RESEARCH PROJECT

TITLE OF STUDY

MICROBIOLOGY OF CHRONIC OTITIS MEDIA AT QUEEN ELIZABETH CENTRAL HOSPITAL, BLANTYRE, MALAWI

Principal researcher:

Dr Moses Chirwa

H58/76484/09

M. Med ENT Surgery Resident

Supervisors:

Dr J.M Aswani, Consultant and Lecturer, Department of ENT/ Head and Neck Surgery, University of Nairobi

Dr P.W Masinde, Head of Department (H.O.D), ENT Department, Kenyatta National Hospital

Dr Wakisa Mulwafu, Consultant ENT Surgeon and Lecturer, College of Medicine/Queen Elizabeth Central Hospital, Blantyre, Malawi

Thesis submitted in partial fulfillment of the requirements for the award of the Degree of Masters of Medicine in ENT, Head and Neck Surgery at the University of Nairobi.

Declaration

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This is my original work which has not been presented before for a degree award at any other university.

Signed .....Date 20/09/2014

Dr Moses Chirwa

This thesis was supervised by:

Dr J.M Aswani (MBChB, MMed (UON))
Consultant and Lecturer
Department of ENT/Head and Neck Surgery
University of Nairobi.

Signed.....Date 19-09-2014

Dr P.W Masinde (MBChB, MMed (UON))
Head of Department (HOD)
ENT Department
Kenyatta National Hospital.

Signed.....Date 20/9/2014

Dr Wakisa Mulwafu (MBChB (UOM), FCS (SA))
Consultant and Lecturer
College of Medicine/ Queen Elizabeth Central Hospital, Blantyre, Malawi

Signed.....Date.....

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Dedication

This dissertation is dedicated to my family for their constant support during its compilation and specifically to my wife Lucy for her patience and support throughout the study. I also dedicate it to my late mum and dad Mr. Chirwa and my children Steve, Lydia, Stella and Duncan for their continued prayers and encouragement. Thank you and God bless you.

Acknowledgement

I would like to thank the entire University of Nairobi, College of Medicine/Queen Elizabeth Central Hospital and Kenyatta National Hospital fraternity for their support in making this project a success. My sincere gratitude goes to my supervisors Dr. Aswani, Dr. Masinde and Dr. Mulwafu for continued guidance and assistance during this study. I also appreciate the contribution of my lecturers towards the completion of this study.

Special thanks to Dr. Mkakosya and Mr. Soko for kindly accepting to offer laboratory services, Mr. Meshark for statistical services and finally, l highly appreciate the support from the Hearing Conservation Council of the United Kingdom.

Operational definitions

Child - COM patient aged below 18 years.

Adult - COM patient aged 18 years and above

Acronyms and Abbreviations

AOM	Acute otitis media
CI	Confidence Interval
CT	Computerized Tomography
COM	Chronic otitis media
DALYs	Daily Adjusted Life Years
EAC	External auditory canal
E.coli	Escherichia coli
ENT	Ear Nose and Throat
ET	Eustachian tube
FB	Foreign body
GERD	Gastro-oesophageal reflux
HOD	Head of Department
KNH	Kenyatta National Hospital
MRI	Magnetic Resonance Imaging
MRSA	Methicillin-Resistant Staphylococcus Aureus
OME	Otitis media with effusion
QECH	Queen Elizabeth Central Hospital
RCT	Randomized Control Trial
SPSS	Statistical Package for Social Sciences
TOM	Tuberculous Otitis Media
TM	Tympanic membrane
UON	University of Nairobi
URTI	Upper respiratory tract infection
WHO	World Health Organisation

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Abstract

Type of research study: This was a hospital based cross sectional descriptive study carried out at the ENT Out-patient clinic and the Microbiology department of Queen Elizabeth Central Hospital, Blantyre, Malawi, a government referral and teaching hospital.

Statement problem: Chronic Otitis Media is still a significant health problem in children and adults in developing countries, therefore it was pertinent to determine the local microbiology in order to achieve adequate treatment, avoid complications and provide records for future references.

Objectives: The study sought to determine the COM causing microorganisms at Queen Elizabeth Central Hospital and establish their relationship with the demographic pattern of the study population and the symptoms/ signs.

Methodology: The sample constituted of 104 patients with unilateral or bilateral active COM attending the ENT Out-patient clinic who met the inclusion criteria. All patients were evaluated through a detailed history and clinical examination. Pus samples from draining ears were collected by aspiration technique using sterile pipette. The specimens collected were immediately sent for microbiology analysis in the microbiology laboratory. Data was analyzed using SPSS Vs. 20.

Findings: The study found out that Proteus mirabilis, Pseudomonas aeruginosa and Staphylococcus aureus were the most prevalent aerobic bacteria while Bacteroides species and Peptostreptococcus species were the commonest anaerobic bacteria COM causing micro-organisms respectively. These COM causing micro-organisms were predominant among males aged 18 years and below. There was also significant association between COM causing micro-organisms and quantity of pus drainage, mode of onset, otalgia, hearing loss, location of TM perforation and mucosal appearance.

CHAPTER ONE: Introduction

1.0 Background information

Chronic otitis media (COM) is defined as a perforation of the tympanic membrane with persistent drainage of pus from the middle ear lasting at least two weeks.[1] It is a major cause of acquired hearing impairment of varying severity mostly in developing countries.[2]

Chronic otitis media is common in infants and children of lower socioeconomic status and causes hearing loss, has an impact on speech and language development and also affects school performance and social interaction.[3] Ear infections are common in children because their Eustachian tubes are shorter, narrower and more horizontal than the adult ear,[4] and children are at this age prone to frequent upper respiratory tract infections which ascend to the middle ear and may subsequently progress to COM. The difference in anatomy of the paediatric ET favours creation of stasis of nasopharyngeal secretions making their movement difficult favouring the growth of microorganisms than in adults.

1.1 Aetiology

Childhood AOM and otitis media with effusion (OME) can both cause long term changes of the tympanic membrane.[7] These changes may reduce the elastic properties of the TM, making it more susceptible to chronic perforation or retraction.[8]

Genetic and racial factors have been associated as risk factors for the development of COM. The incidence of COM varies in different populations and, in the developed world is highest among the Eskimos, Native Americans, New Zealand Maoris and Australian Aborigines.[9] It is significantly more common in cold and dump areas like among the Inuit (Eskimos) and American Indians.[10]

Environmental factors have also been associated as risk factors; the prevalence is higher in lower socioeconomic groups. In a cohort study, with results of 12,000 children, factors significant for draining ears were general health scores, maternal smoking and day care attendance.[11]

Other factors associated with COM are ET dysfunction which is more common in patients with COM than normal individuals.[12] Craniofacial abnormalities are associated with increased risk of COM. The incidence in cleft palate patients is around 20%, 2% of them have cholesteatoma.[13] The tensor veli palatine muscle is hypoplastic in cleft palate children and may predispose to ET dysfunction.[14]

1. 2 Epidemiology

Global burden of illness from COM is estimated to involve about 63-330 million individuals with draining ears, 60% of whom (39-200 million) suffer from significant hearing impairment. It accounts for 28,000 deaths and a disease burden of over 2 million Disability Adjusted Life Years (DALYS). Over 90% of the burden is borne by developing countries in South-east Asia, Western Pacific regions and Africa. COM is uncommon in the Americas, Europe, the Middle East and

Australia.[3] In Britain, 0.9% of children and 0.5% of adults have COM. In Israel, only 0.039% of children are affected. The prevalence of COM in Kenya is about 4.8%.[2]

Certain population subsets are at increased risk for developing COM. The Native American and Eskimo populations demonstrate an increased risk of infection. 8% of Native Americans and up to 12% of Eskimos are affected by COM. The anatomy and function of the Eustachian tube (ET) play a significant role in this increased risk. The ET is wider and more open in these populations than others, thus placing them at increased risk for nasal reflux of bacteria common to acute otitis media (AOM) and recurrent AOM and leading to more frequent development of COM. The prevalence of COM appears to be distributed equally between males and females.[96] Exact prevalence in different age groups remains unknown; however, some studies estimate the yearly incidence of COM to be 39 cases per 100,000 in children and adolescents aged 15 years and younger.[4]

1.3 Microbiology of COM

Typical pathogens reach the middle ear through insufflations of respiratory pathogens through the ET from the nasopharynx and spread from the external ear canal inwards through a non-intact TM.[15, 16] Studies on microbiologic diagnoses of COM differ in regard to patient age, geography and the presence of complications such as cholesteatoma and these inconsistencies likely impact some of the variation in reported pathogens. A portion of the variability observed may be related to differences in sampling and processing methods .[15, 17]

