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ORIGINAL RESEARCH

Microbiological profile and associated factors of chronic suppurative otitis media and antimicrobial sensitivity pattern in a tertiary care hospital in Eastern India

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ABSTRACT

Background: Chronic Suppurative Otitis Media (CSOM) is considered as one of the important health issue which has imposed significant challenges to otorhinolaryngologists . Globally about 65 to 330 million people suffer from CSOM. Keeping the scenario in mind the present study was conducted to determine the prevalence and related risk factors, microbiological profile and its sensitivity pattern of CSOM. **Materials and Methods:** This cross-sectional study included a total of 122 ear swab specimens of clinically diagnosed individuals with active CSOM. Swabs were cultured in appropriate media, biochemical reactions were performed for the microbial organism identification according to a standard protocol.The Kirby-Bauer disc diffusion method was used where the diameter of the inhibition zone was interpreted according to Clinical Laboratory Standards Institute(CLSI) guidelines. **Results**: Microbial growth was seen in Seventy-five (75, 61.47%) samples, but forty-seven (47,38.5%) samples had no growth. Among the samples with growth, 72 (96%) were monomicrobial, while 3(4%) were polymicrobial. The most common bacteria isolated was Pseudomonas aeruginosa (23.77%) followed by Staphylococcus aureus (20.49%) and Klebsiella spp.(3.27%). The most sensitive antibiotics against P. aeruginosa was Meropenem. S aureus showed highest sensitivity towards vancomycin (100%). Females were more commonly affected than males. Culture positive CSOM was more common in patient with Diabetes mellitus, people from rural area, in those having frequent respiratory tract infections, throat infections during the episode ear discharge, and vertigo. **Conclusion:** Upper respiratory tract infection patients and Diabetics are highly prone for developing CSOM with high anti-microbial resistance of P.aeruginosa.

Keywords: Chronic suppurative otitis media, Risk factors ,bacterial infection, antibiotic susceptibility, Pseudomonas. aeruginosa.

INTRODUCTION

Chronic suppurative otitis media (CSOM) is defined as a prolonged and recurring bacterial infection of the middle ear characterized by perforation of the tympanic membrane and ear discharge lasting more than two weeks according to the World Health Organization (WHO), although a commonly used clinical definition is usually six weeks.[1]CSOM is classified into two types namely mucosal and squamosal depending upon whether the disease process affects the pars tensa or pars flaccida of the tympanic membrane[2].

Various studies from different countries showed that CSOM is mainly caused by the bacteria Pseudomonas aeruginosa, Staphylococcus aureus and Enterobacteriaceae such as Proteus sp. and Klebsiella pneumoniae[1] whereas fungus etiology mainly due to Candida sp.,Aspergillus sp. [3]

The prevalence of CSOM is highest among the populations of Inuits of Alaska, Canada and Greenland, American Indians and Australian Aborigines (7–46 %). Intermediate prevalence has been reported in the South Pacific Islands, Africa, Korea, India and Saudi Arabia[4].The prevalence rate of CSOM in India is around is 7.8%[5].The prevalence of CSOM is more common in developing countries due to various reasons like poor living conditions, inadequate hygiene, low socioeconomic status, overcrowding, malnutrition, improper and

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inadequate antibiotic treatment. Rural population is affected more than the urban community[6].

If we look into the age preponderance, globally the children are most commonly affected. Hearing impairment is one of the most common sequelae of CSOM that ultimately results in negative impact on a child's speech and development. In general other than hearing impairment, it can lead to various extracranial complications like mastoiditis, facial nerve paralysis and intracranial complications which include meningitis, lateral sinus thrombosis, cerebral and epidural abscess[7]. Considering the gravity of the consequences of CSOM, and the paucity of research in the local area, the current study was conducted to find out the prevalence of the microorganism, and associated risk factors with their anti-microbial sensitivity pattern. This will guide the clinician to initiate empirical and appropriate treatment and may debar the emergence of resistant strains of microorganisms in the community and the hospital as well.

