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Original Article

The Pattern of Bacteriological Profile and Antimicrobial Resistance in Children with Chronic Suppurative Otitis Media

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ABSTRACT

BACKGROUND

Chronic Suppurative Otitis Media (CSOM) is one of the most common infectious diseases in the pediatric age group, globally. CSOM has multi-factorial etiologies and is well known for its persistence and recurrence despite adequate antibiotic treatment. Considering the evolving trend of antibiotic resistance, the effective treatment is based on early detection of causative organism and its antibiotic sensitivity via culture and sensitivity test of ear swab. Unfortunately, in resource-limited countries like Pakistan and India, CSOM is a common cause of disabling hearing impairment. **OBJECTIVE:** This study aims to assess the spectrum of bacteria causing CSOM, their antimicrobial resistance and susceptibility pattern, and the efficacy of its empirical treatment regimen in children. **METHODOLOGY:** In this cross-sectional observational study, 150 children with recurrent CSOM, fulfilling the inclusion and exclusion criteria, were enrolled. Samples of ear swabs of middle ear discharge were collected using sterile method and were analyzed for causative microbial identification in accordance with standardized protocol. The antibiotic sensitivity test was performed using modified Kirby-Bauer disc diffusion method. **RESULTS:** Out of 150 samples with positive microbial growths, 50 (33.3%) were aerobes and 100 (66.6%) were anaerobes. The most common CSOM causing bacteria was Methicillin Resistant Staphylococcus Aureus (MRSA) n= 41 (27.3%), followed by Pseudomonas Aeruginosa n= 29 (19.3%), Proteus Mirabilis n=28 (18.6%), Moraxella Catarrhalis n=14 (9.3%), Enterobacteriaceae n= 6 (4%), and Staphylococcus Aureus n= 5 (3.3%). The susceptibility of the above-mentioned resistant strains of CSOM was analyzed against 20 commonly prescribed antimicrobial agents. **CONCLUSION:** This study highlights the need for culture and sensitivity of ear swabs in the patients with CSOM and the revision of empirical antibiotic treatment of CSOM in pediatric population considering the antibiotic sensitivity pattern.

KEYWORDS: Chronic suppurative otitis media, CSOM, Antimicrobial resistance, Children, Culture and Sensitivity

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) is the commonest pediatric medical health problem, worldwide [1]. Unresolved and recurrent CSOM is the most common cause of preventable Disabling Hearing Impairment (DHI) in children [2]. The prevalence of CSOM varies greatly all over the world, ranging from 1% to 46% being more common in developing countries like Pakistan[3]. The developed regions like USA, Australia, Middle East, Canada, and Europe have a very low prevalence of CSOM (<1%) [4] where as, more than 90% of the cases worldwide are recorded annually, in Asia, Africa, and Western Pacific region [5]. A prevalence of 4% or greater indicates a medical emergency that the CSOM in that certain region needs urgent medical attention [6]. In developing countries, chronic ear infection accounts for very high disease burden resulting in the prevalence of 72 per 1000 inhabitants [7].

According to WHO (World Health Organization), CSOM is defined as a chronic inflammation of the middle ear and mastoid air cells with persistent otorrhea from the middle ear through the perforated tympanic membrane lasting for at least 2 weeks [8]. But usually, the general physicians and ENT specialists label a patient with CSOM when the otorrhea persists for 6 weeks to 3 months, despite the adequate medical attention [8, 9]. It starts with acute infection of middle ear called Acute Otitis Media (AOM) or a less severe form of otitis media with effusion called Secretary Otitis Media. If the acute infection is left untreated or undertreated, the AOM will get transformed into CSOM [10]. Yet again, the duration required for a AOM to become CSOM is controversial, ranging from 2 to 6 weeks [11]. There are numerous risk factors to take in account for CSOM in individuals of all ages. However, it is more prevalent in the young children mainly due to anatomical reasons as the Eustachian tubes in children are smaller in length and more straightened than in the adults [12].Ear infections are mostly related to upper respiratory tract infections [13]. It is easier for the microorganisms to access the middle ear through throat. The bacteria or viruses from upper respiratory tract infections move along the Eustachian tubes and colonize the middle ear causing AOM and later CSOM [14]. If left untreated, it can lead to several complications including Meningitis, Brain Abscess, Lateral Sinus Thrombosis, Subdural Abscess, Chronic Mastoiditis, etc. [15,16] In 1990, about 28,000 deaths were recorded due to the complications of CSOM, specifically due to the Brain Abscess [17, 18]. Since then, CSOM has the undivided global attention as USA spends 2 billion dollars of the annual health budget on the prevention and treatment of CSOM [19].