Aerobes, anaerobes and fungi are all potential pathogens in COM. Knowledge of the true frequency of polymicrobial infection, particularly the extent of anaerobic involvement, is limited by differences in collection and culture techniques. [18, 19]

In COM bacteria can be aerobic (e.g. Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Streptococcus pyogenes, Proteus mirabilis, Klebsiella species) or can be anaerobic (e.g. Bacteriodes, Peptostreptococcus, Proprionibacterium).[20] These bacteria are infrequently found on the skin of the external ear canal, but may proliferate in the presence of trauma, inflammation, lacerations or high humidity. These bacteria may then gain entry to the middle ear through a chronic perforation.[21, 22] Pseudomonas is the most commonly isolated organism in COM. Various researchers over the past few decades have isolated Pseudomonas from 48 to 98% of patients with COM although other studies have shown that Staphylococcus aureus is the most common especially when cholesteatoma is present. [23, 24, 25] Fungi, particularly Aspergillus and Candida species, although rare are reported as pathogens as well.[26]

1.4 Pathophysiology

Chronic otitis media is initiated by an episode of acute infection. The pathophysiology begins with initiation and subsequent inflammation of the middle ear mucosa. Ongoing inflammation eventually leads to mucosal ulceration and consequent breakdown of the epithelial lining. The cycle of inflammation and ulceration continues to late chronic phase with well established

intractable mucoperiosteal disease. The recurrent episodes of otorrhoea and mucosal changes are characterized by osteogenesis, bony erosions and osteitis that include the temporal bone and ossicles. This is followed by ossicular chain destruction and or ankylosis which together with the tympanic membrane perforation contribute to hearing loss .[27, 28]

Perforations of the TM are classified as central when the annulus is preserved and marginal when a portion of the annulus or the entire annulus is involved. Marginal perforations are more frequently associated with cholesteatoma .[29]

1.5 Investigations

The diagnosis of COM is based on history, examination findings on otoscopy, supplemented by culture of the ear discharge and radiology of the temporal bone. Gram stains and cultures will assist in guiding therapy and are usually reserved for cases that fail standard topical therapy. Formal audiometry should be considered in all patients with COM to establish the type and degree of hearing loss. Additionally, if there is no response to medical treatment in presence of granulation tissues, then granulation tissues should be biopsied to rule out a neoplastic or granulomatous process.[29]

Computed tomography (CT) scan should be performed if extracranial complications are suspected. A high resolution CT scan in both coronal and axial planes of the temporal bone is preferred to conventional radiology or magnetic resonance imaging (MRI). MRI particularly delineates intracranial pathology that complicate COM. CT scan has a role in diagnosis of COM when the TM cannot be visualized, for example by narrowing or stenosis of the EAC. It may reveal bone erosion from a cholesteatoma or point to area of potential fistula formation.[35, 36]

1.6 Management

Treatment of COM can be medical intervention and/or surgery including rehabilitation through use of hearing aids. The goals of treatment of COM are to stop otorrhoea, heal the TM, eradicate current infection, and prevent complications and recurrence. Medical treatment includes aural toilet and use of topical or systemic antibiotics, topical steroids and topical antiseptics.

Although there are no randomized controlled trials (RCTs) evaluating its use, most experts agree that aural toilet is a key component of treatment of COM. [37] Aural toilet should be used as supplement to antibiotic therapy.[38] These can be administered as either topical or systemic agents. Topical antibiotics are the first line treatment of uncomplicated otorrhoea.[39] Various topical agents have been compared over the years: antibiotics, steroids, anti-fungals and antiseptics. Topical antibiotics with steroids are better than dry mopping alone. Topical antibiotics are more effective than oral or intramuscular antibiotics.[40] In a RCT study by Macfadyen, et al in 2005 in Kenyan school children with COM, topical quinolone (ciprofloxacin) performed better than topical antiseptic (boric acid) in resolution of otorrhoea and improvement of hearing.[41]

Van Hasselt conducted an RCT study among patients with COM in Nkhota- Kota district in Malawi where antiseptic eardrops consisting of 2% acetic acid/25% spirit proved to be ineffective in treatment of COM compared to 0.5% neomycin/0.1% polymixin- B and 0.3% ofloxacin.[42]

Systemic antibiotics should be considered in patients at risk for complicated or invasive ear infections, or in those who receive several courses of empiric topical therapy and are at risk of developing resistant organisms.[43]

Surgical intervention is the treatment of choice to effect closure of perforation since spontaneous healing of chronic TM perforations is uncommon and medical interventions are not effective in promoting closure. Surgery is indicated for patients who develop complications of COM to remove infected tissue in the middle ear or mastoid and to repair ear damage that results in hearing loss. Irreversible disease such as cholesteatoma, polypoid disease, and infected bone must be removed in order to create a dry, safe ear that is free of infection. Preservation of anatomic contour is also important to preserve the acoustic characteristics of the ear, when possible, though some patients with intractable disease will require more aggressive approach such as mastoidectomy. Reconstruction of the sound transmission mechanism is important through use of ossicular prosthesis to replace damaged ossicles. Restoration of tympanic and mastoid aeration is required for both maintenance of a disease- free state and for maximal auditory function.[44]

CHAPTER TWO: Review of Literature

Many studies have been conducted on microbiology of chronic otitis media and show different results from region to region.[15, 16, 17] Microbiological cultures in some studies show many, frequently multiple organisms and these vary depending on climate, patient population, collection and processing techniques of specimens and prior use of antibiotics. [17] Traditional swab specimen collection method has been associated with introducing contaminants with normal skin flora like Staphylococcus epidermidis, diphtheroids and anaerobic organisms e.g. Propionibacterium acnes.[45]

Anaerobes and aerobes play a pathogenic role in COM and they usually grow together in mixed cultures. Experiments show that when anaerobes and aerobes are inoculated together, they produce intense inflammation with production of pus.[46] This reaction is attributed to the synergistic relationship between aerobes and anaerobes.[47] The production of beta-lactamase by anaerobes and some aerobes and their ability to pass on their protective role to other organisms increase their pathogenicity in the mixed state.[48]

In terms of polymicrobial versus monomicrobial cultures various researchers have shown different results.[49,50] In one study of 204 cases of COM, monomicrobial growth was obtained in 118(57.84%) samples, 63(33.33%) samples yielded polymicrobial growth, whereas 18(8.82%) showed no growth[51].[51]

Pseudomonas aeruginosa and Staphylococcus aureus are the most commonly isolated aerobic bacteria in several large case series. [14, 17-20] The ability of these organisms to form biofilms may contribute to their frequency in COM. Fungi particularly Aspergillus species and Candida species although rare are reported as pathogens as well.[26]

Studies conducted by various researchers showed that Pseudomonas aeruginosa followed by Staphylococcus aureus were the commonest isolated aerobic bacteria.[52,53,54,55,56] These findings differ from other studies which showed instead that Staphylococcus aureus was the commonest aerobic bacteria followed by Pseudomonas aeruginosa.[57, 58, 59]

In a study conducted in a central district of Malawi in 1998 in 124 ears, results of the study showed that most ears (91%) incubated faecal bacteria[60]. Proteus mirabilis (74%) and enterococci (60%) were the most frequently isolated microbes. Similar findings were seen in studies done in Ethiopia and DR Congo[61, 62].

Although the majority of studies [54, 55, 56] and other large case series[14], [17-20] on microbiology of COM show that Pseudomonas aeruginosa and Staphylococcus aureus are the commonest aerobic COM causing micro-organisms, a study in Nigeria that looked at retrospective chart review of 128 patients[63], showed different microorganisms causing COM which was also different from those studies that found Proteus mirabilis as the most frequent aerobic bacteria causing COM[60, 61, 62]. The study in Nigeria found out that the most prevalent organisms causing COM were coliform bacteria with Klebsiella species as commonest, followed by E.coli. The authors in the Nigerian study attributed this change in pattern to be probably due to bacterial genome evolution

with the development of bacteria that are more virulent and resistant to some antibiotics. Other studies also isolated coliform bacteria like Klebsiella species as a cause of COM[64, 65, 66] although isolation rates were lower compared to the study conducted in Nigeria[63].

It is generally accepted that anaerobes make up to 20% to 50% of isolates in COM.[61, 62] This high yield can be attributed to improved techniques of collection, transportation and inoculation of specimens. The role of anaerobes in COM has often been questioned as they are most often detected in cases with extensive cholesteatoma or granulation tissue[61].

