Aspergillus species* and *Candida species* are also isolated in CSOM [15].

The Etiological organisms for otitis media vary with time and geographical area as well as continent to continent [35, 15]. This variation can be attributed to differences in climatic conditions, emergence of antibacterial resistance (which could be due to indiscriminate use of antibiotics), differences in cultural practices, nutrition and social economic factors among many others [15].

2.3.4 Pathophysiology and Complications of CSOM

Chronic inflammation in CSOM leads to proliferation of mucosal lamina propria, granulation tissue formation, enzymatic mucosal ulceration and bone destruction. Ossicular chain destruction and/ or ankylosis together with the tympanic membrane perforation contribute to hearing loss [36]. It is often conductive, but with involvement of the cochlear and cranial nerve VIII, it can be sensorineural hearing Loss.

Complications of chronic otitis media are divided into extra-cranial (extra temporal and intra temporal) and intracranial complications. The extra-temporal complications include abscess formation such as the Luc's (temporalis region), Citelli (sub-periosteal), and the Bezold's (sternocleidomastoid) abscesses. The intratemporal components of the extra-cranial complications include: mastoiditis, petrositis, facial paralysis and labyrinthitis. The intracranial complications include meningitis, brain abscess, subdural abscess, sigmoid sinus thrombophlebitis, and otitic hydrocephalus [37].

2.3.5 Types of CSOM

Clinically CSOM is divided into Tubotympanic type (safe type) and Atticoantral type (unsafe type). The Tubotympanic disease involves the anteroinferior part of the middle ear cleft and is associated with a central perforation, with no risk of serious complications. The Atticoantral type of CSOM involves the posterosuperior part of the middle ear cleft. It is associated with an attic or a marginal perforation, cholesteatoma, granulation tissue or osteitis. Risk of complications is high in this variety and is considered unsafe. CSOM is also divided into active (with Otorrhea) and inactive (with no Otorrhea) types. Each of these are subdivided into squamosal (associated cholesteatoma) and mucosal (not associated with cholesteatoma) types [38].

2.3.6 Diagnosis of CSOM

CSOM diagnosis is based on history and clinical examination (otoscopy) [1, 28].

CSOM patients present with a history of prolonged or recurrent ear discharge which typically is not associated with pain, discomfort or fever [1, 38]. The discharge varies from fetid, purulent, and cheese like to clear and serous. It can be bilateral or unilateral. Otorrhea in CSOM without cholesteatoma is usually copious, mucopurulent and non-foul smelling, whereas scanty foul smelling and sometimes sanguineous Otorrhea is seen in CSOM with cholesteatoma [38]. A common presenting symptom that is often associated with otorrhea is hearing loss in the affected ear. [28].

On Otoscopic examination the external auditory canal may or may not be oedematous and is not typically tender. It may contain discharge from the Middle ear. The examination also shows evidence of TM perforation. TM perforations are of varying features with regard to location, size, shape, dryness or wetness [38].

TM perforations can be central or marginal, total or subtotal. The middle ear may show additional features of chronic inflammation such as an aural polyp, granulation tissues, atrophic areas and ossicular destruction [1,39]. A 512-Hz tuning fork examination is a critical part of the evaluation to establish if hearing loss is present and whether it is conductive or sensorineural [39].

2.3.7 Investigations of CSOM

CSOM investigations include appropriate ear discharge swab that are taken for microscopy, culture and sensitivity tests. This is reserved for cases that fail standard topical antibiotic therapy. This is a useful guide to the identification of causative agents and appropriate choice of antibiotics [1]. In the event that there is no response to medical treatment in the presence of granulation tissue, then biopsies of the granulation tissue should be taken to rule out a neoplastic or granulomatous process [40].

Audiometry (Pure Tone Audiometry and Speech Audiometry) should be done in all patients with CSOM to establish the type and degree of hearing loss and thus determine the mode of rehabilitation and management of choice. High resolution Temporal bone CT scan is done in the event that extracranial or intracranial complications are suspected and when surgery is being planned for this patients.

It allows for assessment of the bony architecture of the middle ear and mastoid, the status of the middle ear ossicles, and the integrity of the cochlea and semicircular canals [39].

2.3.8 Management

The aims of management of CSOM are eradication of disease, closure of the tympanic membrane perforation and restoration of function to as near normal as possible. Treatment could be medical, surgical or both, including rehabilitation through use of hearing aids. Medical treatment consists of aural toilet, use of topical steroids, topical antiseptics and topical or systemic antibiotics. Aural toilet must be combined with antibiotics or antiseptics to be effective [1].

Topical antibiotics are the first line of treatment of uncomplicated otorrhea [41]. Some of the topical drugs used in management of CSOM include ciprofloxacin, tobramycin, gentamicin and chloramphenicol. Topical antibiotics have been found to be more effective in treating otorrhea than antiseptics or systemic antibiotics [42, 43].

Systemic antibiotics are considered in patients at risk for complicated or invasive ear infections [43].

Surgical intervention is treatment of choice to effect closure of TM perforation as spontaneous closure of TM perforation is uncommon in CSOM even after adequate medical therapy. Surgery done for TM perforation closure includes myringoplasty and tympanoplasty.

Tympanomastoidectomy has been advocated as the surgical treatment of choice in CSOM with mastoiditis [1, 39]. Surgery is also indicated for diseases such as cholesteatoma, polypoid disease and infected bone in order to create a dry and safe ear that is free of infection. Reconstruction of the sound transmission mechanism is vital through ossicular chain reconstruction and use of ossicular prosthesis to replace damaged ossicles.

Chapter Three: OBJECTIVES OF THE STUDY

3.1 General

- ❖ To describe Epidemiological And Clinical Profile Of Patients with Chronic Suppurative Otitis Media attending ENT OPD clinics at SPHMMC in Addis Ababa, Ethiopia.

3.2 Specific

- ❖ To describe the Epidemiological Profile Of Patients with Chronic Suppurative Otitis Media attending ENT OPD clinics at SPHMMC in Addis Ababa, Ethiopia.
- ❖ To describe Clinical Profile Of Patients with Chronic Suppurative Otitis Media patients attending ENT OPD clinics at SPHMMC in Addis Ababa, Ethiopia.

Chapter Four: METHODOLOGY

4.1 Study Area

This study was conducted in the ENT outpatient clinics at SPHMMC in Addis Ababa, Ethiopia. St Paul's Millennium Medical College, as it is known today, was established through a decree of the Council of Ministers in 2010, although the medical school opened in 2007 and the hospital was established in 1968 by the late Emperor Haile Selassie. It is governed by a board under the Federal Ministry of Health. The College initiated Ethiopia's first integrated modular and hybrid problem-based curriculum for its undergraduate medical education. The college has 1 separate operation theater for ENT, a ward which has 10 beds, 3 outpatient department clinics and 1 audiology unit having 1 digital audiometry machine, 1 otoacoustic emission machine and 1 tympanometry machine, and all are operated by one trained nurse. And it serves as among the 3 ENT surgery referral center in the country. It has 1 head and neck oncologic surgeon subspecialist, 1 otology subspecialist, and 4 general ENT surgeons. And currently it has a total of 16 residents in its post graduate program in Otorhinolaryngology, Head and Neck surgery. The estimated monthly average outpatient department patient flow is 1350 and about 40 major operations are done. A rough estimate, due to poor health management information system (HMIS) documentation format of patients' specific diagnosis, of patients with chronic suppurative otitis media to the OPD clinics is about 50 new patients with CSOM per month. It is the main hospital where patients with CSOM from Addis Ababa and from almost all the regional states of the country are managed and followed up.

4.2 Study period

The study period was from February 1st through April 30th, 2019 G.C.

4.3 Study design

The study was a hospital based descriptive cross-sectional study.

4.4 Population

4.4.1 Source population

The source population comprised all CSOM patients attending ENT outpatient clinics at SPHMMC.

