RWANDA College of Medicine and Health Sciences

EVALUATION OF PATHOGENIC AGENTS AND ANTIMICROBIAL SUSCEPTIBILITY OF CHRONIC SUPPURATIVE OTITIS MEDIA AT KIGALI UNIVERSITY TEACHING HOSPITAL

Submitted for partial fulfillment of requirements for the Award of Master of Medicine in ENT, Head and Neck Surgery.

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ACRONYMS AND ABBREVIATIONS

CSOM: Chronic Suppurative Otitis Media CHUB: Centre Hospitalier Universitaire De Kigali KUTH: Kigali University Teaching Hospital **ENT:** Ear, Nose and Throat WHO: World Health Organization **OM:** Otitis Media **AOM:** Acute Otitis Media **OME:** Otitis Media with Effusion **USA:** United State of America EAC: external auditory canal **MEE**: middle ear effusion **TM**: tympanic membrane CLSI: Clinical and Laboratory Standards Institute MS: community health insuarance « mutuelle de santé » MS-UR: mutuelle de santé of University of Rwanda **RSSB:** Rwanda Social Security Board

ABSTRACT

Background: Chronic suppurative otitis media is a chronic inflammation of the middle ear and mastoid cavity, with more than 2 weeks of otorrhoea. Bacteria migrate into the middle ear either from the nasopharynx through the Eustachian tube or from the external auditory canal via a perforated tympanic membrane. Various studies have shown that both gram-positive and gram-negative bacteria are responsible for infection of middle ear. The knowledge of the prevailing flora and their susceptibility to antibiotics is an important step for an appropriate treatment.

Objectives: To determine the etiological agents and their antimicrobial susceptibility pattern in patient with CSOM at KUTH

Patients and methods: The current study was crossectional survey involving enrolled 110 patients who consulted ENT Department at KUTH with active chronic suppurative otitis media or its complication, from November 2014 up to January 2015. The patient demographics, clinical presentation, microbiology and antibiotic sensitivity were collected using data collection sheet. A head light was used to examine ears and status of the tympanic membrane after aural toilet

Results: The age of our population ranged between 2 and 89 years, the maximum was in the age range of 16- 30 years (55.5%). The proportion of male to female was almost similar, male constituted 50. 9% while female were 49.1%. The majority had discharge for more than 5 years. For the results of culture and sensitivity, 65.5% showed significant microbial growth of single organism, with majority being *Staphylococcus aureus* 35%, followed by *Klepsiella spp* 15%, and *Pseudomonas aeruginosa* together with *Enterobacter spp* accounting for 10 % for each. For overall of antimicrobial used, ciprofloxacin was revealed to be most effective antimicrobial drug against many organisms at 51.8%. Chloremphenicol was effective at 14.5% while cefotaxim and augmentin showed to be effective at 10% and 8.2% respectively.

Conclusion: *Staphylococcus aureus* were the most common organisms isolated and showed high sensitivity to ciprofloxacin and clindamycin, but it were resistant to penicillin. Ciprofloxacin revealed to be an antimicrobial drug of choice for majority of isolated organisms in our study as well as in many other studies done. There is variation in isolated organisms as well as antimicrobial drugs. For this reason, to know the exact sensitive antibiotic to a certain ear infection treated without success, it is advisable to do culture of discharge and sensitivity.

DEDICATION

To the Only Almighty, Our God.

To my beloved family,

This work is dedicated.

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CHAPTER I: INTRODUCTION

I. 1. Background

Otitis media is defined as "an inflammation of the middle ear without reference to etiology or pathogenesis" (1)Accordingly, otitis media is conceived as an inflammatory disorder of the entire tympanomastoid compartment.

Chronic suppurative otitis media (CSOM) is defined as a chronic inflammation of the middle ear and mastoid cavity, with tympanic membrane perforation and recurrent or persistent episodes of pus discharge from the ear. It is the result of an initial episode of acute otitis media and the main characteristic is a persistent discharge from the middle ear. The WHO defines it as chronic inflammation of the middle ear and mastoid cavity, with more than 2 weeks of otorrhoea (2), but otolaryngologists tend to adopt a longer duration, e.g. more than 3 months of active disease . (3)

Chronic suppurative otitis media (CSOM) concerns otologists, pediatricians or general practitioners. It is a disease of multiple etiologies and is well known for its persistence and recurrence in spite of treatment (4)

It can be classified according to the location of perforation into:

- Tubotympanic (benign and safe form): the perforation is central and does not involve the margin of the drum. Cholesteatoma is much less likely to occur, although this may not be the case in children.
- Atticoantral (unsafe form and progressive): the perforation is marginal; the annulus or the margin of the drum is destroyed. Usually it occurs in the posterior superior quadrant of the tympanic membrane, in the region known as pars flaccida. This perforation allows squamous epithelium from the external auditory canal to grow into the middle ear, resulting in cholesteatoma formation. It tends to be recurrently infected and is characterized by foul discharge and production of debris. Granulation tissue or polyps can form in the middle ear. As the cholesteatoma develops, it may erode the ossicles resulting in hearing loss.

Risk factors for the development of otitis media include young age, overcrowding, inadequate housing and poor hygiene, lack of breast feeding, poor nutrition, and exposure to cigarette or wood burning smoke, nasopharyngeal colonization with bacteria, Eustachian tube dysfunction and inadequate treatment. In developing countries poverty and ignorance sometime play a major contributing factor.