In a study of 100 patients with COM[67], anaerobic bacteria were isolated in 20(20%) of patients while in another study of 130 patients with COM[68], anaerobes were isolated in 52(40%) of the patients. In contrast in a prospective study conducted in Saudi Arabia in 102 ears with COM[69], only 1(0.9%) anaerobe (Bacteroides species) was cultured. Cultures were for 72 hours so probably not enough time was given to allow growth of slow growing anaerobes. For best results, culture test for anaerobes are to be carried out for 7 days duration.

In a study of COM patients conducted in 2008, 12% of the microorganisms isolated were anaerobes comprising Peptostreptococcus, Bacteriodes and Peptococcus species with Peptococccus species as the commonest[70]. In contrast other studies isolated Bacteroides species as most prevalent[71], while Peptostreptococccus was common among paediatric patients and Provotella melaninogenicus was common in adults[72].

Fungal infections of the middle ear are more common as fungi thrive well in moist ears[73]. The most commonly found fungi in COM are Candida and Aspergillus species[74]. A study of 204 clinically diagnosed patients with COM in India found fungal aetiology in 25(12.25%), of which 7(29.17%) were Candida and 18(70.83%) Aspergillus species[75]. In a study done on patients with COM in Nepal in 2010, Aspergillus species were isolated in 16(6.9%) and Candida species 6(2.6%).[76] A study done in Bosnia in 2010 Aspergillus species were isolated in 6(7.1%), Candida species in 8(9.4%) and Saprophytic flora 12(14.1%). The authors attributed this unusually high prevalence of fungi to an excessive and uncontrolled use of antibiotics. There is also a possibility that in some cases unrecognized fungal inflammations of the auditory canal might be the cause of the infection, as well as the insufficient toilet of the auditory canal (moist, basal environment in the pre-tympanal area).[57]

An additional group of organisms that can cause COM are Mycobacterium species. Tuberculous otitis media (TOM) although uncommon in the developed world is increasing in incidence especially in the developing world[77]. One of the previous study conducted in patients with TOM showed that 9.5% of the children with Tuberculous otitis media were less than 5 years of age[78].

2.1 Problem Statement and Study Justification

COM is a persistent, insidious and potentially dangerous disease because of its various complications. It is still a significant health problem especially in developing countries where not many institutions are able/have facilities for microbiology which attributed to blind treatment.

COM is a common childhood disease that can cause conductive hearing loss which may lead to delayed development of speech and language in children.

Change in bacteriological profile due to indiscriminate use of antibacterial agents has been associated with emergence of multiple drug resistant strains. Information regarding the common pathogens responsible for COM is essential in the selection of the most appropriate treatment regimen and can minimize complications that may require surgery.

2.2 Research question

What is the microbiology of chronic otitis media at QECH?

2.3 Study Objectives

2.3.1 General objective

To determine the COM causing micro-organisms and associated factors among COM patients attending the ENT clinic at QECH

2.3.2 Specific objectives

To determine the COM causing micro-organisms among COM patients attending ENT clinic at QECH

To determine the relationship between demographic factors of patients that is associated with COM causing micro-organisms.

To determine the relationship between COM causing micro-organisms and symptoms/signs

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.1 Study design

This was a hospital based cross sectional descriptive study.

3.2 Study area

This study was carried out in the ENT Outpatient clinic, Queen Elizabeth Central Hospital. QECH has bed capacity of 1,200 beds and serves the population of Blantyre district of 5.5 million people. Queen Elizabeth Central Hospital microbiology laboratory and College of Medicine laboratory were used for the tests done.

3.3 Study Population

These were COM patients attending ENT Outpatient clinic, QECH during the study period.

3.4 Sample size determination

The sample size was determined by the Cochran (1963:75) formula to yield a representative sample for proportions. (Cochran,G., 1977)

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where

n_0 Is the sample size

Z^2 is the abscissa of the normal curve that cuts off area desired at 95% confidence level (The value for Z is found in statistical tables which contain the area under the normal curve.)

p= estimated proportion of population with desired characteristic (COM)

q is 1-p

e is the desired level of precision (sampling error i.e. range in which the true value of the population is estimated to be) (5%)

Required sample

COM Patients

$$n_0 = \frac{(1.96^2)(0.218)(.782)}{.05^2} = 261.96$$

=262 Patients

Since the number of COM patients that fit the inclusion criteria is less than the 10000, we applied the finite population correction for proportions.

COM Patients

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

$$n = \frac{262}{1 + \frac{(262 - 1)}{144}}$$

$$n = 93.16$$

$$n \simeq 94$$

Thus a sample size of 104 COM patients was taken to increase the representativeness of the sample, minimize sampling errors and increase generalizability of the result and cater for attrition (10%).

3.5 Sampling method

All patients with COM were included. . Subjects were recruited into the study as they came to the clinic until the required number was obtained with strict application of the inclusion/exclusion criteria.

3.6 Inclusion and exclusion criteria

3.6.1 Inclusion criteria

All patients with actively draining COM who consented or whose guardians consented to participate in the study.

3.6.2 Exclusion criteria

1. Patients on antibiotic and anti-fungal treatment (ear drops/systemic) within the previous 2 weeks

2. Patients with draining ears of less than 2 weeks duration

3. Patients with draining ears with intact tympanic membrane (otitis external)

4. Patients who refused to consent to participate in the study

3.7 Data collection instrument

3.7.1 Social demographic and medical history

Detailed clinical history regarding age, gender, duration of discharge and antibiotic therapy was taken. Patients of any age, both gender, unilateral or bilateral draining ears due to COM of more than two weeks (WHO- definition) were included in the study. Demographic data was taken and together with the patient's medical history and physical examination findings were entered in the patient's proforma.

3.7.2 Bacterial isolation

Pus specimens from draining ears were taken on the first day of contact with the patient before any topical or systemic antibiotic and anti-fungal medication was started in the previous 2 weeks.

The ears were inspected first; pus from the outer part of the ear canal was then cleaned by suction. Sterile pipette was then introduced through a sterile aural speculum placed in the external auditory canal and specimen aspirated from the bony part of the ear canal (inner two-thirds) or the middle ear cavity. Pus specimens were collected from both ears for patients with bilateral disease.

The specimen collected were immediately placed in an anaerobic jar, under aseptic conditions and transported within one hour of collection to the Microbiology laboratory for routine microbiological culture and identification.

For bacterial isolation, the specimens collected were inoculated on Blood Agar, Maconkey's media, chocolate agar and Robertson's cooked meat media for aerobic and anaerobic cultures. For anaerobic bacteria, anaerobic blood agars were incubated in an anaerobic jar to permit recovery of anaerobic pathogens. For fungi isolation, a part of the pus specimen was cultured on Sabouraud´s dextrose agar. The culture plates were incubated at 37°C for 24-48 hours. Anaerobic culture plates were incubated for 7 days as turn-around time to allow growth of anaerobes which grow slowly compared to aerobes. The isolates from the culture plates were identified using gram staining, colony morphology, catalase, coagulase, oxidase and biochemical strips. For fungal growth lactophenol cotton blue was used for final identification and culture was for 7 days.

3.8 Quality assurance procedures

The patient's history and physical examination was carried out by the principal investigator and research assistant who entered the findings in the patient's proforma. The principal investigator carried out the specimen collection. Only one microbiology laboratory technician was used to process the specimens while reporting on the results of gram staining and growths was done by a single microbiologist.

3.9 Data management

All data collected in the study was sorted, coded and entered in a computer using SPSS software. Data was cross checked against the data files for any inconsistencies and obvious data entry errors. The laboratory request form was also checked for the desired test. The data entry and editing was done throughout the study process. Data was stored for 5 years for further consultation.

The demographic details and characteristics and the particulars of the subjects in terms of predictability and determination of risk of COMs were analyzed using CHI– square. Central tendencies measures like the mean were computed; cross tabulations were done to establish relationships between variables and CHI-square tests used to test association. Data from bacterial isolation was analysed using qualitative methods. The study finding was presented using tables, pie-charts and bar-graphs. Conclusions and recommendations were made based on the results.

3.10 Ethical Consideration

Ethical approval was obtained from the Ethical and Research Committee of College of Medicine and Queen Elizabeth Central Hospital. Participation in the study was voluntary after being consented for by the patient or parent/guardian of the child.

Participants had access to the culture results and treatment.

3.11 Expected findings

The findings of the study included the microorganisms causing Chronic Otitis Media at Queen Elizabeth Central Hospital. In addition, the demographic pattern of the study population and COM symptoms/ signs associated with COM causing micro-organisms.