Exposure to the risk factors contributing to CSOM is equal in rural and urban inhabitants [20]. In rural areas, low socioeconomic status, lack of general health awareness, swimming in dirty ponds, poor hygiene, nasopharyngeal colonization with opportunistic pathogenic bacteria, and malnutrition exposes children to develop URTIs and middle ear infections [21]. Limited access to healthcare facilities results in persistent AOM eventually leading to CSOM [22]. On the other hand, the children in the cities are susceptible to developing CSOM due to poor air quality, passive smoking, unaffordable transport, and medical expenses, longer waiting times between consecutive hospital visits and overpopulated neighborhood [23]. Nevertheless, CSOM is found more common among the children living in the rural areas due to above mentioned factors [24].

Among all the reasons that contribute to the development of CSOM, the most important ones are non-compliance to the medical treatment and the resultant antibiotic resistance of the causative agents [25]. When asked, most of the mothers confirmed that they stopped giving their children antibiotics as soon as the ear discharge dried out [26]. Repetitive self-medication and incomplete treatment regimens result in the growth of antibiotic resistant strains of bacteria in the middle ear resulting in undertreated CSOM [27, 28]. Reportedly, with the emergence of highly resistant gram-positive and gram-negative bacterial strains, ear infections became recurrent and resistant to the most effective known antibiotics such as Extended Spectrum Beta Lactamases (ESBL) [29].

Recent studies show that the formation of biofilm in CSOM plays a vital role in maintaining its multi-drug resistant status [30]. Biofilm is a slimy thick, extracellular matrix containing mixed bacterial growth that adheres to the external layer of an implanted material or mucosa. The complex biochemical composition of the biofilm makes it very difficult for doctors to manage it. This is how biofilms significantly add to the multi-drug resistance. Additionally, the mixed growth of microorganisms is difficult to treat [32]. The anaerobes and fungi may form a biofilm in symbiosis with aerobic bacteria. So, a given antibiotic might be affective against one strain but would be ineffective against the other, resulting in partially treated or recurrent CSOM. Hence concluded, the knowledge of culture and sensitivity of the infective organism is pivotal while treating CSOM before it develops its complications i.e., Tympanic Perforation [30-32].

In the developing countries, the medical health resources are limited. To treat the infectious diseases like CSOM, the physicians rely greatly on the empirical regimens. However, it is a common observation that the infection does not resolve with the first line treatment for CSOM. The aim of this study is to identify, isolate, and characterize the bacteriological profile of un-resolving CSOM, persisting for more than 6 weeks despite the medical treatment. The results can be used to evaluate the pattern of antibiotic resistance against the commonly prescribed medical treatment.

MATERIALS & METHODS

After taking Institutional Ethical Approval, this prospective, observational study was conducted in pediatric medical outpatient unit of Children Hospital and Institute of Child Health (CHICH) Faisalabad. One hundred and fifty patients who fulfilled the pre-determined inclusion and exclusion criteria were recruited for this study. Informed consents were obtained from the parents or guardians of the children, in their own language.

The established inclusion and exclusion criteria used for the selection of the patients is as follows:

INCLUSION CRITERIA

1. Children of pediatric age group 1 month to 14 years of age, having complaint of persistent or recurrent ear discharge for6 weeks or more.
2. Patients who were already given antibiotic treatment for CSOM.
3. Patients whose signs and symptoms of CSOM were refractory to oral or intravenous medication.
4. Patients who had perforated tympanic membrane on otoscopic examination.
5. Patients with confirmed bacterial infection of middle ear leading to CSOM, proven by culture report, were included.