METHODOLOGY

The present observational Cross sectional study was conducted in clinically diagnosed CSOM patients attending the ENT Out Patient Department (OPD)of the teaching hospital under study. The study was initiated after getting ethical clearance from the Institutional Ethics Committee. The required sample size was calculated using prevalence from previous literature review. [5] The prevalence of CSOM among the Indian population in a previous literature was 7.8%. Considering this prevalence and error at 5%, the sample size was 110. After adding 10% non-response rate, the final sample size became 121. The current study included a total of 122 individuals. The inclusion criteria was any individual with clinically diagnosed CSOM, aged more than six months irrespective of any gender. The individuals with existing ear disease, hearing problems, already took antibiotics in past one week were excluded from the study. In case of infants and minor, the accompanied parents or care giver were interviewed with the help of pre-designed proforma. In other individuals, data were collected directly from the sample population. After taking written consent, ear discharge was collected under aseptic precautions with the aid of an aural speculum by an otorhino laryngologist. All the specimens received were sent for bacterial culture and sensitivity testing to the microbiology laboratory. Part of the sample was inoculated in both MacConkey agar and Blood agar. Gram staining was done from rest of the received swab. The samples inoculated in culture media kept incubated at 37°C in aerobic condition. Bacterial isolates was identified with the help of colony morphology and standard biochemical tests. After identifying the isolate, their antimicrobial susceptibility testing was performed by the Kirby-Bauer disc diffusion method according to the Clinical and Laboratory Standards Institute (CLSI) [8] guidelines on Muller Hinton agar. The plates will be read out after overnight incubation, by measuring the zone of inhibition around the antibiotic discs as per Clinical Laboratory Research Institute (CLSI) standards.

Quality control: Reference strains of *Escherichiacoli*(ATCC 25922), *Staphylococcus aureus* (ATCC 25923), *Klebsiella pneumonia* (ATCC700603) were used as control reference strains for identification and drug susceptibility.

Statistical analysis: The presence or absence of bacterial growth was considered as a dependent variable in the present study. The data were coded, entered into SPSS (licensed 22.0) and analyzed. Quantitative variables were analyzed by frequency, percentage. Chi square test was done to test out the difference in proportion between the variables. P value less than 0.05 was considered as significant.

RESULTS

In this study,females (65,53.3%) were more affected. The maximum number of study population was between age group 31 years to 40 years (31.1%). The mean age of the population was 37 years. Unilateral infection (95,77.9%) was more common compared to bilateral infection of which left ear affected more than right ear. The study revealed (1088,8.5%) as mucosal variant and (14,11.5%) as squamosal variant. Two-thirds of sample was from rural area. History of upper respiratory infection associated was found in nearly every two out of three individuals (63.9%). Thirty-four (27.9%) individuals gave a history of pond bathing. (Table 1)

Our study found 61.47% of samples as culture positive, out of which 41 were gram-negative and 34 were gram-positive isolates. Bacterial growth is more prevalent among individuals residing in rural areas and urban place of residence (70.88% vs.44.18%), the difference in the proportion was significant (P<0.004). The presence of vertigo, throat infection, history of URTI and Diabetes too were emerged as risk factors of CSOM in the current study. (Table 2)

Pseudomonas aeruginosa (29, 23.8%) was the most commonly isolated organism followed by Staphylococcus sp(25,20.5%). Out of these, Methicillin-sensitive Staphylococcus(MSSA) aureus was present in twenty-three samples. Coagulase-negative Staphylococcus(CONS) species were found in eight (8, 6.5%) individuals. (Table 3) Pseudomonas was most sensitive to Meropepenem(27,93.10%), Ceftazidim(25,86.2%), Amikacin(21,72.4%), levofloxacin and Ciprofloxacin(20,68.9). Moderate sensitivity was seen for Nelimicin(NET), cefotaxim,Piperacillin tazobactam (PIT) and least sensitive toAmpicillin and amoxycillinclavulinic acid (Table 4). All the Methicillin sensitive Staphylococcus aureus (MSSA) were 100% sensitive to vancomycin and a good sensitivity (86.7%) was seen for linezolid. A very low sensitivity was

