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Changing trends in microbiological profile in patients with active chronic suppurative otitis media in rural based tertiary care hospital

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ABSTRACT

Background: Chronic suppurative otitis media (CSOM) is a major health issue in developing countries causing persistant problem and may lead to life-threatening complications. This major health issue and its complications can be best avoided by early and effective treatment based on the knowledge of causative micro-organisms and their antimicrobial sensitivity which ensures prompt clinical recovery. **Aims and Objectives:** The aim is to study the recent microbiological pattern of patients with active CSOM and to determine the *in vitro* antibiotic sensitivity pattern in order to scientifically guide the patient management rather than trying emperical therapy alone. **Materials and Methods:** This prospective study was conducted in Otorhinolaryngology and Microbiology Department of a Burdwan Medical College and Hospital, Burdwan, a tertiary care hospital in Burdwan from January 2019 to December 2020 and 117 clinically diagnosed cases of COM were included in this study after through history taking and meticulous clinical examination. Two Aural swabs were collected from the affected ear by an ENT specialist as outpatient department procedure, under strict aseptic precautions using sterile swabs, after cleaning external auditory canal with a spirit swab. In cases with bilateral disease, ear swabs were taken separately from both the ears. Pus swabs collected were immediately sent to microbiology department for aerobic culture and sensitivity as well as mycological study as per standard procedure. **Results:** In the present study, the predominant organism which was isolated from the ear swabs of this region was *Pseudomonas aeruginosa*, followed by *Staphylococcus aureus*, *Proteus mirabilis*, *Klebsiella pneumoniae,* and *Escherichia coli*. *P. aeruginosa* showed maximum susceptibility to Colistin, Aztreonam, Piperacillin, and Tazobactum, Polymixin B in decreasing order and showed moderate sensitivity to Levofloxacin and Ceftazidime. Amikacin is found to be the most effective antibiotic against *Proteus* and *Klebsiella* spp. isolated from CSOM patients. **Conclusion:** Knowledge of the local microorganism pattern and their antibiotic sensitivity is essential to allow effective and cost saving treatment to patients who will lead to reduction in morbidity and mortality.

Key words: Microbiological profile; Chronic suppurative otitis media; Pus culture and sensitivity

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INTRODUCTION

Chronic suppurative otitis media (CSOM) implies a permanent abnormality of the pars tensa or flaccida, most likely a result of earlier acute otitis media (OM), negative middle ear pressure or OM with effusion.[1] The prevalence of CSOM and its complications is poorly documented globally[2] but it is estimated that 65–330 million people worldwide are affected by CSOM, of whom 50% suffer from hearing impairment and approximately 28,000 deaths/annum are attributable to the complications of OM. The WHO recorded CSOM incidence of 31 million cases globally. Although its poorly understood, risk factors commonly attributed includes persistent local

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bacterial infection, recurrent acute OM, upper respiratory tract infection, poor hygiene, trauma to middle ear, and tympanostomy tube insertion.[3-7]

CSOM has a profound impact on society in terms of hearing and can have dangerous adverse effects in the absence of timely intervention. Complications of CSOM were frequent in pre-antibiotic era; however, the introduction of antibiotics gave clinicians a tool to be used without the precise etiological diagnosis.

Type of organism involved in CSOM depends on climatic conditions and geographical areas.[8] Since topical preparations containing antibiotics and steroids, to reduce otorrhea and to provide local anti-inflammatory effect are the mainstays of medical management of chronic OM, knowledge[9,10] of the local microbiological flora in CSOM is essential for initiating empirical therapy pending culture results.

Misuse and overuse of antibiotics along with increasing drug resistance among the common pathogens encountered in CSOM makes it mandatory for periodic surveillance of microbiological and sensitivity profile of CSOM. *In vitro* antibiotic susceptibility pattern is very important to the clinician to initiate an appropriate treatment and prevent the complications of CSOM.

The objective of this study was to investigate the clinico–microbiological profile of CSOM and to analyze the susceptibility pattern of the isolates at our tertiary care center, so that an antibiotic policy is formulated for CSOM, for better patient management.