EXCLUSION CRITERIA

1. Immunocompromised, treatment-naïve patients, or those with co-morbidities were not included in this study.
2. Patients with fungal or viral infection of the middle ear or those with sterile ear discharge were not recruited.
3. The patients whose attendants or guardians, who were not willing to participate in the study, were not included.

Keeping the anonymity of the patients, all were thoroughly examined via detailed history, systemic and clinical evaluation by consultants. The results were verified and compiled. Otoscopic examination of every patient was performed by ENT specialists. Ideally, before performing culture and sensitivity test of ear discharge sample, an antibiotic-free period should be ensured. Since the data of the study was collected from outdoor patients, their antibiotic free period was uncertain and could not be assessed.

Hearing assessment of the patients was done by specialized audiologists of audiology department by using Pure Tone Audiometry (PTA), Tympanometry, and Auditory Brainstem Response (ABR) tests. The ear swab samples were taken by pathologists in sterile environment and were taken to the lab right away for culture and sensitivity tests. The samples were assessed according to standardized protocol of the hospital lab and the results were provided after 7 days.

Statistical Data Analysis was performed using Statistical Package for Social Sciences Version 20 (SPSS-20). The prevalence of causative agents and other parameters were determined and expressed in the form of percentages. P-value greater than 0.05 was considered significant for this study.

RESULTS

In this study, a total of 150 patients with confirmed diagnosis of CSOM were recruited. Out of 150 patients, n=96 (64%) were male and n=54 (36%) were female, showing male predominance with male to female ratio of 1.7:1. The incidence of CSOM was comparatively higher in the age group of 2-3 years, n=45 (30%, Mean= 2.4 years, SD= 1.7). The duration of CSOM (starting from the onset of its symptoms) was divided into 3 groups: 6 weeks to 6 months n=43 (28.6%), 6-12 months n=60 (40%), and more than 12 months n=47 (31.3%). The most common associated symptoms of CSOM were (in descending order) earache n=133 (88.6%), itching n=118 (78.6%), impaired hearing n=73 (48.6%), and fever n=68 (47.3%).

Age	Frequency (n)	Duration of Ear Discharge			Associated Symptoms			
		6 Weeks-6 Months (n)	6 Months - 12 Months (n)	> 12 Months (n)	Impaired Hearing	Itching	Earache	Fever
1 - 6 Months	15	15	0	0	3	14	14	12
6 - 12 Months	19	5	14	0	14	16	17	8

1 - 2 years	32	5	18	9	12	25	28	15
2 - 3 years	45	17	21	7	17	34	39	17
3 - 5 years	16	1	2	13	10	13	15	8
5 - 10 years	10	0	3	7	6	7	9	5
10 - 14 years	13	0	2	11	11	9	11	6

Table 1. Distribution of CSOM in different age groups, stratified into 3 periods of duration of CSOM infection as well as the frequency of symptoms associated with it

The findings of otoscopic examination done by expert ENT specialists are given in the table 2. The data is explained in terms of frequency, or the number of patients involved (n) and percentage of the total number of subjects (%).

Affected Side	**Frequency (n)**	**Percentage %**
Unilateral	126	84%
Right Ear	84	56%
Left Ear	42	28%
Bilateral	24	16%
Type of Ear Discharge	**Frequency (n)**	**Percentage %**
Mucoid	34	23%
Purulent	67	45%
Mucopurulent	35	23%
Blood stained	14	9%
Odor of Discharge	**Frequency (n)**	**Percentage %**
Foul Smelling	124	83%
Non-Foul Smelling	26	17%
Size of Tympanic Membrane Perforation	**Frequency (n)**	**Percentage %**
>25%	104	69%
26-50%	22	15%
51-75%	5	3%
>75%	19	13%
Location of Perforation	**Frequency (n)**	**Percentage %**
Marginal	14	9%
Central	131	87%
Attic	5	3%
Presence of Granulation	**Frequency (n)**	**Percentage %**
Yes	43	29%
No	107	71%

Table 2. Otoscopic findings of the selected CSOM patients in a tabulated form

The association between type of the causative organism and hearing impairment was assessed, but the results were not found significant (p-value=0.243). Table 3 demonstrates the predominance of gram-negative bacteria as causative agents of CSOM, accounting for about 2/3rd of the total CSOM infections (n=98, 65.3%). Where as gram-positive bacteria were responsible for only 34.7% of the total cases (n=52, 34.6%). The nature of the pathogen colonization was divided into 4 categories, Polymicrobial (n=114, 76%), Monomicrobial (n=27, 18%), Mixed growth (n=9, 6%), and No growth (n=16). Polymicrobial colonization means growth of more than one bacterium at a time, causing COSM.