CHAPTER FOUR: STUDY FINDINGS

4.0 Demographic characteristics

Data collection for this study to determine the COM causing micro-organisms among COM patients attending the ENT clinic at QECH was carried out during a period from July to September, 2013. The study was carried out among 104 patients with clinical evidence of COM. 97(93.3%) of the patients had unilateral disease while 7(6.7%) had bilateral disease. There were 64(61.5%) males and 40(38.5%) females. The mean age was 17.79 years where 64(61.5%) were aged below 18 years and 40(38.5%) aged 18 years and above. The range of the age was 2 to 64 years while the median age was 14 years.

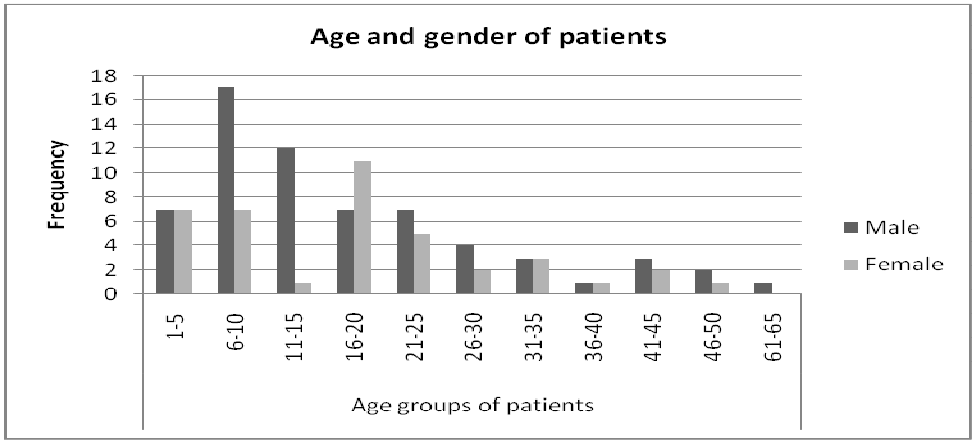

Figure1: Age and gender of patients

4.1 History

The commonest mode of onset was acute ear pain in 87(73.8%), URTI in 19(16.1%), trauma in 7(5.9%) and FB in 5(4.2%) patients.

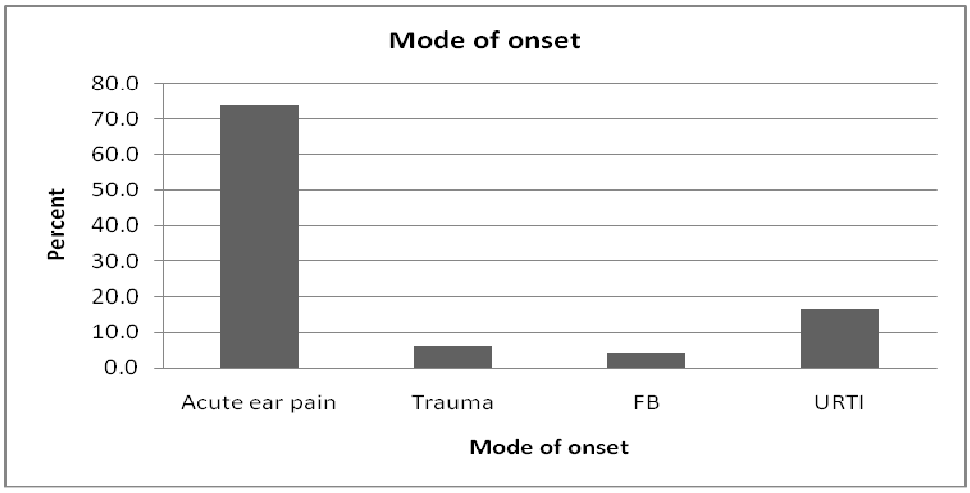

Figure3: Mode of onset

Otalgia was present in 111(94.1%) ears. Otorrhoea was observed in the left ear in 61(51.7%) cases and in the right ear in 57(48.3%) cases. Pus drainage was foul smelling in 90(76.3%) ears and odourless in 28(23.7%). Pus drainage was purulent in 77(65.3%), followed by mucopurulent in 27(22.9%), mucoid in 13(11.0%) and blood stained in 1(0.8%) ears. The pattern of drainage was continuous in 65(55.1%) and recurrent in 53(44.9%) ears.

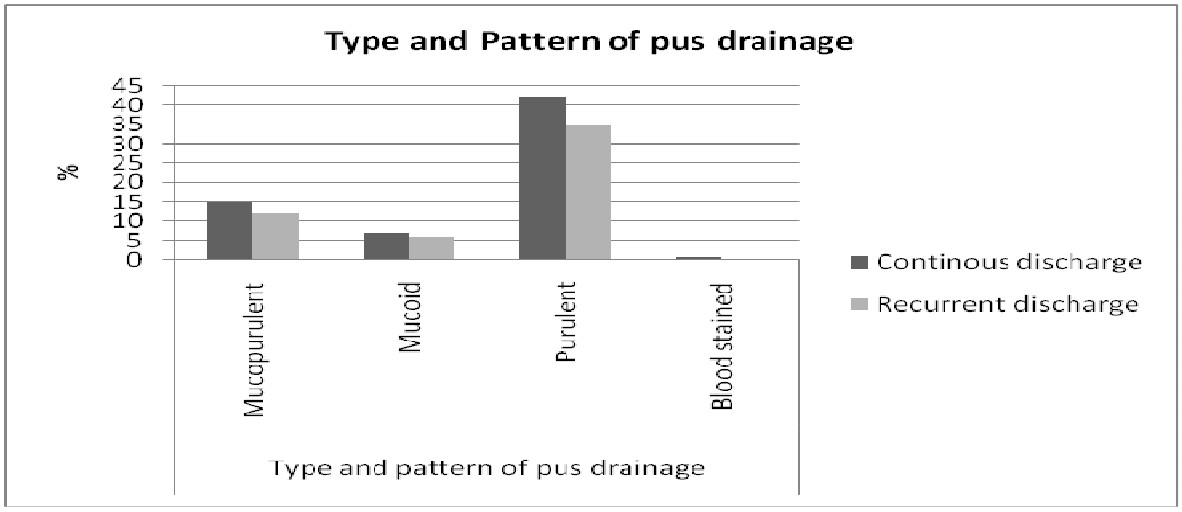

Figure2: Type and pattern of discharge

Hearing loss was reported in 100(84.7%) ears It was persistent in 69(68.6%) ears and fluctuating in 31(31.4%).

4.2 Examination

Examination findings showed that the quantity of pus in canal was scanty in 63(53.4%) ears and copius in 55(46.6%) ears. The pus was foul smelling in 90(76.2%) and oduorless in 28(23.8%) specimens. Foul smelling pus drainage was purulent in 73(61.9%) specimens while the odourless ones were mainly mucopurulent (21(17.8%)).

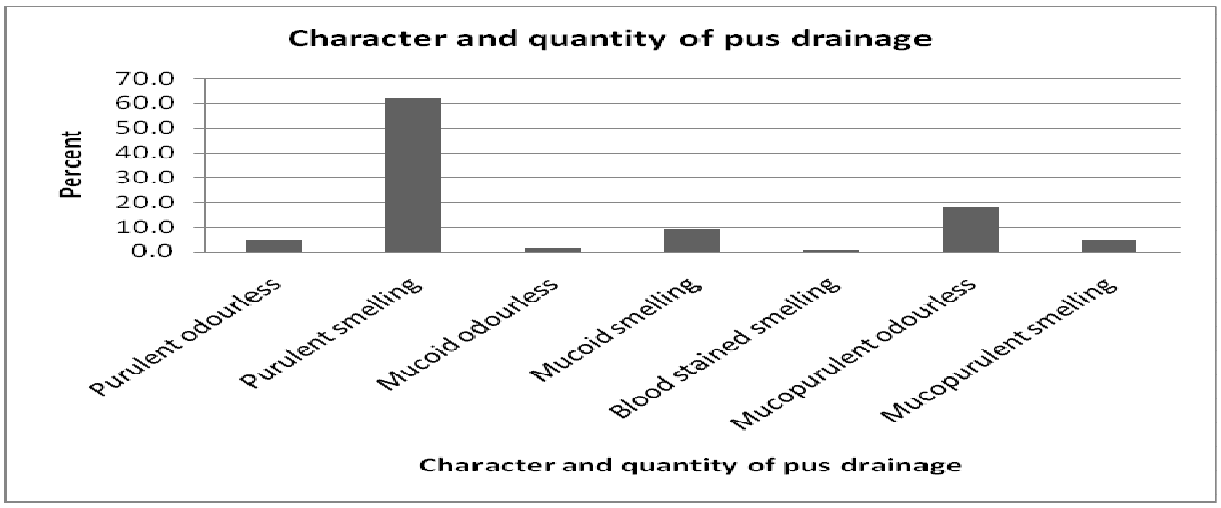

Figure4: Character and quantity of pus drainage

The location of TM perforation was central in 54(45.8%), subtotal in 27(22.9%), marginal in 26(22.0%), attic in 9(7.6%) and total in 2(1.7%).