Aims and objectives

The aim is to study the recent microbiological pattern of patients with active CSOM and to determine the in-vitro antibiotic sensitivity pattern in order to scientifically guide the patient management rather than trying emperical therapy alone.

MATERIALS AND METHODS

This prospective study was conducted in Otorhinolaryngology and Microbiology Department of a Burdwan Medical College and Hospital, Burdwan, a tertiary care hospital in Burdwan from January 2019 to December 2020 and 117 clinically diagnosed cases of COM were included in this study after through history taking and meticulous clinical examination.

Inclusion criteria

The following criteria were included in the study:

1. Patients with active stage of CSOM
2. Age between 5 year and 60 year.

Exclusion criteria

The following criteria were excluded from the study:

1. Patients with inactive stage of COSM
2. History of ear surgery in past
3. Acute OM
4. Congenital ear anomaly
5. Those who were not giving consent.

Two Aural swabs were collected from the affected ear by an ENT specialist as outpatient department procedure, under strict aseptic precautions using sterile swabs, after cleaning external auditory canal with a spirit swab. In cases with bilateral disease, ear swabs were taken separately from both the ears. Pus swabs collected were immediately sent to microbiology department for aerobic culture and sensitivity.

For isolation of bacteria, semi-quantitative culture from pus swabs were done on Nutrient agar, Blood agar, MacConkey agar and Chocolate agar media and were identified based on standard microbiological technique. For isolation of aerobic bacteria, and 1st samples were incubated aerobically at 37°C for 16–18 h.

Second swab was used for mycological culture and was inoculated on two slants of Sabouraud Dextrose Agar with chloramphenicol (0.05%) and were then incubated at 28°C and 37°C. The slants were later examined for macroscopic and microscopic morphology of the fungi.

The antibiotic susceptibility testing (AST) of the clinical isolates to some routinely used antibacterial agents was done by Kirby–Bauer disk diffusion method as per CLSI guidelines.

Ampicillin	Amikacin	Gentamicin
Ciprofloxacin	Levofloxacin	Piperacillin-tazobactum
Ceftriaxone	Ceftazidime	Meropenem
Cotrimoxazole	Imipenem	Polymixin B
Ofloxacin	Cefuroxime	Cefixime
Azithromycin	Linezolid	Teicoplanin
Aztreonam	Colistin	Cefoperazone sulbactam

The above antibiotics were tested against *Pseudomonas aeruginosa*, *Staphylococcus aureus,* and *Enterococcus* spp.

All the data collected were sorted in hard and soft copies. Data were analyzed with appropriate statistical methods and have been presented in simple proportions, mean, standard error, etc.

RESULTS

In this present study, a total of 117 patients were included in the study. The range of age in this study was from 5 year child

to 70 year old patient. The gender and age analysis of this study showed a variation in the ratio of suspected CSOM patients and their bacterial infestation. Highest number of patients belonged to the age group 11 years–20 years and the highest bacterial infestation was also found in this group (Chart 1).

The mean age group of the study is 26.35 year for men and 27.91 years for women. In this study, 50% patient were male and 49 % were female.

The most predominant symptom seen in the study was otorrhea which included 47% of the population. Maximum patients showed pale yellow greenish secretion in ear canal. 17.9% of population showed otalgia as main presenting symptoms. Hard of hearing was the main complain of 15.3% of population. About 8.5% of population presented with ear bleeding along with pustular secretion. Less than 10% of population showed other symptoms such as ear blockage, tinnitus, and dizziness.

Pure tone audiogram of the study population showed 61.9% had pure conductive hearing loss and 34.1% had mixed hearing loss and 4.2% had pure sensorineural hearing loss. Hearing loss was confirmed by audiometry and more than 50% of population showed mild conductive hearing loss. Only 7% of population showed moderate to severe loss. None showed profound hearing loss. History of hearing loss had a range of 3 months–1.5 years.

In the present study, unilateral infection of CSOM ear (77.7%) was more common compared to bilateral infection of CSOM ear (22.2%).