Gram Staining	Frequency (n)	Percentage (%)
Gram Positive	52	35%
Gram Negative	98	65%
Types of Colonization	**Frequency (n)**	**Percentage (%)**
Monomicrobial	27	18%
Polymicrobial	114	76%
Mixed Growth	9	6%
No growth	16	-

Table 3. Nature and types of colonization of bacteria found in the ear swab culture test. Note: sterile ear discharges or the ear discharges with no bacterial growth were not included in the further analysis

The gram-positive bacteria found in the ear swab culture were Staphylococcus Aureus (n=5, 3.33%), Streptococci (n=3, 2%), Enterococcus (n=1, 0.66%), and Methicillin Resistance Staphylococcus Aureus MRSA (n= 41, 27.3%). MRSA was most prevalent among all the other gram-positive, obligate, or facultative aerobes.

Antibiotic	Gram Positive Bacteria			
	SA (n= 5)	Streptococcus (n =3)	Entrococcus (n= 1)	MRSA (n= 43)
AMX	3	2	1	0
AMP	4	3	0	0
AMC	3	2	0	0
TEC	2	2	0	1
VA	3	3	1	11
CFM	5	3	1	1
CTX	4	3	1	5
CAZ	4	3	0	2
CRO	3	2	0	2
SCF	5	3	1	2
CIP	3	2	0	3
F	4	1	2	4
MEM	5	2	1	15
AK	5	2	1	2
CM	5	2	1	4
CLR	3	2	1	5
TZP	4	3	2	12
LZD	3	1	1	5
PB	2	2	0	0
CB	3	2	0	0

Table 4. Obligate and Facultative gram-positive Bacteria and their sensitivity for 20 different commonly used antibiotics in the light of Culture and Sensitivity test results

AMX= Amoxicillin, AMP= Ampicillin, TEC= Teicoplanin, VA= Vancomycin, CFM= Cefixime, CTX= Cefotaxime, CAZ= Ceftazidime, CRO= Ceftriaxone, SCF= Sulbactam/Cefoperazone, CIP= Ciprofloxacin, F= Nitrofurantoin, MEM= Meropenem, AK= Amikacin, CN= Gentamycin, CLR= Clarithromycin, TZP= Piperacillin/Tazobactam, LZD= Linezolid, SA= StaphylococcusAureus, PB= Polymyxin B, CB= Colistin B

For the ease of data analysis, the gram-negative Bacteria were subdivided into aerobic and anaerobic bacteria. The obligate and/or facultative aerobic bacteria were n=75 (50%) out of total 150 cases of CSOM, including Pseudomonas Aeruginosa PA n= 27 (18%), Proteus Mirabilis PM n= 28 (18.6%), Enterobacter n=6 (4%), Klebsiella n=5 (3.3%), Escherichia Coli n=5 (3.3%), Citrobacter n=2 (1.3%), and Serratia Marcescens n=2 (1.3%).

Antibiotic	Gram Negative Bacteria (Anaerobic)						
	PA (n= 27)	Klebsiella (n= 5)	PM (n= 28)	Enterobacter (n= 6)	Citrobacter (n= 2)	E. Coli (n= 5)	Serratia Marcescens (n= 2)
AMX	2	0	15	0	0	0	0
AMP	3	3	11	4	1	2	0
AMC	2	2	13	2	1	2	0
TEC	6	3	6	2	1	2	0
VA	6	2	6	6	0	3	2
CFM	9	2	7	2	0	1	1
CTX	9	2	7	2	0	2	1
CAZ	7	1	5	4	1	1	0
CRO	8	2	4	4	1	2	0
SCF	5	2	19	3	1	2	1
CIP	14	4	22	1	2	2	0
F	2	3	2	3	1	1	0
MEM	24	4	14	5	2	4	1
AK	2	4	12	3	2	1	2
CM	9	4	24	2	2	1	2
CLR	9	3	23	2	1	2	2
TZP	26	5	26	2	2	5	2
LZD	16	3	12	2	2	4	2
PB	1	3	1	0	2	4	0
CB	3	2	3	0	0	1	1