Predominantly a disease of infants and young children, the greatest susceptibility to otitis media may be due to the increased frequency of respiratory infections at this age, an immature immune response to respiratory pathogens, and postural feeding practices in the presence of decreased Eustachian tube competency.

The disease usually begins as a spontaneous tympanic membrane perforation due to an acute infection of the middle ear, acute otitis media (AOM), or as a result of other forms of otitis media (e.g. secretory OM) (5,6).

In CSOM bacteria migrate into the middle ear either from the nasopharynx through the Eustachian tube or from the external auditory canal via a perforated tympanic membrane.

Chronic suppurative otitis media is among the top five common childhood illnesses. It affects 84% of children by the age of 3 years (7). Infection usually results from bacterial and fungal causes and, in some cases, is secondary to viral infections (upper respiratory tract infections) or other bacterial infections such as tuberculosis. Fungal otitis is often associated with a secondary or superimposed bacterial infection, and should be suspected when the ear discharge does not respond to antibiotics.

The most common symptom of CSOM with or without cholesteatoma is a painless discharge from the ear that may or may not be foul smelling. Otoscopy, or, preferably, examination with binocular microscopy, reveals a tympanic membrane perforation and, in active disease, a mucopurulent discharge (8); in case of fungal infection, the discharge is typically odorless, watery, and contains whitish or blackish flakes of fungal debris (9).

The presence of an aural polyp or malodorous otorrhea should raise the clinician's suspicion regarding the presence of cholesteatoma. After careful aspiration of any debris, the status of the middle ear mucosa can be assessed through the perforation.

Pain or vertigo is not expected to be present in uncomplicated CSOM. The presence of either symptom may indicate an impending complication.

Various studies have shown that both gram-positive and gram-negative bacteria are responsible for infection of middle ear. Gram-negative aerobes and anaerobes outnumber the gram-positive ones. The most common bacterial isolate of chronic otitis media is *Peudomonas aeruginosa* (1,10). Other isolates include aerobic organisms, such as enteric gram-negative bacilli, *Staphilococcus aureus*, *streptococci*, *Klepsiella pneumoniae*, and *Hemophilus influenzae*. Anaerobic isolates, associated with a foul smelling otorrhea, include *Peptostreptococcus* and *Bacteroides species* (10). The most commonly fungi are *Candida* and *Aspergillus* (11).

The causatives organisms of CSOM has acquired resistance to both topical and systemic antibiotics, leading to chronicity, increasing the frequency of hospital attendance and medication seek, therefore becoming an economic burden to the population (12). Being destructive and persistent disease it can proceed to serious intra- or extra-cranial complications which can even lead to death (4).

The treatment of chronic suppurative otitis media focuses on the mucosal infection in the tympanomastoid compartment. The basic principles are aural hygiene and the use of a topical antimicrobial agent. Cleaning the ear of mucoid discharge could facilitate middle ear penetration of topical antimicrobials and reduce the quantity of infected material from the middle ear (13). Any underlying allergies and/or nasopharyngeal disorder should be managed. Tympanoplasty of the affected ear has to be planned as soon as the ear becomes dry (14).

The knowledge of the prevailing flora and their susceptibility to antibiotics will guide the clinician to give an appropriate treatment to the patients.

The choice of antibiotic to prescribe so that it could be combined with aural toilet is an important step in the management of CSOM. An agreement of 141 physicians with expertise and interest in middle ear infections recommended the following treatment: do aural toilet by suctioning out the discharge, take the swab on the discharge for culture and sensitivity, prescribe oral antibiotics, and adjust according to results obtained in laboratory (15). Ludman (13) and Nelson (16)

advocated similar approaches and cited potential ototoxic effects as a major disadvantage of topical antibiotics. Other otolaryngologists recommend topical antibiotic therapy and reported the penetration, by most antibiotics into a middle ear mucosa devascularized having subepithelial scarring and widening, to be poor (15). It is recommended to treat first with topical antibiotic and add systemic if culture and sensitivity has been confirmed.

I.2. Literature review

Paradise and colleagues reported their experience in following more than 2,253 children from birth to age 2. The frequencies of episodes of otitis media at 6, 12 and 24 months were 47.8%, 78.9%, and 91.1% respectively (17).

Some studies indicate greater frequency of otitis media among males (61-70%). The basis of the male predilection has not been investigated and may relate to overall sex difference in the rate of childhood infection (17). For Rao and Reddy there was 54% incidence in males and 46% in females, Gulati et al showed the sex distribution of 61% males and 39% females (4).

The higher incidence in males can be explained on presumption that the males are more actively involved in outdoor activities, hence more likely to be exposed to contaminated environment (9). Others indicate no much difference between male and female sex distribution of chronic suppurative otitis media; Kenna et al and Papastavros T. Giamarellouh et al showed an equal distribution (18,19).

In the result of the study done by Rao and Reddy, *Staphylococcus species* was the most prevalent organism (4) Poorey V.K and Arati Iyer (2002) in Iran undertook a study of bacterial flora in CSOM and its clinical significance in S.S Medical College, Rewa. Among 100 cases examined they found that *Pseudomonas species* (35.2%) were the most common organism isolated followed by *Klebsiella species* (25.4%), *Staphylococcus aureus* (14.7%), *Bacillus species*, *Proteus species* (9.8%), *E.coli* (5.88%), *Staphylococcus albus* (4.9%) and *haemolytic streptococci* (3.92%). Amikacin was the most effective antibiotic followed by ciprofloxacin, cefoperazone, gentamicin, cefotaxime and amoxicillin (4).