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observed for ciprofloxacin and ceftriaxone.No resistance was seen to vancomycin and linezolid in case of Methicillin resistant staphylococcus aureus(MRSA). (Table 5)

Table 1: Profile of the study participants (n=122)

Variables		Frequency (n, %)
Gender	Male	(57,46.72)
	Female	(65,53.27)
Age(years)	<10 yrs	(9,7.4)
	11-20	(15,12.3)
	21-30	(12,9.8)
	31-40	(38,31.1)
	41-50	(24,19.7)
	51-60	(15,12.3)
	> 60	(9,7.4)
Ear involved	Both ear	(27,22.1)
	Left ear	(46,37.7)
	Right ear	(49,40.2)
Type of CSOM	Mucosal	(108,88.5)
	Squamosal	(14,11.5)
Socio class (As per Modified Kuppuswamy SES)	Lower	(4,3.3)
	Lower Middle	(80,68.9)
	Upper Middle	(38,31.1)
Location	Rural	(79,64.8)
	Urban	(43,35.2)
Frequency of URTI	Not present	(44,36.1)
	Present	(78,63.9)
Pond bathing	No	(88,72.1)
	Yes	(34,27.9)

Table 2: Risk factors for culture positive CSOM

Variables		Bacterial Growth		STATISTICS					
		Present (n,%)	Absent (n,%)	X^2	df	OR	CI (95%)		P
							UPPER LIMIT	LOWER LIMIT	
Place of residence	Rural(n=79)	(56,70.88)	(23,29.11)	8.38	1	0.325	0.705	0.150	**0.004**
	Urban(n=43)	(19,44.18)	(24,53.48)						
Vertigo	Present(n=49)	(36,73.47)	(13,26.53)	4.97	1	2.41	5.28	1.10	**0.026**
	Absent(n=73)	(39,53.42)	(34,46.57)						
Rhinitis	Present(n=74)	(46,62.16)	(28,37.84)	0.0375	1	1.08	2.27	0.511	0.847
	Absent(n=48)	(29,60.42)	(19,39.58)						
Throat Infection	Present(n=43)	(32,74.42)	(11,25.58)	4.70	1	2.44	5.51	1.08	**0.030**
	Absent(n=79)	(43,54.43)	(36,45.57)						
History of frequent URTI	Present(n=78)	(54,69.23)	(24,30.77)	5.49	1	2.46	5.28	1.15	**0.019**
	Absent(n=44)	(21,47.73)	(23,52.27)						
Pond Bathing	No(n=88)	(55,62.5)	(33,37.5)	0.140	1	0.857	1.92	0.382	0.708
	Yes(n=34)	(20,58.82)	(14,41.18)						
DM	Present(n=33)	(25,75.76)	(8,24.24)	3.90	1	2.44	5.99	0.991	**0.048**
	Absent(n=89)	(50,56.18)	(39,43.82)						
HTN	Present(n=16)	(9,56.25)	(7,43.75)	0.212	1	0.779	2.26	0.269	0.645
	Absent(n=106)	(66,62.26)	(40,37.74)						

Table 3: Microbiological profile ofear swabs (n=122)

Type of bacteria	Bacterial isolates	Frequency (n,%)
Gram Positive Bacteria	MRSA	(23,20.5)
	MRSA	(2,0.8)
	CONS	(8,6.5)
	Diptheroids	(1,0.08)
Gram Negative	Pseudomonas sp	(29,23.8)

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Bacteria	Escherichia coli	(1,0.8)
	Klebsiella sp	(4,3.3)
	Providencia stuarti	(1,0.8)
	Citrobacter sp	(1,0.8)
	Acinetobacter baumannii	(1,0.8)
	P. mirabilis	(4,3.3)