4.4.2 Study population

The study population included all patients attending ENT outpatient clinics at SPHMMC and diagnosed to have CSOM and fulfill the inclusion criteria during the study period.

4.5 Eligibility Criteria

4.5.1. Inclusion Criteria

- ❖ Patients of all ages and both sexes with simple CSOM (using WHO CSOM definition).
- ❖ All patients of CSOM with complications.

4.5.2. Exclusion Criteria

- ❖ Patients who underwent previous ear surgeries
- ❖ Presence of Otitis externa and
- ❖ Tumors of the ear.

4.6 Sample size determination and Sampling procedure

4.6.1 Sample size determination

All patients with CSOM who visit ENT outpatient clinics at SPHMMC during the study period and those who fulfill the inclusion criteria were included in this study.

4.6.2 Sampling Procedure and Technique

All the eligible CSOM cases during the study period were included.

4.7 Study Variables

- ❖ Demographic characteristics:
 - Age, Sex, Religion, Level of education of adult patients,
 - Residence and Size of household family
- ❖ Medical History Findings
 - Laterality of ear discharge: unilateral or bilateral
 - Side : right and left
 - Mode of onset
 - Associated Upper respiratory tract infections (URTI), pain, FB and Hearing Loss
 - Duration of otorrhea
 - Character of the discharge

- Mode of previous treatment: Modern or traditional healer
- Complications
- ❖ Examination findings
 - Character of the discharge
 - Type of tympanic membrane perforation by size and site

4.8 Data Collection Instrument and Technique

Data collection was carried out by resident physicians whom were selected from the ENT OPD working team and they were given the important demonstrations and short training which guides them in collecting the appropriate data from the patients under investigation. After obtaining informed consent from patients who were eligible for the study, data was collected using the structured adapted questionnaire which was prepared in English and translated to Amharic language. And patients who didn't understand the consent in anyway were not included in the study.

Data was collected using interviewer administered structured questionnaires which was translated to Amharic (Appendix IV). Section A consisted of socio-demographic data on patients' characteristics. Section B consisted of the patients' medical history. Section C consisted of physical middle ear examination findings. Section D consisted of audiometry data obtained from the audiology unit. Thus, using the questionnaire both epidemiologic and clinical data was obtained.

4.9 Data quality assurance

Content validity of the questionnaire was assessed by my advisors from ENT and public health departments and meanings of all items were checked accordingly. The principal investigator trained the data collectors. The training included detail explanation on the objectives of the study, meanings of the lists of questions on the questionnaire, approach to study participants; and clear explanation on the ethical procedure.

The data collectors were resident physicians working in the ENT OPD at SPHMMC. Items interpretability and understandability by the data collectors was evaluated by the principal investigator by pre-testing the questionnaire on 15 patients of the sample population prior to data collection and necessary correction was taken accordingly.

And the audiometric examination was done by only one trained nurse throughout the study and the validity and reliability of the results were consistent.

Data quality was assured by checking the data collection sheet for completeness and errors daily by the principal investigator and necessary correction was made immediately. Questionnaires with incomplete or inconsistent responses were omitted. Data cleaning, coding and entering was made carefully using the standard instruments and operating procedures listed above. Quality control was a continuous process throughout the study to maximize validity and reliability of the findings of the study.

4.10 Data Processing and Analysis

The checked data was coded and entered to SPSS version 20 for analysis. The demographic details and clinical characteristics of CSOM were analyzed.

Descriptive statistics included measures like percentage, median, range and interquartile range. The study finding were presented using narrations and with tables and pie-charts. Conclusions and recommendations were made based on the results.

4.11 Ethical Consideration

Ethical clearance was obtained from SPHMMC institutional review board (IRB). Permission from study setting (ENT OPD) was obtained. The respondents, those who were above 18years gave their consent to participate in the study upon recruitment and those who were below 18 years adolescents and minor children were asked for their assent to participate in the study depending on their specific age and their parents or legal guardians were asked for permission. They were informed that it was voluntary and was informed of their right to accept or withdraw or refuse to participate. The data collectors gave full information about what the research entails and ensure respondents were competent enough to give consent. Full explanation and consent is in Appendix IV. The questionnaires were administered only after obtaining consent from the patients or permission from their legal guardians.

Participants' privacy was highly maintained by ensuring that they will not be exposed when filling questionnaires. The researcher ensured the anonymity of respondents by concealing their identity and kept the research data confidential for research purposes only.

All concerns causing any sort of discomfort to respondents were resolved immediately and mitigation strategies put in place. The patients didn't incur any extra cost by participating in the study and they were not coerced to take part in the study. The Questionnaires were destroyed after the study was completed. The findings of the study will be shared with other medical practitioners in different forum through publication, scientific conferences to mention but two. Ideas extracted in the literature were acknowledged.

4.12 Dissemination and Utilization of Results

The study was reviewed by Supervisors from the departments of ENT & Public Health & was presented to the University Community as part of research thesis defense. Soft and hard copy of the result were submitted to the department of ORL-HNS. It will also be disseminated to the stakeholders who are concerned with the diagnosis and management of patients with CSOM. The results of the study will be published in local and international journals and shall be presented in scientific meetings and conferences.

4.13 Operational Definitions

Total tympanic membrane perforation: ear drum is perforated completely and there is no remnant of it on ear examination.

Subtotal tympanic membrane perforation: ear drum is perforated partially and there is remnant of it on ear examination.

Odorous ear discharge: presence of malodorous ear discharge at least at one of the discharging ears either from the patients/care givers history or physician confirmed on ear examination.

Atticoantral tympanic membrane perforation: confirmed isolated pars flaccida perforation by physician on ear examination.

Tubotympanic tympanic membrane perforation: confirmed isolated pars tensa perforation by physician on ear examination.

Both atticoantral and tubotympanic tympanic membrane perforation: confirmed perforation of both pars flaccida and pars tensa by physician on ear examination that can be from both total and subtotal type of tympanic membrane perforation.

Urban: areas of living of the patients where claimed as “urban” by participants or care givers even if it is not known by the data collector as urban or rural.

Rural: areas of living of the patients where claimed as “rural” by participants or care givers even if it is not known by the data collector as urban or rural.

Regional state: a regional state of Ethiopia where the patient is currently residing permanently.

Scanty ear discharge: amount of ear discharge claimed as small in amount from history of the patient or confirmed as scanty by physician on ear examination.

Copious ear discharge: amount of ear discharge claimed as excessive in amount from history of the patient or confirmed as copious by physician on ear examination.