Ettehad GH, Rejahi S, Nemmati A, Pirzadeh A, Daryani A (2006) undertook a study on microbial and antibiotic susceptibility patterns from patients with chronic suppurative otitis media in Ardebil revealed that most frequently isolated organism was *Staphylococcus aureus* (31.95%), followed by *Pseudomonas aeroginosa* (26.35%), and *Proteus species* (19.67%). Sensitivity results showed that the majority of the isolates were susceptible to ciprofloxacin (85.7%) and resistant to penicillin (84.97%) (20). PK Maji (2007) undertook a study on aerobic bacteriology of CSOM in a tertiary care hospital. Out of 160 samples studied, *Pseudomonas aeruginosa* was the most common isolate (64.4%) followed by *Staphylococcus aureus* (33.8%). Majority of the *Pseudomonas aeruginosa* isolates were sensitive to amykacin followed by gentamycin and cefotaxim (21).

In Ethiopia, the most frequent isolates were *Proteus species* (31%), *Staphylococcus aureus* (18%), *Escherichia coli* (16%), *Klebssiela species* (12%), and *Pseudomonas species* (6%). Most of the isolates were resistant to commonly used antibiotics but sensitive to kanamycin (72%), augmentin (84%) and gentamicin (88%) (22).

In ENT department of Ouagadougou University Hospital, the bacteria isolated most frequently were *Staphylococcus aureus* (29%), *Pseudomonas aeruginosa* (26%) and *Proteus mirabilis* (18%). These organisms were most sensitive to fluoroquinolones (84%) and third-generation cephalosporins (77%). Amoxicillin and tetracycline, on the other hand, were fairly ineffective against these pathogens, with sensitivity rates of respectively 19% and 7% (23).

Afolabi OA et al, from the University of Ilorin, in north central Nigeria, the majority of the bacteria isolated from the middle ear of patient with CSOM were *Pseudomonas aeruginosa* and *Klebsiella Spp* (respectively 31.3% and 23.9%); the minorities were *Streptococcus spp*, *E.coli* and fungal contaminants. Almost all of the organisms in the middle ear were sensitive to ciprofloxacin except *Proteus mirabilis*. *Pseudomonas aeruginosa*, and *Streptococcus faecalis* showed highest sensitivity to ciprofloxacine respectively. Gentamicin was also found to be an effective antibacterial agent to *Streptococcus faecalis*. Ciprofloxacin, azithromycin and amoxicillin - clavulanic acid were found to be effective against *Pseudomonas aeruginosa* (3).

At Muhimbili University College of Health Sciences in Tanzania, the isolates included *Pseudomonas aeruginosa* (51.7%), *Staphylococcus aureus* (17.2%), *Proteus mirabilis* (13.2%), *Klebsiella spp.* (8.0%), *Escherichia coli* (5.8%) and unidentified *coliforms* in 4.0%. Gentamicin showed greatest sensitivity. Kanamycin was active to *Pseudomonas aeruginosa* and *Proteus mirabilis*: 98.5% and 100%, respectively. *P. aeruginosa* was sensitive to chloramphenicol, ampicillin and tetracycline by 58.1%, 10.1% and 8.3%, respectively (24).

For Cochrane review, to resolve otorrhoea and eradicate middle ear bacteria, topical antibiotics were more effective than systemic antibiotics (25). Six studies included in the review (15), chloramphenicol, ofloxacin, and ciprofloxacin were used as topical antibiotics; hydrogen peroxide, and topical antiseptics, boric acid with iodine powder, were used; and cephalexin, flucloxacillin, cloxacillin, amoxicillin, coamoxiclav, erythromycin, metronidazole, piperacillin, ciprofloxacin, azactam, trimethoprim-sulfa, ofloxacin, and intramuscular gentamicin as systemic antibiotics; and showed that topical antibiotics are better than systemic antibiotics. Among topical antibiotics reviewed, topical fluoroquinolones are more effective than other types of topical antibiotics (7). Five studies (15) found that topical ofloxacin or ciprofloxacin was more effective than intramuscular gentamicin, topical gentamicin, tobramycin or neomycin polymyxin in resolving otorrhoea and in eradicating bacteria.

The earlier strains of causative organisms were sensitive to streptomycin, tetracycline and chloramphenicol. Now the trend has changed to aminoglycosides, quinolones and cephalosporins (4).

Though, the treatment of CSOM is getting complicated particularly in developing countries. The antibiogram of these organisms reported is changing with time and geographical area, probably due to inappropriate use of antibiotics. For that reason, there is need to update the antibiogram for effective antibacterial therapy and management of CSOM (26). Therefore, this study is undertaken to better understand the bacterial flora associated with CSOM and their antibiogram profiles in our community.

I.3. Research questions

What is the microbiology of chronic suppurative otitis media?

What is/are the most effective drug(s) in chronic suppurative otitis media?

I.4. Study objectives

General objectives

> To determine the etiological agents and their antimicrobial susceptibility pattern in patient with CSOM at KUTH

Specific objectives

- > To identify the most predominant etiological agents of chronic suppurative otitis media.
- To detect the antimicrobial susceptibility patterns of the pathogens isolated in CSOM patients.

I.5. Hypothesis

Inadequate treatment of chronic suppurative otitis media is related to the development of its chronicity.

I.6. Significance of the study

Many patients at the Ear Nose and Throat (ENT) department present purulent discharge from the ears. Some of them have had long standing symptoms that have been untreated, while others have been treated in different health facilities without success. There is also a large population of patients who have complications of chronic suppurative otitis media due to lack of appropriate treatment.