Table 5. Culture and sensitivity results of CSOM ear swabs samples for gram-negative Anaerobes

AMX= Amoxicillin, AMP= Ampicillin, TEC= Teicoplanin, VA= Vancomycin, CFM= Cefixime, CTX= Cefotaxime, CAZ= Ceftazidime, CRO= Ceftriaxone, SCF= Sulbactam/Cefoperazone, CIP= Ciprofloxacin, F= Nitrofurantoin, MEM= Meropenem, AK= Amikacin, CN= Gentamycin, CLR= Clarithromycin, TZP= Piperacillin/Tazobactam, LZD= Linezolid, PA= Pseudomonas Aeruginosa, PM= Proteus Mirabilis, PB= Polymyxin B, CB= Colistin B

Among the anaerobic gram-negative bacteria, the strains that were found in CSOM ear swab cultures were (in descending order): Moraxella Catarrhalis n=14 (9.3%), Acinetobacter spp, n=4 (2.6%), Haemophlis Influenzae n=3 (2%), and Alcaligenes spp. n=2 (1.3%).

Antibiotic	Gram Negative Bacteria (Aerobic)			
	Acinetobacter Spp. (n= 4)	**Moraxella Catarrhalis (n= 14)**	**Alcaligenes Spp. (n=2)**	**Haemophylis Influenzae (n= 3)**
AMX	0	1	2	0
AMP	1	1	1	2
AMC	3	1	1	2
TEC	3	3	0	1
VA	4	8	1	3
CFM	4	6	2	2
CTX	3	6	1	2
CAZ	3	8	1	2
CRO	4	8	1	2
SCF	4	6	2	3
CIP	1	12	1	1
F	1	2	1	0
MEM	3	2	2	3
AK	2	12	2	2
CM	2	12	2	2
CLR	1	10	1	1
TZP	4	3	2	2
LZD	2	11	2	2
PB	2	2	1	2
CB	1	0	2	1

Table 6. Frequency and antimicrobial sensitivity of gram-negative obligate/facultative aerobes causing CSOM
AMX= Amoxicillin, AMP= Ampicillin, TEC= Teicoplanin, VA= Vancomycin, CFM= Cefixime, CTX= Cefotaxime, CAZ= Ceftazidime, CRO= Ceftriaxone, SCF= Sulbactam/Cefoperazone, CIP= Ciprofloxacin, F= Nitrofurantoin, MEM= Meropenem, AK= Amikacin, CN= Gentamycin, CLR= Clarithromycin, TZP= Piperacillin/Tazobactam, LZD= Linezolid, PB= Polymyxin B, CB= Colistin B

Twenty routinely prescribed antibiotics were assessed for their sensitivity against different bacterial pathogens in 150 cases of CSOM. Most of the first line medications against CSOM were found ineffective against the resistant/modified infectious strains. The antibiotics with superior antimicrobial sensitivity were (in descending order): Tazobactam/Piperacillin 67%, Meropenem58%, and Gentamycin 49%. Rest of the details are elaborated in Figure 1.