Chapter Five: RESULTS

5.1. Socio-demographic characteristics of the study participants

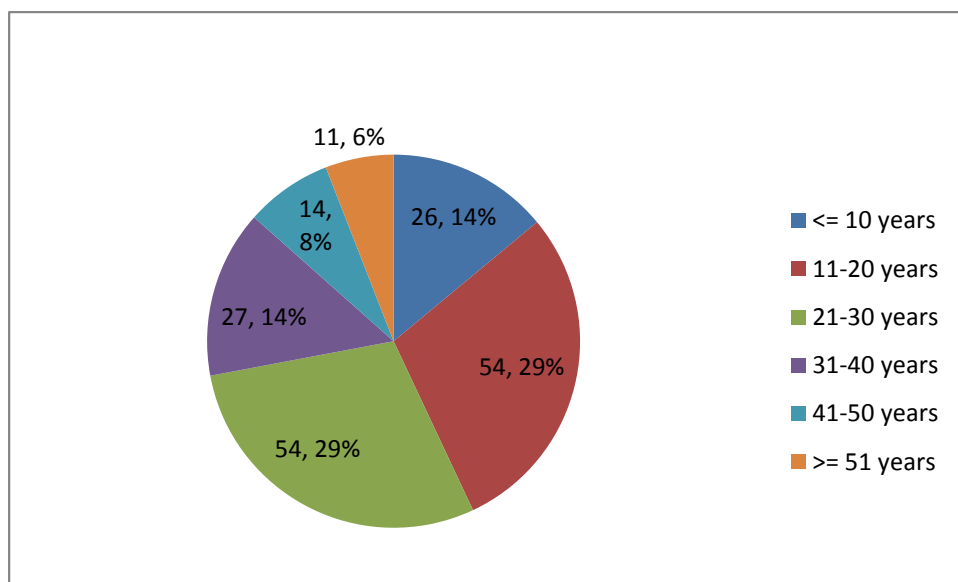
In this study, we evaluated 186 participants suffering from CSOM, of which 51.1% were females with comparable F: M ratio and 72.0% of them were below the age of 30 years and 5.9% were above the age of 50 years. The median [IQR] age of the patients was 22.5 [22.5±15] and the age range was 07 months – 77 years old (Figure 1). Around two third (65.6%) of the patients were orthodox Christian followers in religion and 9.1% were Protestants. Most of the patients (82.8%) stayed at urban areas and 36.6% of the patients were employed with only 5.4% farmers in occupation and students accounted for 30.1% of the patients. More than half (54.8%) of the patients were from Addis Ababa followed by 30.1% from Oromia region with only one patient (0.5%) from Somali regional state. 44.6% of the patients attended secondary school and above in their level of education and 9.7% of the patients were preschool children with 8.6% of the patients who cannot read and write. The median [IQR] of the house hold family size of the patients was 5 [5±3] with range of 1-15.

The socio-demographic characteristics of the study patients are summarized in table 1.

Table 1: Socio-demographic characteristics of CSOM patients, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

Characteristics	Category	Frequency	Percent (%)
Gender	Male	91	48.9
	Female	95	51.1
Level of education of patients	Cannot read and write	16	8.6
	Can read and write	4	2.2
	Primary school	65	34.9
	Secondary school	49	26.3
	Higher education	34	18.3
	Preschool children	18	9.7
Occupation of patients	Farmer	10	5.4
	Daily laborer	17	9.1
	Employed	68	36.6
	Merchant	6	3.2
	Student	56	30.1
	House wife	11	5.9
	Preschool children	18	9.7
Religion of patients	Orthodox Christian	122	65.6
	Muslim	47	25
	Protestant	17	9.1
Residence of patients	Urban	154	82.8
	Rural	32	17.2
Size of household population	<6	128	68.6
	6-10	51	27.4
	>10	7	3.7
Regional state of the patients	Addis Ababa	102	54.8
	Oromia	56	30.1
	SNNPR	10	5.4
	Amhara	13	7
	Afar	2	1.1
	Ethiosomale	1	0.5
	Harari	2	1.1

CSOM: chronic suppurative otitis media, SPHMMC: Saint Paul's Hospital Millennium Medical College, SNNPR: southern nations, nationalities and peoples region.



SPHMMC: Saint Paul's Hospital Millennium Medical College

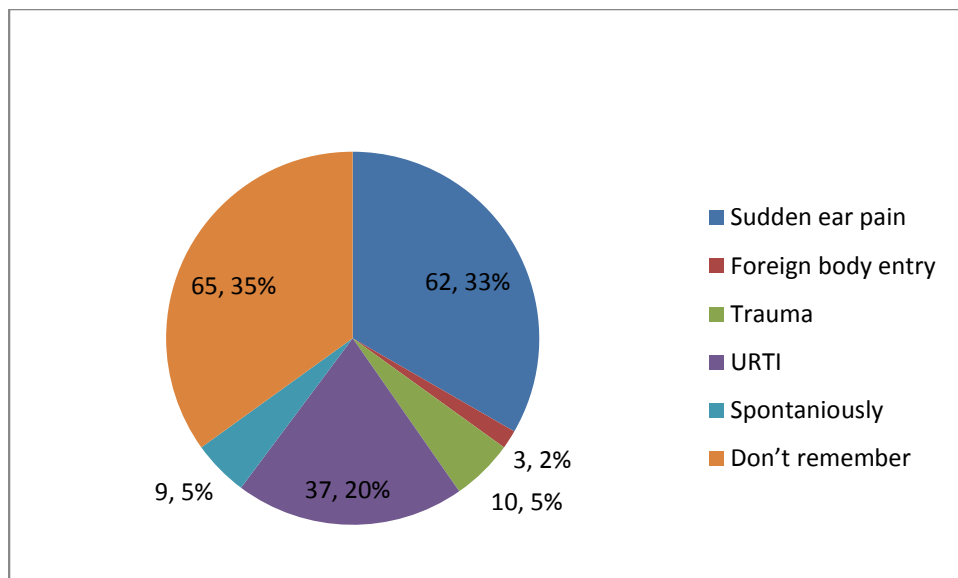
Figure 1: Age distribution of respondents, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

5.2. Clinical profiles of the study participants

5.2.1. Clinical history profiles of the study participants

Of the 186 patients with complaint of ear discharge that participated in the study, 89(47.8%) had unilateral complaint, of which the left side ear was affected more frequently (64.0%) as compared to the right side ear, while 97(52.2%) had bilateral complaint, making a total of 283 ears that were examined. 85.5% of all the patients reported intermittent type of ear discharge.

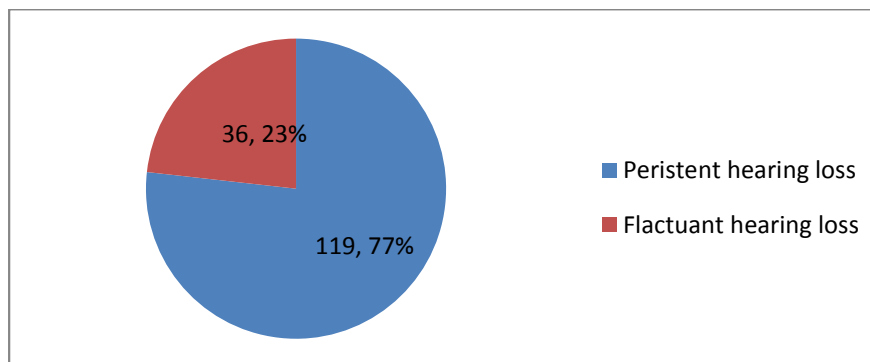
The commonest mode of onset for CSOM was sudden ear pain in 62 (33.3%) followed by upper respiratory tract infection (URTI) 37(19.9%) while majority of the participants do not exactly remember the preceding event 65(34.9%) (Figure 2).



CSOM: chronic suppurative otitis media, SPHMMC: Saint Paul's Hospital Millennium Medical College, URTI: upper respiratory tract infection,

Figure 2: Mode of onset of CSOM patients, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

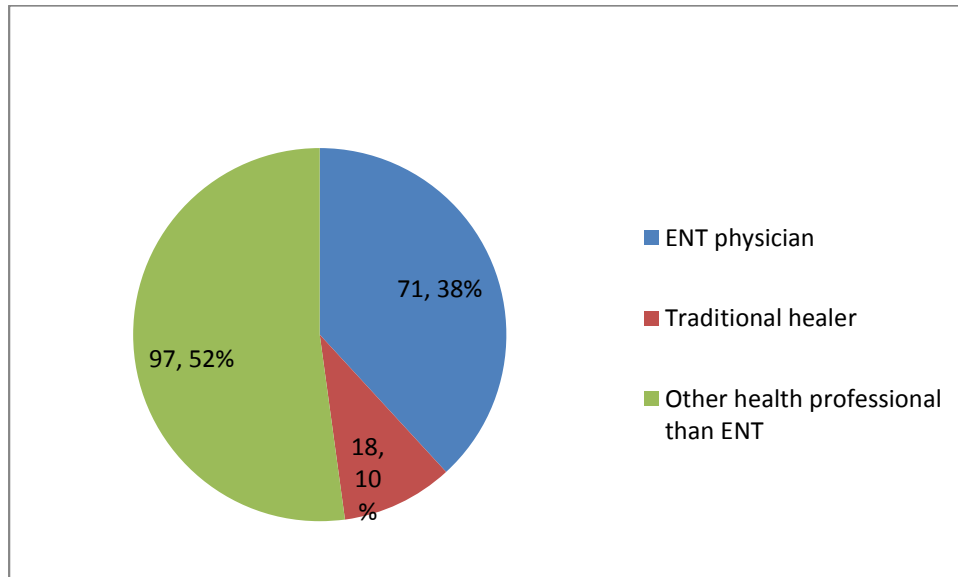
The median [IQR] duration of ear discharge of the patients was 11 [11±18] years with a range of 01 month – 60 years and was greater than 5yrs in 119(63.9%) of the patients and less than 8 weeks in 1(0.5%) patient. The ear discharge was foul smelling in 179(96.2%) ears and copious in 43(23.1%) ears. Hearing loss complaint was reported in 155(83.3%) patients and was said to be persistent in 119(76.8%) of them and fluctuant in 36(23.2%) patients (Figure 3).



SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 3: History of associated Hearing Loss of respondents, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

Only 31 (16.7%) of the patients complained ear pain at presentation. With regards to the first time treatment visit of the patients, 71 (38.2%) of them reported to have visited ENT specialist while 18 (9.7%) of them consulted traditional healers, which is 12.5% of the rural residents and 9.0% of the urban residents. (Figure 4)

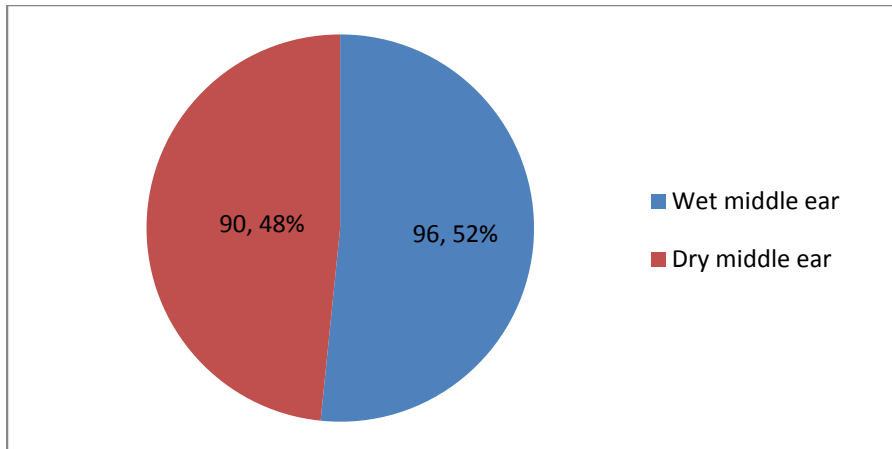


SPHMMC: Saint Paul's Hospital Millennium Medical College, ENT: ear, nose and throat

Figure 4: Respondents' first time visit for treatment of ear discharge, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

5.2.2. Middle ear examination finding profiles of the study participants

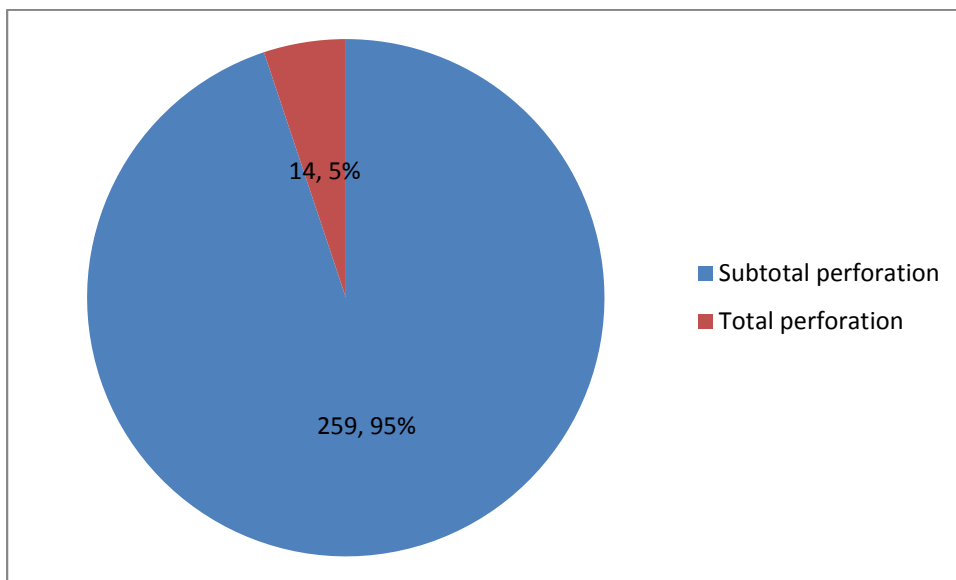
On middle ear examination of the 283 ears, we found that 273 (96.5%) had tympanic membrane perforation, of which 87 (46.8%) were bilateral and 99 (53.2%) were unilateral with left ear preponderance of 68 (68.0%) patients. 52% of the patients had wet middle ear in at least either of their ears (Figure 5).



SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 5: Distribution of cases by discharge status of the middle ear, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

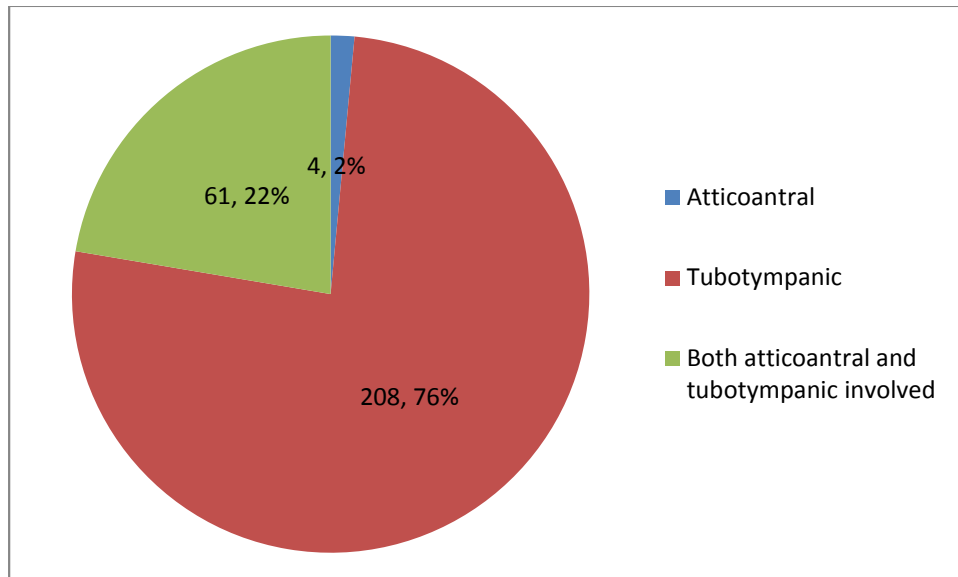
The tympanic membrane perforation was subtotal in 259 (94.9%) of the ears (Figure 6)



SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 6: Distribution of cases by size of the tympanic membrane perforation, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

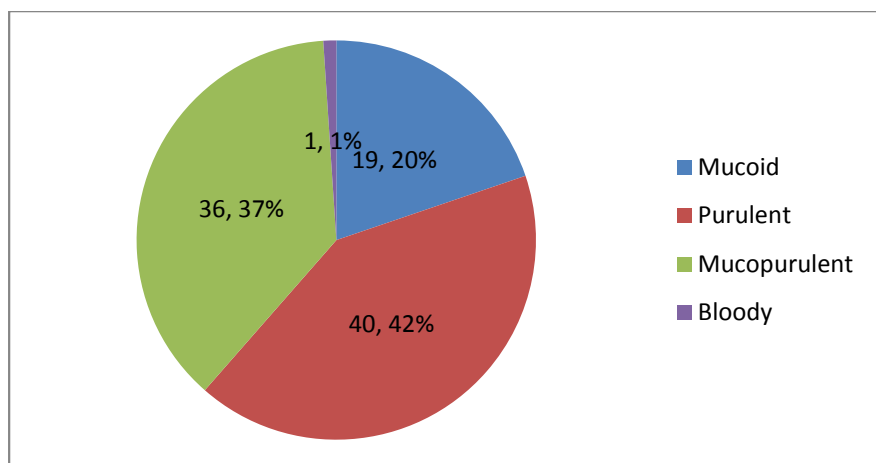
Based on the location of the TM perforation, tubotympanic perforation accounted three fourth 208(76.2%) of the ears and atticoantral 4(1.5%) of the ears (Figure 7).



SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 7: Distribution of ears by the location of TM perforation, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

Purulent type of ear discharge was the most common which accounted for 40 (41.7%) of the patients and only 1 (1%) patient had bloody discharge (Figure 8). Only 16 (8.6%) of the patients had imaging confirmed complications in at least one of their ears and 16 (100%) of the complications were cholesteatoma. Based on the site of perforation of the TM, 33.3% of the patients with atticoantral perforation, 24.3% of the patients with perforation involving both atticoantral and tubotympanic area and only 4.1% of the patients with tubotympanic perforation developed cholesteatoma.



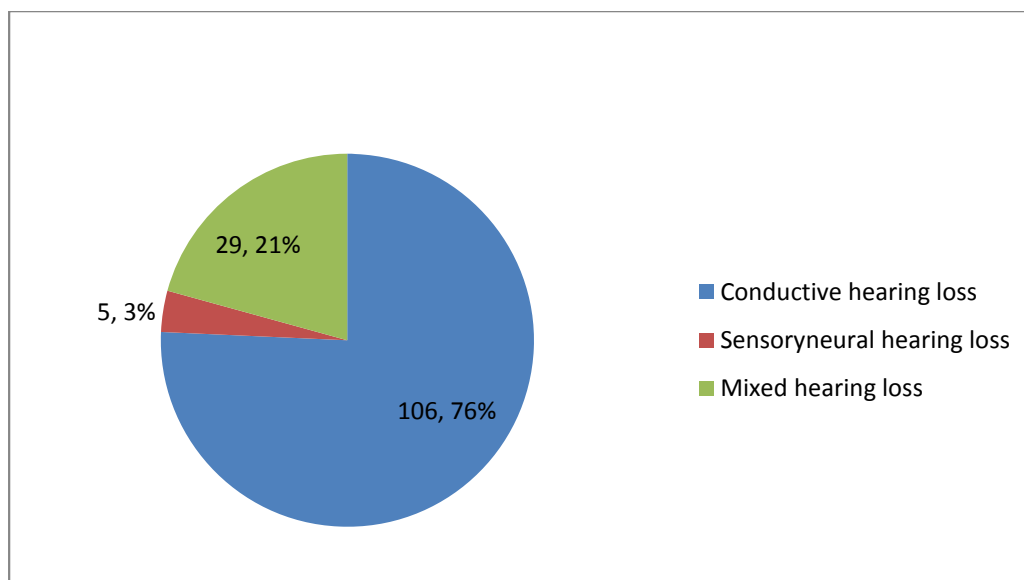
SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 8: Distribution of cases by character of the middle ear discharge, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

5.2.3. Audiometric result profiles of the study participants

Of all the 186 study participants, 88 (47.3%) patients had audiometric evaluation, of which 43 (48.9%) are males with comparable male to female ratio and 57 (64.8%) of them are between the age range of 11-30 years (table 2). And about 52 (59%) of the patients had bilateral ears audiometric hearing loss of certain degree and type and 36 (41%) had unilateral ear audiometric hearing loss with left ear commonly affected 26 (72.2%) and both sexes are exact equally (male to female ratio of 1:1) affected with the audiometric hearing loss.

Of the 176 audiometric tested ears, 36 (20.5%) of the ears had normal hearing, 140 (79.5%) ears had audiometric hearing loss of certain degree and type with conductive type of hearing loss being the commonest for accounting 106 (76%) of the ears followed by mixed hearing loss in 29 (21%) of the ears while the least common is sensorineural hearing loss type accounting for 5 (3%) of the ears (Figure 9).



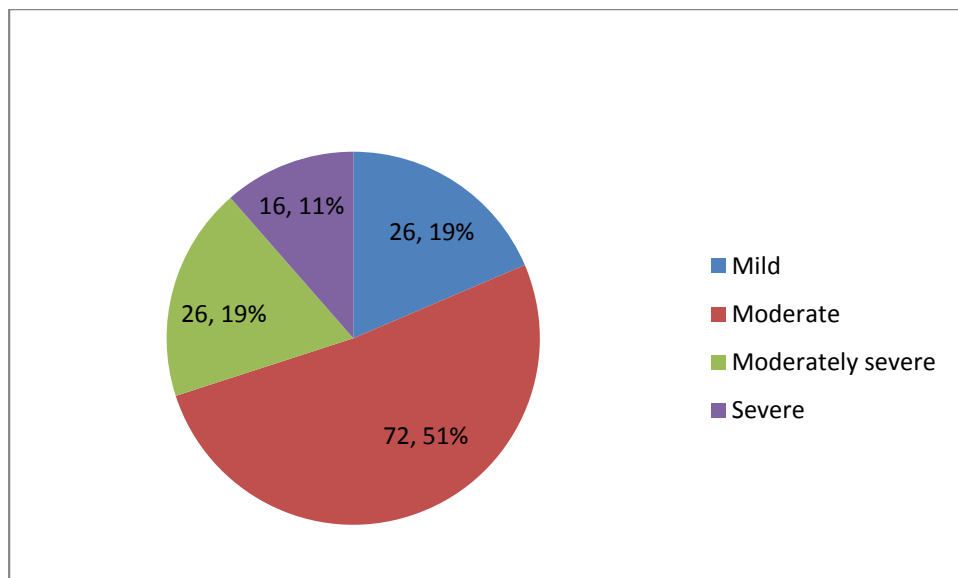
SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 9: Types of audiometric hearing loss of patients, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

More than half, 72 (51.4%) of the ears had moderate degree of hearing loss being the commonest degree of loss while 16 (11.4%) of the ears had severe degree of hearing loss being the least common degree of loss. (Figure 10)

Table 2: Distribution of audiometric evaluation of patients by age, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

Age category of patients in years	Number of patients	Percentage (%)
<=10	2	2
11-20	29	33
21-30	28	32
31-40	14	16
41-50	8	9
>=51	7	8



SPHMMC: Saint Paul's Hospital Millennium Medical College

Figure 10: Degree of audiometric hearing loss of patients, SPHMMC, Addis Ababa, Ethiopia, 2019 (N=186)

Chapter Six: DISCUSSION

Chronic Suppurative Otitis Media (CSOM) is frequently associated with symptoms of inflammation like discharge from the ear or pain and is a serious health care concern worldwide due to its substantial financial and non-financial burden. In many cases, patients suffer from hearing loss causing communication problems and social withdrawal. And the magnitude of this burden is not statistically supported in our country apart from worry some day to day observation of the burden.

In this study of 186 patients, 51.1% were females with comparable female to male ratio (1:1.04) where both sexes are almost equally affected which is in contrast with to other previous studies in Zambia and India [44,45,46] where they showed male preponderance. This might possibly be due to the fact that majority of our patients were from Addis Ababa and nearby unlike the studies in Zambia and India where majority of them were from rural back ground, where the researchers believe that there was male dominance in the house holds and females were usually denied of their health care needs.