The results of this study will be useful to us and the hospitals referring to KUTH: as we have defined the majority of germs encountered in chronic suppurative otitis media and the antibiotic sensitivity pattern in our environment, the clinicians will prescribe medication accordingly.

CHAP II. METHODOLOGY

II.1. Study design

The current study was crossectional survey. It enrolled 110 patients who consulted ENT Department at KUTH from end of October 2014 until we reached the desired sample size.

II.2. Inclusion criteria

All patients with active chronic suppurative otitis media or its complication, presented at ear nose and throat (ENT) out patients department, who were not on antibiotic treatment for CSOM for the last five days were recruited.

II.3. Exclusion criteria

Patients with chronic suppurative otitis media, on treatment since less than five days.
Patients with any treatment which can affect the microbiology of CSOM: any antibiotic.
Patients who underwent ear surgery for CSOM complication
Patients with pus discharge from ear post traumatic
Patients with external otitis
Patients who were not cooperative for aural toilet and swab taking.

II.4. Sample size and sampling techniques

The sample size was calculated as follow:

$$n= \frac{Z^2 \times p(1-p)}{E^2}$$

n = required sample size

 \mathbf{Z} = confidence level at 95% (standard value of 1.96)

p = estimated prevalence of chronic suppurative otitis media at CHUK in 2012:

 $\frac{568}{7419}$ =0.0765=7.65%

 $\mathbf{E} = \text{margin of error at 5\% (standard value of 0.05)}$ Calculation: $n = \frac{1.96^2 \times 0.0765 (1 - 0.0765)}{0.05^2} = 108.5 \sim 109$

Our sample size was at least 109 patients.

All patients with CSOM, fulfilling inclusion criteria, were enrolled and we ended up by having **110**.

II.5. Data collection process and tools

The data from patients with chronic suppurative otitis media consulting the ENT department were collected and computerized using data collecting sheets. This includes patient demographics, clinical presentation, microbiology and antibiotic sensitivity.

The purpose and examination procedure of this study were explained to the patient or guardian, and informed consents were obtained. With headlight, the ear was examined first for clinical assessment. For the presence of pus in EAC, aural toilet was performed by suctioning. After that, the tympanic membrane was also evaluated and classified according to the type of perforation into:

- central for perforation not involving the annulus and bounded on all sides by the remnant of the TM;
- subtotal for a perforation involving 4 quadrants and reaches up to the annulus and total when there is erosion of pars tensa and annulus.

Using sterile techniques, middle ear cultures were obtained by swabbing through a tympanic membrane perforation for total perforation; swab from the surface of the remnant tympanic membrane for subtotal or small perforation were obtained. Pus samples were sent to the laboratory for gram stain, culture, identification and in vitro antibiotic sensitivity. All the samples were taken by the principal researcher.

Most of the patients brought the prescriptions given, for those treated before, and by consulting them, we knew which medication they were treated with.

Each specimen was: inoculated in blood agar, Mac Conkey agar and chocolate agar plates; incubated at 37°C for 18-24 hours and colonies identified by culture characters, morphology, and pigment production, and conventional biochemical tests according to standard microbiologic procedures. Antimicrobial susceptibility testing was performed on Mueller Hinton agar by disk diffusion method following the Clinical and Laboratory Standards Institute (CNLS) guidelines.

II. 6. Data processing and analysis.

The data processing and statistical analyses were performed using the SPSS 16.0. Comparisons of categorical variables were performed using the chi-square test. The limit of significance were established at p = 0.05.

II. 7. Ethical considerations

This study was carried out after approval given respectively by the Department of ENT and the Research Committee and Ethics Committee of KUTH and the College of Medicine and Health Science at UR. Patients who were enrolled into the study are those who gave their written informed consent. A parent or guardian was requested to consent for minors (<18 years), who also gave an assent. Confidentiality was assured for all collected data.

CHAP III: RESULTS

III.1. Socio-demographic characteristics and clinical presentation

Age	0-5 years	2	1.8%
	6-15 years	12	10.9%
	16-30 years	61	55.5%
	31-50 years	22	20 %
	>50 years	13	11.8%
	Total	110	100 %
Sex	Female	54	49.1%
50A	Male	56	50. 9%
	Total	110	100 %
Province	East	26	23.6%
TTOVINCE	North	23	20.9%
	South	14	12.7%
	Kigali City	42	38.2%
	West	5	4. 5%
	Total	110	100 %
Education level	None	22	20.0%
	Primary	54	49.1%
	Secondary	27	24.5%
	University	7	6.4%
	Total	110	100 %
Health	MS	102	92.7%
insurance	Other*	8	7.3%
	Total	110	100 %

Table 1. Social demographic characteristics

(*) Other: COGEBANQUE, MS-UR, RSSB, private.

The age of our population ranged between 2 and 89 years, with the maximum being in the age range of 16- 30 years (55.5%). The standard deviation was 15.255. The male constituted 50.9%

while female were 49.1% with a male to female ratio of 1.03:1. The majority of our population, 38.2% lives in Kigali City. 49.1% have primary school as education level and 24.5%. have secondary school education level. Almost all the study population 92.7% have community health insurance (MS).