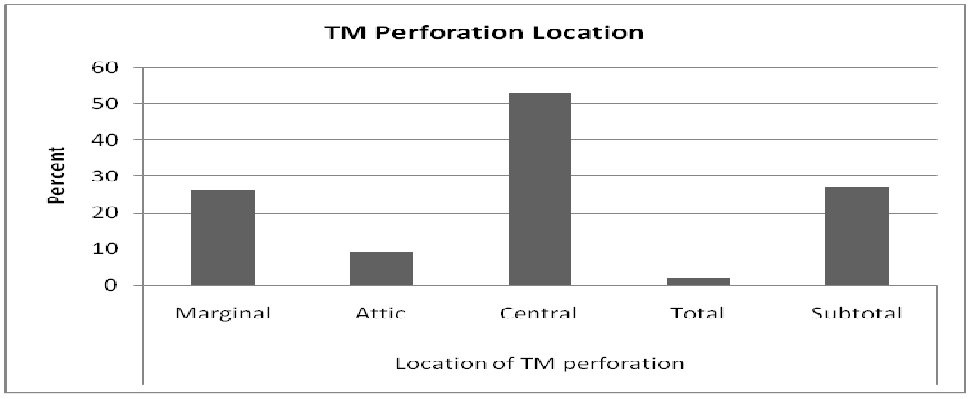

Figure5: TM Perforation location and visibility

Mucosal appearance in the middle ear was injected in 57(48.4%), hyperplastic in 41(34.7%) and sclerotic in 20(16.9%). Granulation tissues were present in 20(16.9%) ears.

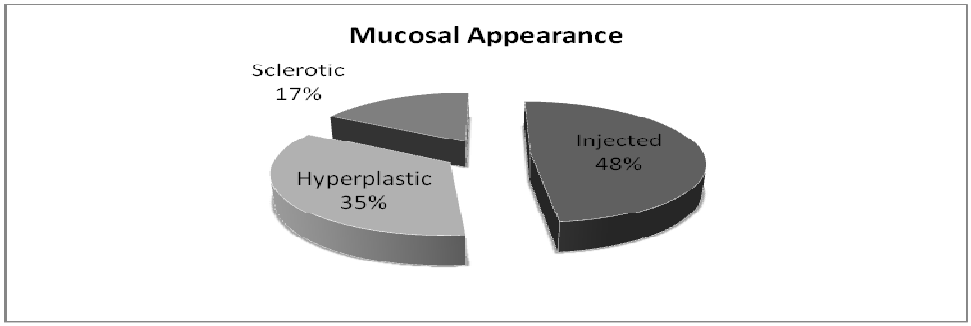

Figure6: Mucosal appearance

4.3 Laboratory findings

There was an equal number of mixed and pure cultures 58(49.05%) each while in 2(1.9%) specimens there was no growth. On gram staining, gram negative bacteria accounted for 84(72.4%) specimens and gram positive bacteria 32(27.6%) specimens.

			Gram stain		
			Gram positive bacteria	Gram negative bacteria	Total
Culture	Pure culture	Count	19	39	58
		% of Total	16.4%	33.6%	50.0%
	Mixed culture	Count	13	45	58
		% of Total	11.2%	38.8%	50.0%
Total		Count	32	84	116
		% of Total	27.6%	72.4%	100.0%
There was significant positive correlation ($\chi 2=0.135$ p=0.026 df=1) between the gram stain and the culture.					

Table1: Correlation between gram stain and culture

Bacterial findings were categorized into aerobes and anaerobes. The most common aerobes identified from the specimens were gram negative bacteria which included Proteus mirabilis 44(28.6%), Pseudomonas aeruginosa 32(20.8%) and E. coli 13(8.4%). The gram positive aerobes identified included Staphylococcus aureus 31(20.1%) and Coagulase negative staphylococcus 6(4.0%). Other organisms were identified in small numbers (Table2)

Name of isolated species		
Gram positive aerobes		
	Frequency	Percent
Staphylococcus aureus	31	20.1%
Coagulase negative staphylococcus	6	4.0%
Streptococcus pyogenes	3	1.9%
Streptococcus pneumoniae	2	1.3%
Gram negative aerobes		
Proteus mirabilis	44	28.6%
Pseudomonas aeruginosa	32	20.8%
E. coli	13	8.4%
Klebsiella pneumoniae	6	4.0%
Proteus vulgaris	6	4.0%
Diptheroides species	4	2.6%
Enterobacter cloacae	3	1.9%
Morganella morganni	1	0.6%
Raultella ornithinolytica	1	0.6%
Coliform species	1	0.6%
Enterobacter cloacae	1	0.6%

Table2: Aerobes isolated

Anaerobes were isolated in 39(33.6%) of total specimens. The most common anaerobes identified were Bacteroides species in 18(15.5%), Peptostreptococcus species 12(10.3%) and Clostridium species 7(6.0%).

Name of anaerobes isolated		
	Frequency	Percent
Bacteroides species	18	15.6%
Peptostreptococcus species	12	10.3%
Clostridium species	7	6.0%
Prevotella melaninogenica	2	1.7%

Table3: Anaerobes isolated

Mixed cultures were 58(50.0%) of total specimens collected. Aerobes were identified in the mixed cultures. Mixtures of Proteus mirabilis and Pseudomonas aeruginosa were the most common 19(16.4%), Proteus mirabilis and E. coli 8(6.9%) each and Staphylococcus aureus and Proteus mirabilis 7(6.0%) each. Other mixtures were found in small numbers (Table4)

Name mixed isolates	**Frequency**	**Percent**
Proteus mirabillis + Pseudomonas aeruginosa	19	16.38%
Proteus mirabilis + E. coli	8	6.90%
Staphylococcus aureus + Proteus mirabilis	7	6.04%
Staphylococcus aureus + Diptheroides species	3	2.60%
Staphylococcus aureus + Proteus vulgaris	3	2.60%
Pseudomonas aeruginosa + Klebsiella pneumoniae	2	1.73%
Staphylococcus aureus + E. coli	2	1.73%
Staphylococcus aureus + Scanty Streptococcus species	1	0.86%
Pseudomonas aeruginosa + Enterobacter cloacae	1	0.86%
Staphylococcus aureus + Coliform species	1	0.86%
Pseudomonas aeruginosa + Clostridium species	1	0.86%
E. coli + Proteus vulgaris	1	0.86%
Coagulase negative staphylococcus + Streptococcus pneumoniae	1	0.86%
Proteus mirabilis + Streptococcus pneumoniae	1	0.86%
Coagulase negative staphylococcus + Klebsiella pneumoniae	1	0.86%
Pseudomonas aeruginosa + Proteus vulgaris	1	0.86%
Staphylococcus aureus + Klebsiella pneumoniae	1	0.86%
Streptococcus pyogenes + Klebsiella pneumoniae	1	0.86%
Pseudomonas aeruginosa + E. coli	1	0.86%
Coagulase negative staphylococcus + Proteus vulgaris	1	0.86%
Coagulase negative staphylococcus + Proteus mirabilis	1	0.86%

Table5: Mixed isolates

Aerobes and anaerobes were isolated in 34(29.3%) of the cultures. These comprised mainly of Bacteroides species 15(12.9%), Peptostreptococcus species 9(7.8%) and Clostridium species 6(5.2%). Others were observed in small numbers. (Table6)

Aerobes and Anaerobes in Mixed cultures	**Frequency**	**Percent**
Bacteroides species	15	12.93%
Peptostreptococcus species	9	7.76%
Clostridium species	6	5.17%
Prevotella melaninogenica	2	1.72%
Diptheroides species	1	0.86%
Enterobacter cloacae	1	0.86%

Table6: Aerobes and anaerobes in mixed cultures

Fungal isolates were identified in 21(18.1%) specimens. The fungal isolates comprised of Aspergillus species in 12(10.3%) of and Candida species 9(7.8%).