The majority of the patients (82.8%) with CSOM in this study resided in urban areas; this might be because of the far location of our hospital from the rural areas and closeness to the town residents on top of the low awareness to the disease of the rural residents.

In the present study, the median [IQR] age of the patients was 22.5 [22.5±15] and the age range was 07 months – 77 years old and the commonest age groups affected were 11–30 years (58%) and were in accordance with studies in Zambia and India [18, 46, 47]. In a previous study, it was found that children are more prone due to a number of reasons such as susceptibility to upper respiratory tract infection, more horizontal nature of Eustachian tube, and immaturity of immune system [48]. With regard to the level of education of the patients, 44.6% of them have attended secondary education and above; this might be because of their awareness to the disease and their health care seeking behavior.

We found that purulent type (21.5%) of ear discharge is most common one in our study; which is consistent with study in Zambia [46] and in contrast with a study in India [18].

We found that subtotal (95.7%) and tubotympanic (78.5%) types are the most common tympanic membrane perforation; which is consistent with previous study findings [18, 46]. This may explain the findings of few patients with complications and pattern of their degree and type of hearing loss in our study. Other types of TM perforation classifications, like based on size as small, medium and large, were not used to avoid inter observer variation.

It was found that 12.5% of the rural residents and 9% of the urban residents have visited traditional healers the first time they seek treatment for their ear discharge.

This might be because of the less access to ENT physicians and lack of awareness to ear discharge in the community. It should be noted that this numbers are possibly under estimations for patients might not disclose their visit to traditional healers. Our daily observation of the middle ear findings goes for the routine entry of herbal medicine to their ear from traditional healers.

About 8.6% of all the patients had cholesteatoma as a complication in this study; this rate might not represent the exact figure in the patients for there was no routine imaging screening throughout the study due logistic constraints where clinically non apparent complications might be missed. There was as well no surgical diagnosis made, only a clinical diagnosis.

In this study, there were 176 ears with the diagnosis of CSOM that had audiometric evaluation and it was found that conductive type of hearing loss was the commonest type (75.7%) of hearing loss while there were 3.5% of the ears with sensorineural hearing loss type. 51.4% of the ears had moderate degree of hearing loss being the commonest degree of loss while 11.4% of the ears had severe degree of hearing loss being the least common degree of loss. This results are similar to previous studies on the evaluation of hearing loss by pure tone audiometry in chronic suppurative otitis media patients in India .[18, 50]

Conventionally, a conductive hearing loss is expected in a patient with CSOM, but sensorineural hearing loss does occur with long standing infections because of the diffusion of bacterial toxins through the round window membrane into the inner ear [51]. In our study, we observed mixed hearing loss in 21 % of the cases. This is comparable to the studies conducted by Shruthi et al, Cusimano et al and Alexandre et al.[51, 52, 53]. Other possible causes of sensorineural hearing loss due to e.g. Ototoxicity from earlier administered drug could not be ruled out.

Chapter Seven: STRENGTHS AND LIMITATIONS OF THE STUDY

Strengths of the study:

- ❖ This study is the first of its kind in our country which tried to address the magnitude of the disease burden of CSOM and the epidemiological and clinical characteristics of patients with CSOM
- ❖ The data was collected prospectively which can minimize gaps from incomplete documentation
- ❖ Limitations of the study as stated below were identified and accepted, and results of this study were considered accordingly.

Limitations of the study include:

- ❖ Due to logistic constraints, imaging results like CT and MRI were not employed in the clinical profile of the patients
- ❖ Owing to the reason that the study is a hospital based study, it may not be reflective of the pattern of CSOM in the community.

Chapter Eight: CONCLUSION

In this study, both sexes are equally affected and most commonly young adults are the sufferers of CSOM. Majority of the patients are Addis Ababa residents who are with relatively better access and option to ENT services and health information on media but still they live with the disease almost for their age. This highlights the magnitude of the burden of the problem in other regions of the country where there is no access to otorhinolaryngologist.

It was shown that 10% of the patients are preschool children. Unilateral ear is commonly affected with left ear preponderance. CSOM has direct implication for the social distress and work withdrawal of the patients and that the patients are in desperate need of treatment of the disease.

Patients with atticointral type of TM perforation showed higher proportion of developing cholesteatoma as compared to tubotympanic one. Sudden ear pain was the most common mode of onset for the ear discharge.

Majority (83.3%) of the patients had hearing complaint and it was persistent in 64% of them. Patients of both urban and rural area background traditional healers visit for their ear discharge are rampant.

Mild and moderate degree of conductive hearing loss was most commonly observed among CSOM patients. Mixed type of hearing loss was the second most common type in our study.

This study reinforces the need for preoperative audiometry to assess the degree and type of hearing loss which is supportive in the event of medico-legal issues where mixed hearing loss is of significant concern in CSOM patients.

CSOM is a preventable cause of hearing impairment. Early diagnosis and management can prove to be effective in reducing socioeconomic burden and prevention of deafness. Thus, it is important to spread awareness among people for discharging ear for its early diagnosis and management.

Chapter Nine: RECOMMENDATION

Based on the findings of this study the following recommendations can be forwarded:

❖ To SPHMMC:

1. To expand and equip ENT service till patients can get all the possible benefit from the set up and the professionals at their first visit.
2. To open other affiliate ENT centers in other areas outside of Addis Ababa
3. To distribute leaflets that teach about general ear health to patients visiting ENT clinics for whatever cases.

❖ To ENT department of SPHMMC:

1. To give health education to patients every working day morning at waiting area by preparing manuals for the trainers.
2. To create ear health awareness to each patient with ear discharge beyond treating their disease
3. To prepare general ear health teaching programs with residents at community level by making schools a primarily target.
4. To have routine audiometry to patients with ear discharge before undergoing surgery and discuss the disease and the expected outcome the surgery in detail.
5. To enhance otological surgical capacity as the surgical demand of patients with CSOM for Tympanoplasty is not met.

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Appendices

Appendix-I) Information Sheet

Title of Study: Epidemiological And Clinical Profile of Chronic Suppurative Otitis Media Patients at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia.

Principal Investigator: Dr. Zinabu Molla (MD), Otorhinolaryngology, Head and Neck Surgery Resident

Advisors: Dr. Uta Fröschl, MD, PHD, FCSORL (ECSA), and Yoseph Worku, MD, MPH

Introduction: Chronic Suppurative otitis media is a disease of the ear characterized by chronic ear discharge, more than 2 weeks, and a perforated ear drum. It is a common cause of Hearing loss which may affect the academic performance and social interactions in those affected.

You are being requested to participate or allow your child to participate in a research study that seeks to describe epidemiological and clinical profile of chronic suppurative otitis media patients.

We ask that you understand this form and ask any questions that you may have before agreeing to participate in this study.

Purpose of Study: The purpose of the study is to describe the epidemiological and clinical profile of chronic suppurative otitis media patients attending outpatient clinic at SPHMMC. The information that will be gathered shall be used to help develop rational strategies to prevent and treat chronic suppurative otitis media at early stage and as a preliminary study for future researches on CSOM.

Description of the Study Procedures: Once you have given consent to participate in this study, you will be requested to undergo a medical examination of the ear, nose and throat and if important, audiometric examination of your hearing for free (investigator will cover the cost). The entire process will last about 30 minutes.

Benefits of being in the Study: The results of the study will be used to improve the prevention strategies and management of chronic suppurative otitis media. If chronic suppurative otitis media or any other ear disease is diagnosed in the respondent, the patient will be management accordingly.

Risk: There is no any risk to the patient at all by participating in this study.

Confidentiality: All the Information about the patient will be kept confidential including the results of the laboratory ear pus analysis.

Payments: No payments are involved in this study.

Right to Refuse or Withdraw: The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time without affecting your relationship with the investigators of this study and will not be penalized.