Table 2. Clinical presentation

Complaints		Frequency	Percent
	Discharge	59	53.6%
	Hearing impairement	41	37.3%
	Itching	8	7.3%
	Pain	2	1.8%
	Total	110	100 %
Duration of discharge	2 weeks to 1 year	9	8.2%
	1 year to 5 years	29	26.4%
	More than 5 years	72	65.4%
	Total	110	100 %
Affected ear	Right	49	44. 5%
	Left	38	34. 5%
	Bilateral	23	20.9%
	Total	110	100 %
TM findings	central perforation	49	44. 5%
5	marginal perforation	2	1.8%
	subtotal perforation	38	34. 5%
	total perforation	21	19.1%
	Total	110	100 %

Even if all enrolled patients were having ear discharge, their chief complaints were different: the majority i.e. (53.6%) was complaining of discharge and 37. 3% had hearing impairment. Concerning the duration of discharge, the majority (65.4%) were having it for more than 5 years. 44.5% of our population were having the discharge in the right ear, while 34. 5% and 20. 9%

were having the discharge in the left ear and bilaterally respectively. Central, subtotal, total and marginal perforations were found in 44.5%, 43.5%, 19.1% and 1.8% of the cases respectively.

III. 2. Treatment used and the microbiology of identified isolate

 Table 3. Treated before and ATB given

Treated before	Yes	68	61, 8%
	No	42	38, 2%
	Total	110	100, 0%
Drug received	Amoxicillin	4	5.88%
	amoxicillin/ chloremphenicol drops	1	1.47 %
	amoxicillin/ polydexa	5	7.35%
	chloremphenicol drops	6	8.82%
	ciprofloxacin drops	3	4.41%
	not aware	10	14.7%
	Polydexa	39	57.3%
	Total	68	100 %

61. 8% of our population was treated before, and the majority (57. 3%) of them, received polydexa and 10 (14. 7%) patients were not aware of the drug received.

Table 4. Microbiology and identified isolates

	I	Frequency	Percent
Isolates	No growth	38	34.5%
	Acinetobacter	4	6%
	Candida albicans	1	1%
	E. coli	4	6%
	Enterobacter spp	7	10%
	Klepsiella spp	11	15%
	Mold	3	4%
	Proteus spp	5	7%
	Providencia stuartii Pseudomonas	4	6%
	aeruginosa	7	10%
	Staphylococcus aureus	25	35%
	Streptococcus groupe		
	B beta hemolytic	1	1%
	Total	110	100%

For the results of culture and sensitivity we had 34.5% of sterile samples and 64.5% of significant microbial growth of single organism. The majority of isolates was *Staphylococcus aureus* 35%, followed by *Klepsiella spp* 15%, and *Pseudomonas aeruginosa* together with *Enterobacter spp* occupying 10%. *Acinetobacter, E. coli* and *Providencia stuartii* were isolated in 6%; while *Proteus spp, Mold, Candida albicans* and *Streptococcus groupe B beta hemolytic* were isolated as 7%, 4%, 1%, 1% respectively.

III. 3 Antibiotic sensitivity of isolates

Table 5. Antibiotic sensitivity

Isolates	AMC	ох	стх	CFX	CRO	CIP	ERY	CN	С
Acinetobacter	-	-	1(25%)	-	-	3 (75%)	-	3 (75%)	-
Candida albicans	-	-	-	-	-	-	-	-	-
E. coli	-	-	2 (50%)	2 (50%)	1 (25%)	_	-	3 (75%)	1 (25%)
Enterobacter sp	2 (28.6%)	-	3 (42.9%)	-	7 (100%)	5 (71.4%)	-	5 (71.4%)	4 (57.1%)
Klepsiella sp	5 (45.5%)	-	- (- (()	-	4 (36.4%)	10 (90.9%)	-	7 (63.6%)	9 (81.8%)
Mold	5 (45.5 %)	-	9 (01.070)	-	4 (30.4%)	-	-	7 (03.076)	- (01.0 <i>%</i>)
Proteus sp	1 (20%)	-	5 (100%)	3 (60%)	1 (20%)	4 (80%)	_	-	1 (20%)
Providencia stuartii	2 (50%)	-	-	0(0%)	-	4 (100%)	-	-	1 (25%)
Pseudomonas aeruginosa	-	_	_	-	_	7 (100%)	_	3 (42.9%)	-
Staphylococcus aureus	-	9 (36%)	_	_	_	24 (96%)	15 (60%)	-	-
Streptococcus groupe B beta hemolytic	-	-	1 (100%)	-	-	-	1	-	-
Total	9 (8.2%)	9 (8.2%)	21 (19.1%)	5 (4.5%)	13 (11.8%)	57 (51.8%)	16 (14.5%)	21 (19.1%)	16 (14.5%)

AMX: augmentin, OX: oxacillin; CTX: cefotaxim; CFX: cefuroxim; CRO: ceftriaxone; CIP: ciprofloxacin; ERY: erythromycin; CN: gentamycin; C: chloremphenicol

Isolates	SXT	PIP	Р	VA	IPM	CLI	TE
Acinetobacter	-	4 (100%)	-	-	-	-	-
Candida albicans	-	-	-	-	-	-	-
E. coli	_	-	-	_	4 (100%)	_	_
Enterobacter sp	4(57.1%)	_	_	-	-	_	_
Klepsiella sp	-	-			-	-	-
Mold	-	-	-	-	-	-	-
Proteus sp	-	-	-	-	-	-	-
Providencia stuartii	0 (0%)	-	-	-	-	-	-
Pseudomonas aeruginosa	3 (75%)	-	-	-	-	-	-
-	-	7 (100%)	-	-	-	-	-
Staphylococcus aureus	-	-	4 (16%)	16 (64%)	-	20 (80%)	13 (52%)
Streptococcus groupe B beta hemolytic	1(100%)	-	1 (100%)	-	-	0 (0%)	-
Total	8 (7.3%)	11 (10%)	5 (4.5%)	16 (14.5%)	4 (3.6%)	20 (18.2%)	13 (11.8%)