Fungus isolated		
	Frequency	Percent
Aspergillus species	12	10.3%
Candida species	9	7.8%

Table4: Fungus isolated

4.4 Association between Age and COM causing micro-organisms

The ages of the patients were grouped into 5-year-intervals. Proteus mirabilis, Staphylococcus aureus and Pseudomonas aeruginosa was commonest among patients aged below 20 years. Streptococcus pyogenes, Klebsiella pneumonia, E. coli and Proteus vulgaris was only identified among patients aged below 20 years ($\chi 2=1.023$ $p=0.725$).

Name species isolated	**Age groups of patients in years**					
	1-20	**21-40**	**41-60**	**61-80**	**Total**	**p-value**
Proteus mirabilis	27	8	3	1	39	0.069
Staphylococcus aureus	22	7	2	0	31	0.059
Streptococcus pyogenes	2	0	0	0	2	0.192
Scanty Streptococcus species	1	0	0	0	1	0.097
Pseudomonas aeruginosa	14	9	3	1	27	0.253
Enterobacter cloacae	2	0	1	0	3	0.301
Coliform species	0	0	1	0	1	0.103
Morganella morganni	1	0	0	0	1	0.129
Clostridium species	0	1	0	0	1	0.132
Klebsiella pneumoniae	4	1	0	0	5	0.060
E. coli	7	0	0	0	7	0.684
Proteus vulgaris	4	1	0	0	5	0.061
Diptheroides species	1	0	1	0	2	0.208
Coagulase negative staphylococcus	3	2	0	0	5	0.511
Streptococcus pneumoniae	1	1	0	0	2	0.239
Raultella ornithinolytica	1	0	0	0	1	0.111

Table7: Association between Age and COM causing micro-organisms

4.5 Association between gender and COM causing micro-organisms

Proteus mirabilis, Staphylococcus aureus, Pseudomonas aeruginosa, Proteus vulgaris and Coagulase negative staphylococcus isolates were mostly common among males. Streptococcus pyogenes, Enterobacter cloacae, Coliform species, Morganella morganni and Raultella ornithinolytica isolates were identified among males only. Clostridium species were only identified among females. Klebsiella pneumonia, E. coli, Diptheroides species and Streptococcus pneumonia isolates were equally distributed between males and females ($\chi 2=0.315$ $p=0.589$).

Name species isolated	Gender of patient		P-value
	Male	Female	
Proteus mirabilis	20	19	0.092
Staphylococcus aureus	21	10	0.062
Streptococcus pyogenes	2	0	0.214
Scanty Streptococcus species	1	0	0.100
Pseudomonas aeruginosa	17	10	0.073
Enterobacter cloacae	3	0	0.313
Coliform species	1	0	0.100
Morganella morganni	1	0	0.100
Clostridium species	0	1	0.100
Klebsiella pneumoniae	2	3	0.514
E. coli	3	4	0.713
Proteus vulgaris	4	1	0.544
Diptheroides species	1	1	0.235
Coagulase negative staphylococcus	4	1	0.514
Streptococcus pneumoniae	1	1	0.235
Raultella ornithinolytica	1	0	0.100

Table8: Association between gender and COM causing micro-organisms

4.6 Association between COM causing Micro-organisms and Symptoms/Signs

Chi-square test was used to determine the relationship between COM causing micro-organisms with symptoms and signs. There was significant association (p-value<0.05) between COM causing micro-organisms and quantity of pus drainage, mode of onset, otalgia, hearing loss, location of TM perforation and mucosal appearance (Table9).

Symptoms/Signs	Wald Chi-Square	df	Sig.(p-value)
Otorrhoea	0.046	2	0.831
Type of discharge	1.027	2	0.598
Quantity of discharge	12.208	2	**0.002**
Type of Odour	0.682	1	0.409
Mode of onset	13.565	4	**0.009**
Presence of Otalgia	5.054	1	**0.025**
Presence of hearing loss	10.628	1	**0.001**
Character of pus discharged	8.518	4	0.074
Location of TM perforation	38.279	3	**0.000**
Mucosal Appearance	35.445	2	**0.000**
Granulation tissue	0.478	1	0.489

Table9: Association between COM causing micro-organisms and symptoms/signs

Quantity of pus drainage was continuous in specimens with Proteus mirabilis 20(17.2%), Pseudomonas aeruginosa 11(9.5%), Bacteroid and Aspergillus species 8(6.9%) respectively. Discharge was mostly recurrent in specimens with Staphylococcus aureus 6(5.2%). The mode of onset was mainly acute ear pain in specimens with Proteus mirabilis 16(13.7%), Pseudomonas aeruginosa 15(12.8%) and Aspergillus species 9(7.7%). Otalgia was present in specimens that mainly had Proteus mirabilis 26(22.0%), Pseudomonas aeruginosa 19(16.1%), Staphylococcus aureus 13(11.0%) and Aspergillus species 14(11.9%). Persistent hearing loss was mainly present in ears whose specimens had Staphylococcus aureus 16(16.0%), Pseudomonas aeruginosa 13(13.0%), Bacteroid species 7(7.0%) and Aspergillus species 7(7.0%). The location of TM

perforation was mainly central in specimens with Proteus mirabilis 15(12.7%), Pseudomonas aeruginosa 9(7.6%) and Aspergillus species 6(5.1%). The location was subtotal mainly in specimens with Staphylococcus aureus 5(4.2%) and marginal in specimens with Aspergillus species 12(12.0%) and Proteus mirabilis 7(5.9%). The mucosal appearance was mainly injected in specimens with Staphylococcus aureus 6(5.2%) and Candida species 5(4.2%), hyperplastic in specimens that had Proteus mirabilis 11(9.3%), Pseudomonas aeruginosa 6(5.1%) and Candida species 3(2.5%) and lastly sclerotic in specimens that had Coliform species, Proteus vulgaris and Peptostreptococcus species.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.0 Discussion

One hundred and four patients with clinical evidence of COM attending ENT Clinic who met the inclusion criteria for the study were recruited.

COM was most prevalent in children and young adults than in the older age group where 64 (61.5%) were aged 18 years and below and 40 (38.5%) were aged 18 years and above with the mean and median ages of 17.79 years and 14 years respectively similar to studies conducted by other authors[50,64]. There are several reasons to explain this observation like the eustachian tube in children is shorter, narrower and more horizontal than in adults and also frequent upper respiratory tract infections which are more common in children.[4] However, these findings differ from the findings of another study which showed that the disease was more prevalent among the age group of 31-40 years[81]. In this study, 64 (61.5%) were males and 40 (38.5%) were females similar to findings from other reported studies[59,61] but differs from findings from some studies which showed that females were more commonly affected than males.[64,81] The male predominance may have been because of lifestyles that exposed them to more risks compared to females such as being in contact with contaminated water in pools or rivers and probably because males may have more health seeking behaviours when ill than females.

Otorrhoea was observed in the left ear in 61(51.7%) ears and in the right ear in 57(48.3%) ears. There were 7 patients with bilateral disease similar to results in other reported studies.[82,83] Patients with bilateral disease had no difference in terms of COM causing microorganisms between the right and left ears. However, in one study conducted in South Africa, 44.4% of patients with bilateral disease showed difference in distribution of bacteriology, indicating that separate pus specimens need to be taken in bilateral disease.[84] The commonest mode of onset was acute ear pain in 87(73.7%) ears. Otalgia was present in 111(94.1%) ears which was higher compared to a study in Iraq where otalgia was present in 50(41.7%) [92]. The pus drainage was mainly purulent foul smelling in 73(61.9%) and mucopurulent odourless in 21(17.8%) ears. Findings in a study done in Iraq indicated that drainage was foul smelling in 30(25%) ears which was different from this study[92]. This is different from a study in Bangladesh where aural drainage was mucoid or mucopurulent in 80(80%) and foul smelling scanty ear drainage was present in 88(88%) [91]. The difference can be attributed to variation in population characteristics and geographical location.