Results Dissemination: The study will be presented to the University Community as part of research thesis defense. It will also be disseminated to the stakeholders who are concerned with the diagnosis and management of patients with CSOM. The results of the study will be published in local and international journals and shall be presented in scientific meetings and conferences.

Right to Ask Questions and Report Concerns: You have the right to ask questions about this research study and to have those questions answered by the research team during or after the research. If you have any further questions about the study, at any time feel free to contact me using the contact details provided below.

Name: Dr.Zinabu Molla (MD)

Tel: +2519 38 79 8274

Appendix-II) Consent Form

Title of the project: Epidemiological and Clinical Profile of Chronic Suppurative Otitis Media Patients at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia.

I have been well aware of that this research to be undertaken is for the partial fulfillment of specialty certificate which is fully supported and coordinated by the Department of Otorhinolaryngology, Head and Neck Surgery, SPHMMC and the designate principal investigator is Dr. Zinabu Molla.

I have been fully informed in the language that I understand best about the research project objectives and all the information I shall provide to the interviewer will be kept confidential.

I understood that the research has no any risk to the patient and also knew that I have the right to withhold any information or to make the patient withdraw from the study any time.

I have assured that the right to ask information that is not clear about the research before and or during the research work and to contact;

- SPHMMC IRB Office: Tel: (.....)
- Principal Investigator: Dr. Zinabu Molla; Tel: +2519 38 79 8274

I have read this form, or it has been explained to me in the language I comprehend best and understood the condition stated above, therefore, I am willing and confirm the participation in the study by signing the consent.

Signature of the Patient/Guardian: _____ Date: _____

Signature of Investigator(s): _____ Date: _____

Appendix-III) Questionnaire

This is a study that is undertaken to explore the Epidemiological and Clinical Profile of Chronic Suppurative Otitis Media Patients at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia.

This research will help to form Chronic Suppurative Otitis Media guide line and to advocate best possible prevention strategies and management of Chronic Suppurative Otitis Media and as background study for future researches.

Your participation is very crucial to this study.

Thank you for participating!

Part one: Socio-demographic Profile of Participants

1. MRN: _____
2. Age: _____
3. Sex: Male ☐ Female ☐
4. Regional state: _____
5. Residence area : Rural ☐ Urban ☐
6. Occupation : 1. Farmer 2. Daily laborer 3. Employed 4. Merchant 5. Student
6. Preschool child 7. House wife 8. Other : _____
7. Size of the house hold : _____
8. Religion : 1. Orthodox 2. Muslim 3. Protestant 4. Catholic 5. Other : _____
9. Level of education : 1. Cannot read and write 4. Secondary education (9-12th)
2. Can read and write 5. Higher education (college/university)
3. Primary education (1-8th) 6. Preschool child

Part two: Past medical and surgical history

1. Condition of ear discharge:
 - a. 1. Right ear 2. Left ear 3. Both ears
 - b. Duration of discharge: right ear: _____ left ear: _____
 - c. Character of the discharge :

	left	right
i. Always	☐	☐
ii. Intermittently	☐	☐
iii. Copious	☐	☐
iv. Scanty	☐	☐
v. Odor	☐	☐
 - d. Event preceding the ear discharge :

i. Sudden ear pain	☐	☐
ii. Foreign body entry	☐	☐
iii. Trauma	☐	☐
iv. URTI	☐	☐
v. Spontaneous	☐	☐
vi. Don't remember	☐	☐
vii. Other: _____		
 - e. Is it painful now? **No** ☐ if yes : **left** ☐ **right** ☐
2. Any hearing difficulty? **No** ☐ if yes :

a. Always	☐	☐
b. Intermittently	☐	☐
3. Any history of treatment for the discharge? 1. No 2. Yes
4. If **yes** to the 3rd question, where was the first visit:
 - a. ENT physician
 - b. Other health professional (Non ENT)
 - c. Used not prescribed drug
 - d. Traditional healer
 - e. Other

Part three : Otoscopic examination findings

Major ear problems		Examination findings				Remark
		Right ear		Left ear		
		Mark X to your answer		Mark X to your answer		
		No	Yes	No	Yes	
1. Ear discharge						
2. Quantity	Scanty					
	Copious					
3. Character of the discharge	Foul smelling					
	Odourless					
	Mucoid					
	Purulent					
	Mucopurulent					
	Bloody					
4. Tympanic membrane perforation						
Subtotal	Pars tensa					
	Pars flaccida					
Total						
6. Complications, specify if any		1. 2. 3. 4.		1. 2. 3. 4.		

Part four : Audiometry results

Ear Tested	Pure tone average		Type Of Hearing Loss		
	Air Conduction	Bone Conduction	CHL	SNHL	MHL
Right ear					
Left ear					

NB: You can put the thresholds in **dB** at 500, 1000 & 2000Hz for both **AC** & **BC** at both ears in the given boxes if you don't want to calculate PTA.

Name of data collector: _____

Appendix-IV) Information Sheet, Consent Form and Questionnaire (Amharic Translation)

የጥናቱ ተሳታፊዎች የመረጃ እና የስምምነት ቅጽ በአማርኛ

ስሜ _____ ይባላል። በቅዱስ ጳውሎስ ሆስፒታል ምሊንየም ህክምና ኮለጅ የአንገት በላይ ህክምና ት /ክ የድኅረምረቃ ትምህርት የመመረቂያ ጽሑፍ ለመስራት የሚያገለግል መረጃ እየሰበሰብኩ ነው። የመመረቂያ/ ጽሑፉ ርእሰም በቅዱስ ጳውሎስ ሆስፒታል በጀርጃ፡አፍንጫ እና ጉሮሮ ክሊኒክ የሚታከሙ የጀር መምገል(እንፈክሽን) ችግር ያለባቸው ታካሚዎችን የጀርው ችግር መጠንና ችግሩን ያመጡት ምክንያቶችን ለማወቅ ይረዳል። ይህ ጥናት ህጋዊ ሲሆን በኮለጁ የምርምር ኮሚቴዎች የታየ እና ፈቃድ ያገኘ ነው። እርስዎም በዚህ ጥናት እንዲሳተፉ ፍቃድዎን በአክብሮት እጠይቃለሁ። ውድ ተሳታፊዎችን በጥናቱ ለመሳተፍም ሆነ ላለመሳተፍ ለመወሰን እንዲያስችልዎት ስለ ጥናቱ የሚከተሉትን ማብራሪያዎች እባክዎ ይመልከቱ / ያዳምጡ።

1. **የጥናቱ ዓላማ:** የዚህ ጥናት ዓላማ በቅዱስ ጳውሎስ ሆስፒታል ጀርአቸውን የሚታከሙ ታካሚዎችን የጀር ችግር መጠንና ችግሩን ያመጡትን ምክንያቶች ለማወቅ ነው።
2. **አጠቃቀም:** የጀርዎትን የጉዳት መጠን ለማቅ አውድዮሜትር በሚባል መሳሪያ ታግዘን ምርመራ እንስራልዎታልን፤ በተጨማሪም ጉዳት የማያደርሱ አንዳንድ አስፈላጊ የሆኑ የጀር ምርመራዎችን እናደርግልዎታለን።
3. **ሊደርስ የሚችል አደጋ:** ጥናቱ በጤናዎ ላይ ምንም አይነት አደጋ ወይም ችግር አያስከትልም።
4. **ከጥናቱ የሚገኘው ጥቅም:** በጥናቱ በመሳተፍዎ ምክንያት ምንም አይነት የገንዘብ ክፍያ አይሰጥም።
5. **ምስጢራዊነት:** የማንኛውም የጥናቱ ተሳታፊ መረጃ በምስጢር ይያዛል። የእያንዳንዱን ግለሰብ መረጃ ከዋናው ተመራማሪና ከአማካሪዎች በስተቀር ማንም ሊያወቀው አይችልም።
6. **ፈቃደኝነት :** እርስ በጥናቱ ለመሳተፍ ፈቃደኛ ያለመሆን፣ ማንኛውንም መረጃ ያለመስጠት እንዲሁም ጥናቱን በማንኛውም ጊዜ የማቋረጥ መብትዎ የተጠበቀ ነው።