In this study, no cases with complications of CSOM (intracranial or extracranial) were observed. Around 30% of the population had a history of or active upper respiratory tract infection at the time of presenting symptoms. Allergic rhinitis was seen in 17% of study population and chronic tonsillitis was seen in 17% of study population as predisposing factor in developing a chronic ear discharge. About 12.8% of the study population had past history of direct trauma to ear. Many patients reported nasal blockage along with otalgia. Reflux related OME was found in 8.5% of population.

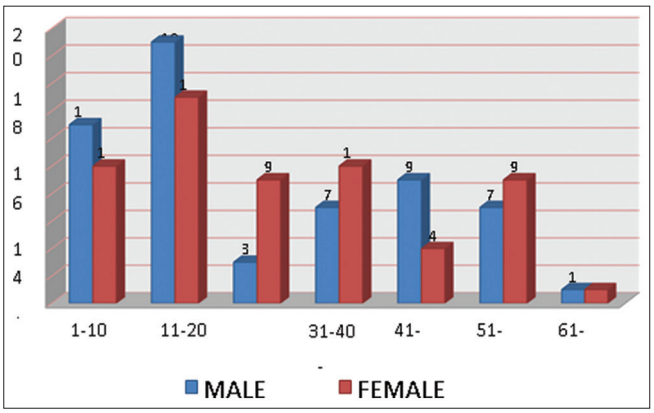

Chart 1: Age and sex distribution

A total of 117 ear swabs were collected and 64.1% of CSOM ear showed monomicrobial growth, 27.3% of CSOM ear showed polymicrobial growth and there was no growth in 8.5% of CSOM ear (Table 1). Among 117 isolates, the bacteriological profile in this study showed aerobic growth in 107 (91.5%) cases and no anaerobic growth was recorded.

It is observed that both Gram-negative organism and Gram-positive organisms are responsible for CSOM. Out of the 117 ear swabs that were collected the Gram-negative organisms (42.78%) outnumbered the Gram-positive organisms (40.45%) in this study. This result was found universally common in all researches done till now.

In the present study, the predominant organism which was isolated from the ear swabs of this region was *P. aeruginosa* (Table 2). The second most common organism isolated was *S. aureus* (27.35%). The high incidence of resistant strains in external auditory canal as well as upper respiratory tract has increased the incidence of *S. aureus* in the middle ear. Methicillin-susceptible *S. aureus* (MSSA) (9.4%) was observed in the present study which was found more than Methicillin-resistant *S. aureus* (5.9%). The high incidence of MSSA in this study is a good indicator. *Proteus mirabilis* (5.1%), *Klebsiella pneumoniae* (4.2%), and *Escherichia coli* (0.8%) were the other organisms isolated in patients with CSOM.

Amikacin is found to be the most effective antibiotic against *Proteus* and *Klebsiella* spp. isolated from CSOM patients (Table 3). The present study showed that *Proteus* spp showed high sensitivity to Amikacin and Gentamicin. *Klebsiella* spp showed high sensitivity to Amikacin only. They both showed resistance to third generation cephalosporin.

Fungal infections of the middle ear are common as fungi thrive well in moist pus. The most common fungi found in this study of CSOM is *Aspergillus fumigatus* (11.1%). In

Table 1: Age wise distribution of various morphotypes in chronic otitis media

Age (in years)	Monomicrobial	Polymicrobial	Sterile
1–10	17	5	1
11–20	18	12	4
21–30	9	3	0
31–40	12	5	0
41–50	7	4	2
51–60	10	3	3
61–70	2	0	0

Table 2: Different types of organisms isolated from chronic otitis media patients

Types of organism	Number of isolates in female	Number of isolates in male	Percentage
Bacterial isolates			
Pseudomonas aeruginosa	17	21	32.4
Staphylococcus aureus	5	9	11.9
Methicillin-resistant Staphylococcus aureus	7	0	5.9
Methicillin-susceptible Staphylococcus aureus	6	5	9.4
Proteus mirabilis	2	4	5.1
Escherichia coli	0	1	0.8
Klebsiella pneumoniae	2	3	4.2
Fungal isolates			
Aspergillus fumigatus	6	7	11.1
Aspergillus niger	8	1	7.6
Penicillium	1	0	0.8
Candida albicans	0	2	1.7
No growth	4	6	8.5

the present study, fungal etiology was found in 21% cases out of which only 1.7% were *Candida* species and 11.1% were *Aspergillus* species.