STX:sulfamethoxazole trimethoprim; PIP: piperacillin; P: penicillin G; VA: vancomycin; IPM: imipenem; CLI: clindamycin; TE: tetracyclin

Table 6: Summary of antibiotic sensitivity

Antibiotic	S. ai	ureus Klebsiella		Pseudomonas		Enterobacter		
	S*	R*	S	R	S	R	S	R
Ciprofloxacin	96.4%	4%	90.9%	9.1%	100%	0%	71.4%	28.6%
Clindamycin	80%	20%	-	-	-	-	-	-
Vancomycin	64%	36%	-	-	-	-	-	-
Erytromycin	60%	40%	-	-	-	-	-	-
Cefitaxim	-	-	81.8%	18.2%	-	-	-	-
Chloremphenicol	-	-	81.8%	18.2%	-	-	57.1%	42.9%
Piperacillin	-	-	-	-	100%	0%	-	-
Gentamycin	-	-	-	-	42.9%	57.1%	71.4%	28.6%
Ceftriaxone	-	-	36.4%	63.6%	-	-	100%	0%
Augmentin	-	-	45.5%	54.5%	-	-	28.6%	71.4%
Penicillin	16%	84%	-	-	-	-	-	-

S*: sensitive; R*: resistant; S Aureus: staphylococcus Aureus

Staphylococcus aureus was the most common organism isolated and showed higher sensitivity toward ciprofloxacin at 96%, clindamycin at 80%, but decreased sensitivity to vancomycine at 64% and 60% to erythromycin. They were 84% resistant to penicillin. *Klebsiella spp* were 90.9% sensitive to ciprofloxacin 81.8% to cefotaxime and 81.8% to chloremphenicol, but 63.6% resistant to ceftriaxone. *Pseudomonas aeruginosa* were a 100% sensitive to ciprofloxacin and piperacillin, but only 42.9% sensitive to gentamycin.

Among antimicrobial tested, ciprofloxacin was revealed to be most effective drug against many isolates at 51.8%. Chloremphenicol was effective at 14.5% while cefotaxim and augmentin

showed effectivity at 10% and 8.2% respectively. The difference between antibiotics used was statistically significant with a P value <0.001.

CHAP IV: DISCUSSION

The age of our population ranged between 2 and 89 years, with the majority being in the age range of 16- 30 years (55.5%). The standard deviation was 15.255. This was comparable with the findings of the studies done by Borlingegowda Viswanatha et al. in Bangalore, India 2014 (27); Srivastava. A et al. in India in 2009 (28); Kumar R et al. in Jaipur in 2013 (29). In their studies, the majority of their age group was also between 10-30 years. In contrast Loy et al (30) in Singapore showed the prevalence of CSOM increased in the age range of 30-40 years. This could be explained by the fact that during that period of age, there is increase in self-care and tendency to seek for medical health care. Moreover, population in this age range is active, either occupied by daily activity, study or any other activity, chronic ear infection or discharge impairs they activity or hearing leading to poor outcome.

We had almost similar proportion of male, 50.9% and female 49.1% in our study. These findings are in agreement with those obtained by P. K Maji et al in 2007 (21), Borlingegowda Viswanatha et al. in 2014 (27) and Srivastava. A et al in 2009 (28). Male population being more exposed than female in daily life could be the cause of this majority.

The majority of our population (38.2%) lives in Kigali City. This could be because of the fact that the site where our study was conducted is based in Kigali City.

49.1% of our study population have primary school as education level followed by secondary school education level consisting of (24.5%). This is consistent with the results of Kamal N et al. in Bangladesh, 2004 (31), in which the illiterate were also 69.5% and 25.2% of primary level. The disease seems to be higher in less educated people at the time of consultation. This may be due to lack of awareness on the disease or the delay to consult the competent health facilities.

The important proportion of our study population was having community health insurance (Commonly known as "*Mutuelle de Santé*") (92.7%). This is an opportunity that people have access to health services. But they used to start consulting the health facility of low level with providers who are not competent to treat sufficiently the ENT diseases. In addition, the majority

of the people who has" mutuelle de santé" as insurance have low social economic status, which is one of the risk factors.

All enrolled population had ear discharge but their main chief complaints were different while explaining their desease. The majority (53.6%) was complaining of discharge, and 37.3% complained of hearing impairment. The majority of our study population was having discharge for more than 5 years (39.1%). Borlingegowda Viswanatha et al. (27) in their study found that the majority of their population had ear discharge for more than 5 years duration. The delay in seeking medical attention could be explained by the fact that our study site, being a referral hospital, our study population passes first in primary and secondary health care level, spending there a lot of time, sometimes even receiving inappropriate treatment leading to chronicity of the disease, or had consulted our study site without improvement. Ignorance could plays also a great role in the delay of consulting even those health facilities.

In the present study, majority (61.8%) of our population were treated before being enrolled in the study, whereas 38.2% were not. As they have to pass through primary and secondary health care facility before consulting referral hospital, they are first of all treated at those levels, it explain this high percentage. Similarly to the result of Kamal N et al. in Bangladesh 2004 (31), the majority had also received medical treatment from primary and secondary health care level.

For the results of culture and sensitivity, 65.5% had significant microbial growth of single organism, while 34.5% had no growth. This differ a little bit with the result of Ghulam Fatima et al in Karacki (32), Sudhindra KS et al (33) and Chakraborty et all (34) who found 17.9%, 16.9% and 12% of sterile samples respectively. In accordance to Sudhindra (33), the sterile samples may be explained by the fact that they can be commensal organisms of the skin reported by many laboratory technicians as negative or, purely sterile sample.