ጥናቱን በተመለከተ ምንም ዓይነት ጥያቄ ካለዎት በሚከተለው አድራሻ ሊያገኙን ይችላሉ።

ስም: ዶ/ር ዝናቡ ሞላ ፤የአንገት በላይ ህክምና ትምህርት ክፍል

ስልክ: 0938 79 82 74

ኢሜል: zinabumed2000@gmail.com

የስምምነት መጠየቂያ ቅጽ ለተሳታፊዎች በአማርኛ

ጥናቱን በተመለከተ በቂ ማብራሪያ ተደርጎልኛል። የጥናቱንም አላማ በሚገባ የተረዳሁ ሲሆን፤ ታካሚዎች ላይ ያለውን የጀር ችግርና የችግሩን ምክንያቶች ለማወቅ እንደሆነና የምስጢራዊ መረጃ ለዚህ ጥናት ብቻ የሚውል በመሆኑ በኔ ላይ ምንም አይነት ጉዳት እንደማያደርስ እና የምስጢራዊ ማንኛውም መረጃ በሚስጥር እንደሚጠበቅ ተገንዝብዋለሁ። ስለሆነም በዚህ ጥናት ለመሳተፍ ፈቃደኛ እንደሆንኩ በፍርማዬ አረጋግጣለሁ።

የተሳታፊ/ቤተሰብ ፊርማ፤ _____ ቀን፤ _____/_____/_____

የመረጃ ሰብሳቢው ስም፤ _____ ፊርማ _____ ቀን፤ _____/_____/_____

ለተሳታፊዎች በአማርኛ የተዘጋጀ መጠይቅ

ይህ መጠይቅ ሰላሳ ደቂቃ ይወስዳል፡፡ እባክዎ መጠይቁ በትክክል ይሞላ ዘንድ ይተባበሩን፤ ምክንያቱም የዚህ ጥናት ውጤት የጀርመን መምህራን ችግርና የችግሩን ምክንያት ለማወቅ ይረዳል፡፡

ስለ ትብብርዎ እናመሰግናለን!!

ክፍል አንድ፡ የተሳታፊዎች ማህበራዊና ኢኮኖሚያዊ ሁኔታ (Demographic Profile)

1. የታካሚ የካርድ ቁጥር፡ _____
2. እድሜ _____
3. ፆታ፡ ወንድ ☐ ሴት ☐
4. የሚኖሩበት ክልል፡ _____
5. መኖሪያ አካባቢ፡ ገጠር ☐ ከተማ ☐
6. የስራ ሁኔታ፡ 1. አርሶ አደር 2. የቀን ሰራተኛ 3. የመንግስት/የግል ሰራተኛ 4. ነጋዴ 5. ተማሪ
6. ቅድመ መደበኛ ትምህርት(ህፃን) 7. የቤት አመቤት 8. ሌላ፡ _____
7. አብሮው የሚኖሩ የቤተሰብ ብዛት፡ _____
8. ሃይማኖት፡ 1. ኦርቶዶክስ 2. እስልምና 3. ፕሮቴስታንት 4. ካቶሊክ 5. ሌላ፡ _____
9. የትምህርት ደረጃ፡ 1. ማንበብና መጻፍ የማይችል/ የማትችል 4. ሁለተኛ ደረጃ ትምህርት(9-12ኛ)
2. ማንበብና መጻፍ የሚችል/ የምትችል 5. ከፍተኛ ትምህርት (ኮሌጅ/ዩኒቨርሲቲ)
3. አንደኛ ደረጃ(1-8ኛ) 6. ቅድመ መደበኛ ትምህርት(ህፃን)

ክፍል ሁለት፡ የተሳታፊዎችን ያለፈ የጤና ሁኔታ በተመለከተ (Past medical and surgical history)

1. የጀርመን መምህራ ሁኔታ፡
 - a. 1. የቀኝ 2. የግራ 3. ሁለቱም
 - b. ለምንደክል ጊዜ መገለፈ፡ የቀኝ _____ የግራ _____
 - c. የአመጋገሉ ሁኔታ፡

	የቀኝ	የግራ
i. ሁሉ ገዜ	☐	☐
ii. አልፎ አልፎ	☐	☐
iii. በጣም ቡዙ	☐	☐
iv. በትንሽ መጠን	☐	☐
v. ሽታ ካለው	☐	☐
 - d. መምህራ ሲጀምር የነበረ ሁኔታ፡

vi. በድንገት የጀርመን ህመም ተሰማኝ	☐	☐
vii. ባእድ ነገር ገብቶበኝ ነበር	☐	☐
viii. ተመትቶ ነበር	☐	☐
ix. ጉንፋን ይዞኝ ነበር	☐	☐
x. መምህራ ብቻ	☐	☐
xi. አላስታውስም	☐	☐
xii. ሌላ፡ _____		
 - e. አሁን የጀርመን ህመም አለ? **የለም** ☐ አዎ ከሆነ፡

	የቀኝ	የግራ
	☐	☐
2. የመስማት ችግር አለ? **የለም** ☐ አዎ ከሆነ
 - a. ሁሉ ጊዜ ☐ ☐
 - b. አልፎ አልፎ ☐ ☐
3. ከአሁን በፊት ታክመው ያውቃሉ? 1. አዎ 2. የለም
4. ለ 3ኛው ጥያቄ ምላሽዎ አዎ ከሆነ፤ ለመጀመርያ ጊዜ የታከሙበት መንገድ
 - a. በየአንገት በላይ ሓኪም
 - b. በሌላ የጤና ባለሙያ (None ENT)
 - c. በራሴ መድሐኒት ገዝቶ ተጠቀምኩ
 - d. በባህል ሓኪም
 - e. ሌላ

ክፍል ሶስት፡ የተሳታፊዎችን የጀሮ ምርመራ የጤና ሁኔታ በተመለከተ (Otoscope examination findings)

Major ear problems		Examination findings				Remark
		Right ear		Left ear		
		Mark X to your answer		Mark X to your answer		
		No	Yes	No	Yes	
1. Ear discharge						
2. Quantity	Scanty					
	Copious					
3. Character of the discharge	Foul smelling					
	Odourless					
	Mucoid					
	Purulent					
	Mucopurulent					
	Bloody					
4. Tympanic membrane perforation						
Subtotal	Pars tensa					
	Pars flaccida					
Total						
6. Complications, specify if any		1. 2. 3. 4.		1. 2. 3. 4.		

ክፍል አራት፡ የተሳታፊዎችን የጀሮ አውድዮመትር ምርመራ የጤና ሁኔታ በተመለከተ (Audiometry results)

Ear Tested	Pure tone average		Type Of Hearing Loss		
	Air Conduction	Bone Conduction	CHL	SNHL	MHL
Right ear					
Left ear					

NB: You can put the thresholds in **dB** at 500, 1000 & 2000Hz for both **AC & BC** at both ears in the given boxes if you don't want to calculate PTA.

Name of data collector: _____

Appendix -V) Assurance of Principal Investigator

I, the undersigned, agree to accept all responsibilities for the scientific and ethical conduct of the research project and for the provision of required progress reports as per the terms and conditions of the requirements of the department. I will provide timely progress report to my advisors and seek the necessary advice and approval from my major advisors in the course of the research.

Name of the principal investigator: Dr. Zinabu Molla (MD)

Signature: _____

Date: _____

Appendix-VI) Declaration

I hereby declare that this MSc thesis is my original work and has not been presented for a degree in any other university and all sources of material used for this thesis have been duly acknowledged.

Signature: _____

Date: _____

Principle Investigator:

Dr.Zinabu Molla, (MD)