AST was carried out for all the aerobic isolates. These findings were mostly parallel to the reports by other authors. With regard to antibiotic susceptibility for organism *P. aeruginosa* showed maximum susceptibility to Colistin, Aztreonam, Piperacillin and Tazobactum, Polymixin B in decreasing order and showed moderate sensitivity to Levofloxacin and Ceftazidime.

S. aureus showed maximum sensitivity to Vancomycin, Linezolid, Cefoxitin whereas showed moderate sensitivity to Ceftriaxone, Azithromycin, and Teicoplanin. It showed maximum resistance to 3rd generation cephalosporin Cefoxitin and Cefuroxime.

DISCUSSION

The present study was conducted on 117 patients who presented with active stage of CSOM attending ENT Outdoor of Burdwan Medical College and Hospital, Burdwan from January 2019 to December 2020. Mofatteh et al.,[11] found the highest numbers of suspected CSOM patients aged between 21 and 30 years old. In the study of Vishwanath et al.,[12] the patients were in the age group of 21–30 years. In his study, Appiah-Korang et al.,[13] the organisms were isolated from the age group 0–5 years, whereas Hiremath et al.,[14] and other researchers elaborated maximum incidence was observed during second decade of life and the incidence decreased as the age advanced. Mane and Basawraju[15] showed male preponderance. Similar results were seen in Poorey and Iyer[16] and Kumar and Seth[17] studies. Prakash et al.,[18] study showed the ratio of female to male was 1.2:1. However, statistical analysis indicated that there were no significant differences between bacterial infestations among the patients in terms of gender or age. Findings of present study tally with findings of other and show that CSOM. is more common in poor class or low socio-economic group.

In the present study, unilateral infection of CSOM ear (77.7%) was more common compared to bilateral infection of CSOM ear (22.2%). These findings were similar to the results of study conducted by Kumar et al.,[9] Sharma et al.,[19] and Hiremath et al.[14]

These findings were similar to the studies conducted by Mane and Basawraju[15] where 63.3% of sample were pure in nature and 16.3% showed mixed nature, 20% sample were sterile. 58.5% samples showed monomicrobial growth whereas 29.8% samples yielded polymicrobial growth in Vishwanath et al.,[12] study. 90.9% showed monomicrobial growth while 9.09% of the cases showed polymicrobial growth in Kumar et al.,[9] study. However in Hiremath et al.,[14] study all the cases had monomicrobial growth.

Out of the 117 ear swabs that were collected 76.9% had tubo-tympanic disease and only 23% presented with attico-antral disease. This finding was consistent with Vishwanath et al.,[12] study who had 68% tubo-tympanic disease and 31.9% presented with attico-antral disease. In the present study, 107 (91.4%) of samples were positive and 10 (8.54%) were negative for the culture. The positivity of culture growth was similar to the results of the studies conducted Vishwanath et al.,[12] (88.3%), and Hiremath et al.,[14] (90.5%).

Studies conducted by Appiah-Korang et al.,[13] showed no anaerobic organism, however it was inconsistent with other studies. A study by Vishwanath et al.,[12] showed 74.8% of aerobic growth and 15.6% of anaerobic growth. In a similar study by Loy and Tan[21] 66.6% of samples showed aerobic growth and 6% showed anaerobic growth. Some of the previous studies have not found significant association of anaerobes with CSOM. Even

Table 3: Antimicrobial susceptibility patterns of microbial isolates from ear discharge