The pattern of pus drainage was continuous in 65(55.1%) and recurrent in 53(44.9%) ears. Hearing loss was reported persistent in 69(68.6%) and fluctuating in 31(31.4%) ears similar to a different study where 80% of patients had reported hearing loss[93]. Hearing loss can be attributed to the presence of a large perforation in the TM. [95]

Quantity of pus in canal was scanty in 63(53.4%) ears and copius in 55(46.6%) ears. Location of TM perforation was mainly central in 54(45.8%), subtotal in 27(22.9%) and marginal in 26(22.0%) ears comparable to findings from previous studies. [59, 90] Mucosal appearance in the

middle ear was injected in 57(48.4%), hyperplastic in 41(34.7%) and sclerotic in 20(16.9%). Granulation tissues were present in 20(16.9%) ears. In a study done in South Africa middle ear mucosa was hyperplastic in 80(70.8%) ears and appeared injected in 76(29.2%) while granulation tissues were found in 42(37.2%) ears.[84]

Microbiology

Analysis of the total 118 specimens collected revealed that pure and mixed culture growth were obtained in equal numbers of 58(49%) each while in 2(2%) specimens there was no growth. Figures reported by other authors vary significantly where pure cultures were isolated in more patients than mixed cultures.[59, 54] It is mostly seen that aerobic gram negative rods outnumber gram positive cocci organisms in COM as reported by some authors [85, 86] which is comparable to the findings in the present study where gram negative rods accounted for 84(72.4%) and gram positive cocci 32(27.6%).

The proportion of different organisms isolated vary from study to study like in this study where the most common bacteria isolate causing COM were aerobic bacteria- Proteus mirabilis 44(28.6%), Pseudomonas aeruginosa 32(20.8%) and Staphylococcus aureus 31(20.1%) . In a study conducted in the rural area of Malawi in 1998 also showed that Proteus mirabilis was the commonest aerobic bacteria[60]. The findings from the rural setting were similar to findings in this study from an urban setting of Malawi in terms of COM causing microorganisms. Comparative findings were in a study done in a rural area of Kenya which showed that Proteus mirabilis was the commonest isolate[87] and also in urban areas of Congo and Ethiopia. [61, 62] Contrary to this study, other studies have reported Pseudomonas aeruginosa as the major organism causing COM.[52, 53, 54] This could be attributed to effect of climate and variation of organisms in different communities and localities and different study sites which are either hospital or community based. In this study E.Coli was isolated in 13(8.4%) specimens and Klebsiella species 6(4.0%) comparable to findings as reported by some authors in literature.[60, 64]. More frequent isolation of faecal bacteria like E.Coli, Klebsiella species indicates that individuals are at high risk of infection due to poor hygiene conditions. Some studies have reported isolation rates of anaerobes of 20% to 50%.[61, 62] In this study anaerobes were isolated in 39(33.6%) of total sampled specimens and most common were Bacteroides species 18(15.5%) followed by Peptostreptococcus species 12(10.3 %) and Clostridium species 7(6.0 %) comparable to findings from other reported studies [71,84] but differ from other research findings which showed Peptococcus[70], Peptostreptococcus species and Prevotella melaninogenicus[72] as the commonest anaerobes. Improved isolation of anaerobes can be attributed to improved collection, transportation and processing techniques of the specimens. Mixed aerobic, anaerobic cultures also characterize chronic infection in COM suggesting a potential synergy between aerobic and anaerobic bacteria. It has been reported that polymicrobial infections are more pathogenic than monomicrobial infections[88]. Fungal infections of the middle ear are common as fungi thrive well in moist ears[73]. The most commonly isolated fungi in COM are Candida and Aspergillus species [74]. In this study fungal isolates were identified in 21(18.1%) of sampled specimens of which

Aspergillus species 12(10.3%) was the commonest followed by Candida species 9(7.8%) comparable with results from another study.[89]

There was significant association between COM causing micro-organisms and quantity of pus drainage, mode of onset, otalgia, hearing loss, location of TM perforation and mucosal appearance contrary to a study where bacteriological findings had no significant effect on symptoms and signs. [94]

5.1 Conclusion

Proteus mirabilis, Pseudomonas aureginosa and Staphylococcus aureus were the most prevalent aerobic bacteria while Bacteroides species and Peptostreptococcus species were the commonest COM causing anaerobic bacteria respectively. These COM causing micro-organisms were predominant among males aged 18 years and below. The disparity in findings from previous research can be attributed to the variation in climate, community, patient population and inadvertent use of antibiotics. There was correlation between COM causing micro-organisms and quantity of pus drainage, mode of onset, otalgia, hearing loss, location of TM perforation and mucosal appearance

5.2 Recommendations

Constant provision of appropriate medication to treat the common COM causing micro-organisms (Proteus mirabilis, Pseudomonas aureginosa, Staphylococcus aureus, Bacteroides species and Peptostreptococcus species) at all levels of health delivery.

Constant provision of information regarding the common pathogens responsible for COM as it is essential in the selection of the most appropriate treatment regimen and formulation of treatment protocols that will minimize complications that may require surgery.

A study is recommended in future to evaluate the drug sensitivities of local microorganisms that cause COM and also subsequently identify change in bacteriological profile due to indiscriminate use of antibacterial agents associated with emergence of multiple drug resistant strains.

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APPENDIX

Appendix1: General Patient Information and Consent Introduction

Participation in this study is voluntary.

What does this study involve?

This study involves an academic research with the aim of finding out the commonest organisms that cause chronic otitis media so that we can give appropriate treatment.

What is chronic otitis media?

It is a disease of the ear characterized by chronic ear discharge, perforated ear drum and causes hearing impairment.

How long am l expected to participate in the research?

Once you consent to participate in the study, it will take you about 30 minutes.

What are the procedures in this study?

Once you consent for your participation, we will take a medical history, examine you and then take some pus from your ear for analysis in the laboratory.

Are there any risks involved?

There are no risks involved but you or your child might experience some discomfort when taking specimens from the ear. However, this will last only a short time.

What benefits will I or my child get if we participate?

Information regarding the common pathogens responsible for COM is essential in selection of the most appropriate treatment regimen.

You or your child can access the results of the specimen collected in follow-up clinics.

What happens if you diagnose other ENT conditions besides COM?

If found to have any other ENT disease, we will treat it accordingly or will be referred appropriately if need be.

What about confidentiality?

All the information we obtain will be kept confidential and the specimen will be handled by a microbiologist.

Whom do I contact for answers to pertinent questions about the research?

In case of pertinent questions, subject's rights among others you can contact the Principal Investigator and the Chairman COMREC through the contacts at the end of the Consent Form.

Will I or my child be penalized for not participating or withdrawing at any time in the course of the research?

No, you or your child will receive the same attention and treatment as those who do not choose to participate or those who withdraw in the course of the research.

How much will it cost me?

No extra cost will be incurred

What are my rights as a participant?

Participation in the study is voluntary. Once inducted in the study, you can choose to discontinue at any time.

What do you do with the information you get?

This information will help us understand the disease better. Like any other scientific information, we will seek to share our findings with other clinicians in Malawi and the rest of the world.

I voluntarily agree to participate in the research.

Name:……Signature ……Date……

Principal researcher: Dr Moses D. Chirwa

Signature ……Date……

If you want to know more or have any queries about this research you can contact the following:

Dr Moses Chirwa (Researcher)
C/o College of Medicine
Department of Surgery
P/bag 360
Chichiri
Blantyre 3
Malawi.
Email: moses_chirwa@yahoo.com

The Chairman
College of Medicine Research and Ethics Committee (COMREC)
P/bag 360
Chichiri
Blantyre 3
Malawi.
Tel: 01 877 245/291
Fax: 01 874 700

MNDANDA WA ZINTHU ZIMENE ODWALA AYENERA KUDZIWA KOMANSO KOPE YA CHILOLEZO (CHICHEWA VERSION)

Mau oyamba

Kutengapo mbali pa kafukufukuyi ndi mozipeleka. Tikufuna kufufuza tizilombo timene timayambitsa matenda a otsegula mkhutu. Zikatero zitithandiza kuti tipeleke ch-ithandizo choyenera kwa odwala

Kodi nanga matenda otsegula mkhutu ndi otani?

Awa ndi matenda amene amakhuza mkhutu ndipo odwala amadandaula kuti mkh- utu mukutuluka mafinya kapena la tseguka komanso nthawi zina samamva kwa- mbiri

Kodi zokhuzana ndi kafukufukiyi ndi zotani?

Mukapeleka chilolezo chotengapo mbali pa kafufukuyi, tizafuna kudziwa zambiri ya matendawa, komanso kukuyezani ndi kutenga mafinya pang'ono ku khutu ndi kutumiza ku malo oyezera

Kodi pangapezeke vuto linalilonse?

Palibe chovuta chachikulu chilichonse komabe nthawi zina odwala atha kumva ululu pang'ono kwa nthawi yochepa panthawi imene tikutenga mafinya ku khutu

Kodi chingachitike nchiana ngati ineyo kapena mwana wanga sanalole kutengapo mbali pa kafufukuyi?