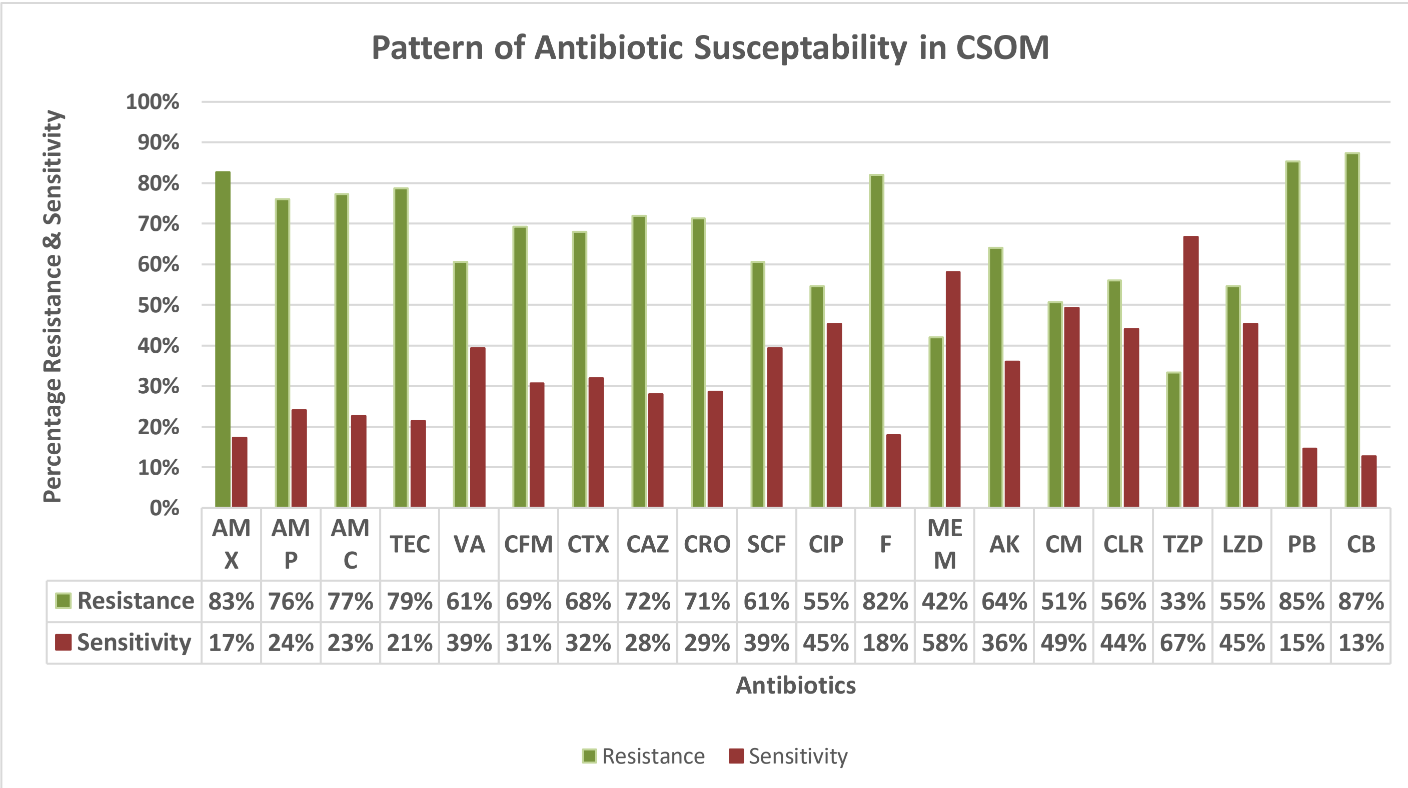

Figure 1. Bar chart showing the Pattern of Antimicrobial susceptibility in CSOM patients AMX= Amoxicillin, AMP= Ampicillin, TEC= Teicoplanin, VA= Vancomycin, CFM= Cefixime, CTX= Cefotaxime, CAZ= Ceftazidime, CRO= Ceftriaxone, SCF= Sulbactam/Cefoperazone, CIP= Ciprofloxacin, F= Nitrofurantoin, MEM= Meropenem, AK= Amikacin, CN= Gentamycin, CLR= Clarithromycin, TZP= Piperacillin/Tazobactam, LZD= Linezolid, PB= Polymyxin B, CB= Colistin B

DISCUSSION

CSOM is one of the major health problems among children and is prevalent in developing countries i.e., Pakistan[1,2]. It has a greater tendency to be persistent and show recurrence with partial or incomplete medical treatment [3,4]. If CSOM stays for long, it results in irreversible complications. Hearing impairment leading to permanent hearing loss is one of them. It starts with the conductive hearing loss (due to ear discharge or wax causing ear canal obstruction and tympanic membrane perforation) and later, results in sensorineural hearing loss (with the involvement of middle ear and damage to the cranial nerves i.e., Facial and Vestibulocochlear Nerve. Presence of mixed hearing loss (conductive as well as sensorineural) indicates extensive and complicated CSOM with the potential involvement of mastoid sinus [33]. It is of special concern in children as hearing impairment in early ages greatly affects their auditory processing, cognitive and speech development, educational process, and psychological and physiological well-being [34]. The incidence of CSOM is more common among children. The preventive measures, early detection, and proper medical attention can eradicate the infection and risks of developing complications, completely [32-34].