Antimicrobial agent	Susceptible	Resistant
Pseudomonas species		
Amikacin	4	-
Ampicilin	5	-
Imipenem	-	2
Polymixin B	10	-
Piperacillin and Tazobactum	10	2
Ceftriaxone	4	2
Aztreonam	14	-
Colistin	15	-
Gentamicin	4	1
Ciprofloxacin	-	2
Meropenam	-	11
Ceftazidime	8	2
Cefoperazonesulbactam	6	4
Levofloxacin	8	-
Ofloxacin	4	1
Cotrimaxozole	-	-
Cefuroxime	2	1
Cefixime	1	1
Azithromycin	-	-
Linezolid	-	-
Teicoplanin	-	-
Staphylococcus spp		
Amikacin	4	-
Ampicilin	-	-
Vancomycin	12	-
Polymixin B	1	-
Piperacillin and Tazobactum	2	-
Ceftriaxone	7	-
Aztreonam	1	-
Colistin	1	-
Gentamicin	3	1
Ciprofloxacin		1
Meropenam		-
Ceftazidime	1	-
Cefoperazone Sulbactam	1	-
Levofloxacin	5	-
Cefoxitin	9	2
Cotrimaxozole	4	-
Cefuroxime	1	2
Cefixime	1	-
Azithromycin	6	-
Linezolid	10	-
Teicoplanin	6	1
Klebsiella spp		
Amikacin	4	-
Piperacillin and Tazobactum	1	-
Ceftazidime	1	-
Cefixime	1	-
Cefoperazonesulbactam	1	-
Proteus spp		
Amikacin	5	1
Ampicilin		
Gentamicin	4	1
Ciprofloxacin		
Ceftriaxone	1	2
Escherichia coli		
Amikacin	1	-
Piperacillin and Tazobactum	1	-
Gentamicin	-	1
Ofloxacin	-	1
Cefoperazonesulbactam	1	-

though anaerobes are thought to play a pathogenic role in CSOM, the large variability in their isolation rates among different studies may be due to differences in sampling and processing techniques, prior use of antibiotics and differences in the timing of sampling during the course of the disease.

Pseudomonas is commonest organism isolated. This observation was parallel with the findings of few authors and in contrast with other researchers. Similar organisms have been found to be associated with CSOM in studies conducted by Kumar et al.,[9] Sharma et al.,[19] Vishwanath et al.[12] A recent study from India showed a little different trend where *E. coli* was reported in 12% and *Klebsiella* in 5% of cases. More frequent isolation of fecal bacteria like *E. coli*, *Klebsiella* indicates that individuals are at high risk of infection due to poor hygiene conditions.

These finding were correlated to the findings of Loy and Tan.[20] The pattern of organism isolated in the tropical countries such as Africa, Nigeria, and Pakistan is similar to India. In contrast, other studies like Singh et al.,[21] from India (36%) showed different trends as *S. aureus* was the most prevalent organism and this could be due to the variation in microorganisms in different regions and effect of climate. Isolate *Pseudomonas* was found in 32.4% of the ear swab. It is the predominant cause of CSOM in tropical region. It does not usually inhabit the upper respiratory tract, its presence in the middle ear cannot be ascribed to an invasion through Eustachian Tube and it should be considered as secondary invader gaining access to the middle ear through defect in tympanic membrane.

The occurrence of *P. aeruginosa* as the predominant organism in this study could be attributed to numerous factors. It survives competition with other pathogens due to its minimum nutritional requirements, its relative resistance to antibiotics, and its antibacterial products — pyocyanin and bacteriocin. Apart from these reasons, it uses the pili to attach to the necrotic or diseased epithelium of the middle ear. Once attached, the organism produces enzymes such as proteases and lipopolysaccharides to elude from normal defense mechanism of the body required for fighting infections. In addition, the organism acts as an opportunistic pathogen, which flourishes in the external auditory canal and causes suppurative OM.

In a study from Haryana, India, fungal etiology was found in 15% of cases, out of which 60% were *Candida* species and 40% were *Aspergillus* species. In another study from Singapore out of 90 patients of OM, fungi accounted for 8.8% of the total isolates out of which *Aspergillus* species was found in 33.3% followed by *Candida* species 22.2%.