Sipakhala chilango chilichonse, inuyo kapena mwana wanu mudzaladira thandizo mofanana ndi amene atavomeleze kutengapo mbali

Kodi pali chopindulitsa chilichonse pakafukufuku ameneyu ndikatengapo mbali?

Zotsatira zakafukufukuyi zitithandiza kuti tipeze tizilombo timene timayambitsa matenda otsegula mkhutu komanso zitithandiza kuti tipeleke mankwala oyenera okhudza matendawa.

Aliyense wotengapo mbali adzapatsidwa mpata wodziwa zotsatira zaku malo oyedzera mafinya (laboratory) ngati angafune kutero komanso tikapeza matenda ali onse a ENT odwala adzalandira chithandizo kapena tizatumiza kwa a madotolo ena ngati pangafunike kutero.

Kodi chinsinsi chisungidwa?

Zonse zimene tipeze zokhudza kafukufukiyi zizasungidwa mwa chisinsi

Kodi ufulu wanga ndi wotani?

Kutengapo mbali pa kafukufukuyi ndikozipeleka ndipo muli ndi ufulu kusapitiliza ndi kafukufukuyi nthawi iliyonse mungafune kutero ndipo sipangakhale vuto

Kodi zotsatira kafufukuyi mupanga nazo chiani?

Zotsatira za kafukufukiyi zizatithandiza kuti matendawa tiwadziwe mozama koma-nso zotsatirazo zitithandiza kuti tigawane nawo madotolo ena ku Malawi konkuno komanso ndi kunja monga mmene zimachitikira pakachitika kafukufuku

Ineyo modzipeleka ndivomeleza kukhala m'modzi wa anthu otengapo mbali pa kafukufuyi

Dzina……Saini……Date……..

Wopanga kafukufuyi: Dr Moses D. Chirwa

Saini…….Date…….

Ngati mungafune kudziwa zambiri kapena muli ndi mafunso okhudzana ndi kafukufukiyi mutha kufunsa kwa:

Dr Moses Chirwa
C/o College of Medicine
Department of Surgery
P/bag 360
Chichiri
Blantyre 3, Malawi
Email: moses_chirwa@yahoo.com

The Chairman
College of Medicine Research and Ethics Committee (COMREC)
P/bag 360
Chichiri
Blantyre 3
Malawi.
Tel: 01 877 245/291
Fax: 01 874 700

Appendis II: Patient Proforma
PROFORMA NO: _____

AGE: _____ YRS: _____MO. SEX: _____

MEDICAL HISTORY

a) Otorrhoea (tick response):	Right	Left
Yes	☐	☐
No	☐	☐

i. Type of discharge:

Watery	☐	☐
Mucoid	☐	☐
Purulent	☐	☐
Blood stained	☐	☐

ii. Quantity of discharge:

Continuous	☐	☐
Recurrent	☐	☐
Scanty	☐	☐

iii. Odour:

Not foul smelling	☐	☐
Foul smelling	☐	☐

iv. Mode of onset:

Acute ear pain	☐	☐
Trauma	☐	☐
Insidious	☐	☐
FB	☐	☐
URTI	☐	☐

	Right	Left
(b) Otalgia (tick response):		
Yes	☐	☐
No	☐	☐
(c) Hearing loss (tick response):		
Yes	☐	☐
No	☐	☐
If yes; persistent	☐	☐
Fluctuant	☐	☐

EXAMINATION

A) Discharge:	Right	Left
i. Quantity of pus		
Scanty	☐	☐
Canal full of pus	☐	☐
ii. Character of pus:		
Foul smelling	☐	☐
Odourless	☐	☐
Mucoid	☐	☐
Purulent	☐	☐
Bloody	☐	☐
B) TM perforation:		
i. visibility:		
Fully visible	☐	☐
Partly visible	☐	☐
Not visible	☐	☐

ii. Location of TM perforation:

Marginal	☐	☐
Attic	☐	☐
Central	☐	☐
Total	☐	☐
Subtotal	☐	☐

C) Mucosal Appearance:

Injected	☐	☐
Hyperplastic	☐	☐
Sclerotic	☐	☐

D) Granulation tissue (Tick one):

Present	☐	☐
Absent	☐	☐

E) Cholesteatoma (tick one)

Present	☐	☐
Absent	☐	☐

F) Complications:

Present	☐	☐
Absent	☐	☐

If present, indicate which ones:

1.

2.

3.

LABORATORY FINDINGS

1. Gram stain:

Gram positive (+ve)	☐
Gram negative (-ve)	☐

2. Morphology:

Cocci ☐

Rods ☐

3. a) Pure culture ☐

b) Mixed culture ☐

If mixed, no of isolates ☐

c) No growth ☐

2. Name species isolated

1.

2.

3. (a) Anaerobes isolated (Tick one)

Yes ☐

No ☐

(b) Name of species

1.

2.

4. Fungus isolated

a) Aspergillus species ☐

b) Candida species ☐

Appendix III: Proposed implementation timetable

	Sept. 2012 – Feb 2013	March – June 2013	July - September 2013	October 2013
Proposal development and presentation in the department				
Ethical review and approval				
Data collection				
Data analysis and Presentation and submission of results				

Appendix IV: Budget

Item	Cost (Ksh)
Examination kit	10,000
Portable light	5,500
Consumables	10,000
Culture media	20,000
Anaerobic jar with gas pack	15,000
Pipettes	10,000
Laboratory technician	15,000
Microbiologist	20,000
Secretarial services	8,000
Data compiling and analysis	15,000
Stationery	10,500
10% Contingency	13,900
10% College of Medicine administration fee	15,290
Total	168, 190

COLLEGE OF MEDICINE

Principal

K.M Maleta, MBBS PhD

Our Ref.:

Your Ref.: P.02/13/1352

College of Medicine
Private Bag 360
Chichiri
Blantyre 3
Malawi
Telephone: 01 877 245
01 877 291
Fax: 01 874 700

Email: comrec@medcol.mw

7th August 2013

Dr. M. Chirwa
C/O Dr. W. Mulwafu
College of Medicine
Surgery Department
BLANTYRE

Dear Dr. Chirwa

RE: **P.02/13/1352** – Microbiology of Chronic Otitis Media at Queen Elizabeth Central Hospital version 3.0 dated 28 June 2013

I write to inform you that COMREC reviewed the above mentioned proposal which you submitted for expedited review. I am pleased to inform you that COMREC has given you a **conditional approval**. However, **full approval** will be given after you address the issues raised below:

1. The sample size is not clear, please give one figure. There is no reason to have different sample size calculations for children and adults.
2. The consent form is of very low quality.
3. Ethics section should include obligation to tell participants culture results and to treat in case of resistant organisms being identified.

Yours sincerely,

Dr. G. Kalanda
Chairperson, COMREC
GCK/ck

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254 020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref. No.KNH-ERC/R&R/331 Link:www.uonbi.ac.ke/activities/KNHUoN 25th June, 2013

Dr. Moses Chirwa
Dept. of Surgery
School of Medicine
College of Health Sciences
University of Nairobi.

Dear Dr. Chirwa

Research proposal: Microbiology of Chronic Otitis media at Queen Elizabeth Central Hospital, Blantyre, Malawi [P283/5/2013]

This is to acknowledge receipt of your research proposal and to inform you that upon review the KNH/UoN-ERC made the following observations and suggestions:

1. For the intext citations, do not include the author initials, e.g. Nikakhlagh S (see page 10).
2. Indicate the correct sample size: 45, 108, 47 appear indifferent sections of the protocol.
3. Define COM in details and give the diagnostic criteria in the methodology.
4. Why would the identification of HIV infection be a limitation? It is recommended that the HIV infection status is determined as a confounder.
5. Indicate the data base to be used in the entry, analysis and the version.
6. Indicate in details how participants shall be managed after identifying the organism. Shall culture and sensitivity be done as well?
7. A section on the consenting process must be included in the methodology. An assent information form for minors is mandatory.
8. Evidence of ethical approval from the Queen Elizabeth Central Hospital must be provided.
9. Take note that the consent information presently provided is poorly presented. Obtain the KNH-UoN guidelines and endeavour to adhere to them.
10. Where is the study budget?

Recommendation

Revise and resubmit three (3) copies of the proposal within a period of eight (8) weeks' time with effect from the date of this letter to facilitate further processing.

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UoN-ERC

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
Supervisors: Dr. J. M. Aswani, Dr. P. W. Masinde, Dr. Wakisa Mulwafu