The predominant pathogen in our study was *Staphylococcus aureus* 35%, followed by *Klepsiella spp* 15%, and *Pseudomonas aeruginosa* together with *Enterobacter spp* occupying 10%. We have the same findings as the study done by R Prakash et al (35) and A Srivastava et al (28) in

India, were *Staphylococcus aureus* predominated in 48.69% (R Prakash) 29.2% (A Srivastava) respectively. The study done by Agrawal et al. (29) in India, revealed a predominance of *Staphylococcus aureus* 37.6 % followed by *Pseudomonas* and *Klepsiella* pneumonia as 32.8% and 4% respectively. Yitayal Shiferaw et al. (36) in Ethiopia also concluded to predominance of *Staphylococcus aureus* (30.2%) followed by *Pseudomonas* (25.9%) (56).

In contrast, the result of Adoga et al in Nigeria (37), R Kumar et al. in Jaipur (33), where the predominant germs were *Pseudomonas* (44%) followed by *Staphylococcus* (27%) and *Pseudomonas* 46.08%, *Staphylococcus aureus* 33.19% respectively. Together with Afolabi OA et al (3), the majority of the bacteria isolated from the middle ear of patient with CSOM were *Pseudomonas aeruginosa* and *Klebsiella Spp* (respectively 31.3% and 23.9%).

These results show that middle ear infection is due to both gram positive and gram negative, the difference observed in the majority between the two may be related to the study population and the environment to which they are exposed to, or by the fact that bacterial organisms causing middle ear infection may change from time to time. Past use of antibiotic can also explain the difference in organism.

For the predominance of *Staphylococcus aureus*, being a skin flora, it has easy access to the middle ear when there is TM perforation. It has also been associated with geographical distribution, depending on the climate, as it is known to be found in the tropical region. The similar point of view has also been reported by Dash M, Padhi S, et al (38) and Jido B A et al in Nigeria (39).

In our study, antimicrobial sensitivity of *Staphylococcus aureus* showed that 96% were sensitive to ciprofloxacin, 80% to clindamycin, 64% were sensitive to vancomycine and 60% to erythromycin. *Klebsiella spp* were sensitive to ciprofloxacin at 90.9%, cefotaxime and chloremphenicol at 81.8%. *Pseudomonas aeruginosa* were a 100% sensitive to both ciprofloxacin and piperacillin, and 42.9% to gentamycin. Similar results were obtained by Srivastava et al. (28) where *Staphylococcus* showed great sensitivity (83%) to fluoroquinolone, and *Pseudomonas* being 100% sensitive. In Agrawal et al's study in India (29), *Staphylococcus aureus* were sensitive to ciprofloxacin, clindamycin, cephalexin, gentamicin, and

chloramphenicol. *Pseudomonas aeruginosa* were found to be sensitive to ciprofloxacin, azithromycin and amoxicillin - clavulanic acid in a study by Afalobi in Nigeria(3).

In contrast to the results of P. K Maji, T.K Chatterjee in India (21), sensitivity rates for a commonly used antibiotic like Ciprofloxacin was 46.6% for *Pseudomonas* and 64.3% for *Staphylococcus aureus*. Asish J et al. (40) in his study concluded that *Staphylococcus* showed great sensitivity to Vancomycin, followed by Fluroquinolones.

Concerning the overall of antimicrobial used for sensitivity, in our study ciprofloxacin was revealed to be most effective antimicrobial drug against many organisms at 51.8%. Chloremphenicol was effective at 14.5% while cefotaxim and augmentin showed effectivity at 10% and 8.2% respectively. Similarly to the findings of Asish J in India (40), ciprofloxacin was shown to have the highest susceptibility rate (89%) of all isolates they tested, followed by gentamicin (76.5%) and chloramphenicol (59.3%).

Ettehad GH et al. (20) have also concluded that majority of the isolates were susceptible to ciprofloxacin (85.7%) and resistant to penicillin (84.97%).

For Afalobi (3), almost all organisms found in the middle ear were sensitive to ciprofloxacin except *Proteus mirabilis*. Gentamicin was also found to be an effective antibacterial agent to *Streptococcus faecalis*.

By these results, ciprofloxacine showed to be the most effective antimicrobial agent in many studies done, followed by chloremphenicol and gentamycin. The difference seen in some studies could be explained by either prolonged use or misuse of antibiotics which could lead to resistance, or to geographical distribution of organisms leading to differences in antimicrobial sensitivity accordingly.

For this reason, to know the exact sensitive antibiotic to a given middle ear infection it is advisable to do culture of discharge and sensitivity.

CHAP V. LIMITATION OF THE STUDY

This study aimed at evaluating pathogenic agents and antimicrobial susceptibility of chronic suppurative otitis media. However, there was among the isolates, fungal species and we did not manage to find appropriate reagent to identify which species of fungal they were especially for aspergillus. Secondly, concerning antibiotic susceptibility, we did not have some antibiotic discs similar to the one routinely used in our department, which are polymixin B and neomycin (polydexa), and ofloxacin.

CHAP VI. CONCLUSION AND RECOMMENDATIONS

VI. I Conclusion.

This study aimed at evaluating pathogenic agent and antimicrobial susceptibility of chronic suppurative otitis media, with objectives to determine the etiological agents and their antimicrobial susceptibility pattern in patient with CSOM at KUTH. The results found in this study showed that *Staphylococcus aureus* were the predominant isolated organisms, followed by *Klepsiella spp*, and *Pseudomonas aeruginosa* together with *Enterobacter spp*.