These findings may be attributed to the environmental effects on the cases of OM, which were studied in this area. Even though fungi are routinely regarded as colonizers, they can be pathogenic in an already inflamed ear. Treatment targeting fungi should be administered in cases of positive cultures especially in hot and humid regions.

It showed maximum resistance to Meropenam drug according to study by Vishwanath et al.,[12] *P. aeruginosa* showed maximum sensitivity to Piperacillin (97.3%), followed by Gentamicin (73%), Amikacin (78.4%), Ceftazidime (91.2%), and resistance to Netilmycin.

According to Sharma et al.,[19] organism showed sensitive to Piperacillin (25%), Gentamicin (30%). which differs from our study. In contrast with others studies by Vishwanath et al.,[12] Sharma et al.,[19] the organism showed maximum sensitivity to Erythromycin, Cotrimoxazole moderate sensitivity to Ampicillin. A study by Deb and Ray[22] showed 50% resistance to Ciprofloxacin Isolation of various aerobic and fungal isolates shows that different conditions of CSOM could be differentiated on microbiological grounds. Thus, for better management of CSOM, microbial classification of infection as well as drug sensitivity test of organism recovered are essential for making appropriate decision of antimicrobials that will effectively eradicate the pathogen.

Ototopical agents are a highly effective and powerful tool for clinicians and are used as first line agents for otorrhoea. Topical agents used in the treatment of chronic middle ear disease are a combination of antibiotics, antifungals, antiseptics, solvents, and steroids. The common topical antibiotics used in the management are the aminoglycosides including Gentamicin, Framycetin, and Neomycin. Neomycin, the most commonly prescribed topical agent at our setting was the least efficacious. Gentamicin and Amikacin were found to be the most effective aminoglycoside; however, topical preparation of above drugs is less available. The risk of ototoxicity by prolonged use of aminoglycoside preparations remains a subject of discussion.

Topical quinolones are considered as promising options in the management of CSOM. In the present study, many isolates were sensitivity to Levofloxacin and Ciprofloxacin. However, there is a concern for secondary fungal overgrowth causing otitis externa as a side effect following treatment with topical quinolones.

Systemic antibiotics are useful in acute exacerbations of chronically infected ear, in patients with signs of complicated or invasive infections or systemic disease and also in children and adolescents as the choice of ototopical antibiotics is complicated because of potential side effects. Piperacillin or ceftazidime or Aztreonam for *P. aeruginosa* and Vancomycin for *S. aureus* were found to be the most effective systemic antibiotics in our study. Systemic aminoglycoside preparations can be used to treat mixed infections with Gram-positive and Gram-negative bacteria as seen in this study.

Limitations of the study

The sample size was small. More sample size is required to reach into confirmed conclusion. The study has been done in a single centre.

CONCLUSION

CSOM is one of the most common conditions presented on outdoor basis to Otologists, Paediatricians and General practitioners. In developing countries, including India, health-care delivery fails to target high-risk groups in low socioeconomic and rural based population causing treatable infections like CSOM to persist and propagate to a debilitating illness. The rising prevalence of antibiotic resistance (especially in developing countries) can be attributed to the overuse and incorrect use of antibiotics. Knowledge of the local microorganism pattern and their antibiotic sensitivity is essential to allow effective and cost saving treatment. Selection of any antibiotic is influenced by its efficacy, resistance of bacteria, safety, risk of toxicity availability and cost. Continuous and periodic evaluation of microbiological pattern and antibiotic sensitivity of isolates is necessary to decrease the potential risk of complications by early institution of appropriate treatment. Therefore, rather than resorting to empirical mode of treatment, culture and sensitivity testing should be advocated in every patient presenting with an ear discharge.

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DB- Concept and design of the study, prepared first draft of manuscript; **GCG-** Interpreted the results; reviewed the literature and manuscript preparation; **RR-** Concept, coordination, statistical analysis and interpretation, preparation of manuscript and revision of the manuscript.

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