Children are more prone to CSOM because of their straighter external auditory canal and higher prevalence of upper respiratory tract infections (URTI). Cold weather, poor hygiene, low socioeconomic status, illiteracy of parents or guardians, failure to get early medical attention, improper medical treatment, and poor compliance also contributes to the recurrent or untreated CSOM [34]. Moreover, the treatment of ear infections with non-traditional herbal concoctions such as natural oils, honey and other mixtures provide medium for exponential growth of pathogenic as well as opportunistic bacteria, thus resulting in Eustachian tube blockage and worsening of pre-existing CSOM infection[35].

The results show male predominance with male to female ratio of 1.7:1. As this was a cross-sectional, observational study based on random selection of the patients, so this result could only be incidental. There are many studies in support of this result, mainly observational [36,37]. But no evidence of any anatomical or physiological difference in the ear structure of male and female has been reported yet.

Analysis of 150 test samples of CSOM revealed that most of the samples had polymicrobial colonization (n= 114, 76%). The polymicrobial culture indicates presence of a group of pathogens where all the pathogens might not be sensitive to the same antimicrobial drug [34-37]. Corresponding figures reported in other researches may vary significantly. The difference in results could be because of the difference intime when the studies were performed as well as geological, socioeconomic, and demographic variations [38]. The presence of polymicrobial culture indicates more extensive CSOM and it explains well the rest of the results of this study i.e., hearing impairment [31,32].

CSOM has both treatment options, medical and surgical. In some complicated cases of CSOM, surgical correction is considered i.e., mastoiditis, cholesteatoma etc. considering the feasibility and availability of the resources. Mainly, CSOM is treated conservatively. The topically applicable antibiotics (Quinolones and Aminoglycosides) are usually preferred due to maximum antibiotic delivery to the effective area, easy application with almost no systemic side effects. These drugs are still effective against ear infections and are widely prescribed by doctors, but misuse/overuse of these drugs is resulting in increased antimicrobial resistance which is evident in our study results. The top two antibiotics with maximum sensitivity against most of the CSOM pathogens were Tazobactam/Piperacillin and Meropenem. Both drugs have only intravenous drug route. On one hand, systemic antibiotics have the advantage of compliance. On the other hand, it is worrisome that drug resistance is getting so prevalent that we must opt for IV medication as a first line management.

According to our recorded data, the gram-negative isolates were two times more prevalent than gram-positive bacterial isolates [36, 37]. However, the previous studies have recorded the high prevalence of gram-positive bacteria in the cultures of CSOM. These contradictory results indicate that the bacteriological spectrum of CSOM has significantly changed over the time. In general practice, the first line antibiotics are prescribed without ordering culture and sensitivity test of ear swabs due to financial restraints. However, most of the patients either do not get treated with this empirical regimen or present again after short time periods with the recurrent CSOM. That is why, a study of a greater magnitude is required to verify and establish the new CSOM guidelines.

CONCLUSION

Like any other chronic disease, CSOM has the tendency to limit growth and productivity in children. As the experts suggest, the prevalence of CSOM greater than 4% should be treated as a national emergency [6]. With the overuse and misuse of antibiotics, the nature, pathogenicity, and resistance of the causative agents of CSOM is evolving. The need of the hour is to evaluate and analyze the bacteriological spectrum and its evolving antibiotic resistance on a larger scale to revise antibiotic treatment, and to reduce incidence and potential complications of CSOM. It is also essential to educate general population regarding the prevention, early detection and hazardous outcomes of CSOM. We believe that our data will help the experts to control the incidence and effectively manage CSOM.

ABBREVIATIONS

CSOM: Chronic Suppurative Otitis Media
DHI: Disabling Hearing Impairment
ESBL: Extended Spectrum Beta Lactamases
MRSA: Methicillin Resistant Staphylococcus Aureus

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