Staphylococcus aureus showed greatest sensitivity to ciprofloxacin and clindamycin, *Klebsiella* sensitive to ciprofloxacine and cefotaxime, *Pseudomonas* to ciprofloxacine and piperacillin. Ciprofloxacin was revealed to be most effective against many isolates.

VI.II Recommendations

The following recommendations are put forward:

- To use ciprofloxacin as a drug most effective to isolated organism in our settings and avoid using those which are less effective.
- To think about culture and sensitivity for the patient not responding to treatment given.

- To increase the knowledge of the health professionals about chronic suppurative otitis media and its proper management.
- To think about early transfer of the population from primary and secondary health facilities to tertiary level as soon as possible when there is no response to treatment given in those levels.

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APPENDICES

Appendix A: QUESTIONNAIRE

I. Identification

Code

Age:

Sex: M F

Address:

- Province:
- District:
- Referring hospital :

Education level:

- none
- primary
- secondary
- university:

Occupation:

Health insurance:

- MS
- Other (to precise).....

II. Presenting complaints (chief complaints)

Discharge

Pain

Itching

Other :(to precise).....

Duration of discharge:

- 2 weeks to one year
- 1 year to 5 years
- More than 5 years.

Affected ear :

- Right
- Left
- Bilateral

III. Clinical signs

Consistence of discharge:

- Watery
- Serous
- Mucoid
- Purulent
- Blood stained

Position of perforation:

- central
- subtotal
- total
- marginal
- Multiple perforations:

IV. Treatment History

Treated:

- Yes
- No

If yes:

- Systemic
- Topical

Drugs received:

Duration:

Last day of treatment:

Any other medical condition on ATB treatment and precise the ATB:

V. Investigations done : Microbiology

Sample Collected: Ear swab

Microscopy:

- Bacterial
- Fungal

Gram stain:

- gram positive
- gram negative

Specie: (to precise)

VI. Antibiogram:

Antibiotics	S	R	Ι
Amoxycillin / clavulanc			
acid			
Oxacillin			
Cefotaxime			
Cefuroxim			
Cefriaxone			
Ciprofloxacin			
Erytromycin			
Gentamicin			
Chloremphenicol			
Trimethoprim/			
sulfaméthoxazole			
Piperacillin-tazobactam			
Penicillin G			
Vancomycin			
Imipenem			
Clindamycine			
Tetracycline			

Appendix B: CONSENT FORM

RESEARCH ON: Evaluation of pathogenic agents and antimicrobial susceptibility of chronic suppurative otitis media at KUTH.

PRINCIPAL INVESTIGATOR: Dr KAYITESI Marie Françoise, postgraduate University of Rwanda.

PURPOSE OF STUDY

The purpose of the study is to obtain information that will be used to understand the delivery of health services better so as to make improvements. It is aimed to evaluate the pathogenic agents and antimicrobial susceptibility of chronic suppurative otitis media. The study will take six months. It will determine the bacteriological or fungal pathogens of CSOM and its antimicrobial susceptibility; identify the most predominant causative pathogens of chronic suppurative otitis media, and will detect the antibiogram of choice of the isolates of bacterial or fungal microorganisms.

STUDY PROCEDURE

Once decided to participate in the study, I will give information about my identification, presenting complaints, history of particulars, history of my ear condition and medication taken, undergo physical examination to find the status of ears. A sample will be taken in the ear for laboratory analysis and culture for sensitivity.

RISKS TO ME

The study process is safe. The information collected about me shall be treated with due confidentiality.

POTENTIAL BENEFITS TO ME

There are benefits to me from this study. I will be treated according to the findings of clinical and paraclinical examinations done. I understand that the results of the study will be used to improve the delivery of health services, which will also be beneficial to me.

COSTS OF THE STUDY

There will be no costs or payment to me for study.

CONFIDENTIALITY

A code will be used instead of my name; I will not be personally identified in any publication or presentation about this study. Personal and medical information about me will not be released to anyone other than the following without my permission; authorized study personnel, University of Rwanda, school of medicine and health science, department of ENT, Research Committee of the faculty of Medicine.

PROBLEMS OR QUESTIONS

For any questions at any time about this research study as a research volunteer, please contact Dr KAYITESI Marie Françoise on the phone number 0788607792 or the supervisor Dr MUGABO Rajab on telephone number 0788300993

SUBJECT'S CONSENT

has described to me what is going to be done, risks, hazards, and benefits involved, and will be available for questions at KIGALI UNIVERSITY TEACHING HOSPITAL. I understand that my decision to participate will not alter my usual health care. In the use of information generated from this study such as publications, my identity will remain anonymous. I understand that by signing this consent form, I do not wave any of my legal rights nor does it relieve investigations of liability, but merely indicates that I have been informed about the research study in which I am voluntarily agreeing to participate.

Volunteer's name	Volunteer's signature	Age	Date

ASSENT FORM FOR MINORS

I.....

Confirm that the purpose of this study and my role have been well explained to me and to my caretaker by Dr KAYITESI Marie Françoise. I agree to the conditions explained and give consent to be included.

For

Who is my dependant by virtue of being a minor or unable to consent.

Name.....

Signature:

Witness

Signature:

Date.....

Contact: Dr KAYITESI Marie Françoise

Tel no : 0788607792

NB: Concern patient aged between 7-18 years old.