Table 4: Anti-microbial sensitivity pattern of Gram negative organisms

Anti Biotics	Pseudomonas sp.(n,%)	Klebsiella sp. n=(4,%)	Proteus mirabilis n=(4,%)	Acinatobacter baumannii n=(1,%)	Citrobacter sp. n=(1,%)	Escherichia coli n=(1,%)	Providencia stuartii n=1 (n,%)
MPR	(27,93.10)	(2,50.0)	(2,50.0)	(1,100.0)	(1,100.0)	(1,100.0)	(0,0.0)
AK	(21,72.4)	(2,50.0)	(2,50.0)	(1,100.0)	(1,100.0)	(1,100.0)	(0,0.0)
NET	(14,48.27)	(0,0.0)	(0,0.0)	(1,100.0)	(1,100.0)	(1,100.0)	(0,0.0)
GEN	(19,65.5)	(1,25.0)	(2,50.0)	(0,0.0)	(1,100.0)	(1,100.0)	(1,100.0)
LE	(20,68.9)	(2,50.0)	(2,50.0)	(1,100.0)	(1,100.0)	(0,0.0)	(1,100.0)
CIP	(20,68.9)	(2,50.0)	(2,50.0)	(1,100.0)	(1,100.0)	(1,100.0)	(1,100.0)
AMP	(1,3.4)	(0,0.0)	(2,50.0)	(0,0.0)	(0,0.0)	(0,0.0)	(0,0.0)
AMC	(2,6.9)	(1,25.0)	(3,75.0)	(0,0.0)	(0,0.0)	(1,100.0)	(1,100.0)
CFM	(5,17.2)	(0,0.0)	(2,50.0)	(0,0.0)	(0,0.0)	(0,0.0)	(0,0.0)
PIT	(13,44.8)	(2,50.0)	(1,25.0)	(0,0.0)	(1,100.0)	(0,0.0)	(0,0.0)
CFS	(5,17.2)	(2,50.0)	(1,25.0)	(0,0.0)	(0,0.0)	(0,0.0)	(1,100.0)
CXM	(3,10.3)	(2,50.0)	(2,50.0)	(0,0.0)	(0,0.0)	(1,100.0)	(1,100.0)
CTX	(16,55.2)	(1,25.0)	(3,75.0)	(1,100.0)	(0,0.0)	(1,100.0)	(1,100.0)
CAZ	(25,86.2)	(2,50.0)	(2,50.0)	(1,100.0)	(1,100.0)	(1,100.0)	(1,100.0)
CTR	(9,31.0)	(1,25.0)	(2,50.0)	(1,100.0)	(1,100.0)	(1,100.0)	(1,100.0)
CPM	(12,41.4)	(0,0.0)	(1,25.0)	(0,0.0)	(1,100.0)	(0,0.0)	(1,100.0)

Table 5: Anti-microbial sensitivity pattern of Gram positive organisms

Anti Biotics	S. aureus (n,%)	S. aureus (MSSA) n=23 (n,%)	S. aureus (MRSA) n=2(n,%)	CONS n=8(n,%)
CX	(23,92.0)	(23,100.0)	(0,0.0)	(1,12.5)
CXM	(17,68.0)	(16,69.56)	(1,50.0)	(6,75.0)
CTX	(17,68.0)	(15,65.21)	(2,100.0)	(5,62.5)
CIP	(11,44.0)	(9,39.13)	(2,4.3)	(6,75.0)
VA	(25,100.0)	(23,100.0)	(2,100.0)	(8,100.0)
TE	(15,60.0)	(14,60.86)	(1,50.0)	(4,50.0)
LZ	(22,88.0)	(20,86.71)	(2,100.0)	(6,75.0)
AMC	(17,68.0)	(17,73.91)	(0,0.0)	(5,62.5)
CFM	(13,52.0)	(13,56.52)	(0,0.0)	(6,75.0)
CTR	(4,16.0)	(4,17.39)	(0,0.0)	(4,50.0)

DISCUSSION

CSOM is a chronic persistent disease having a higher risk of irreversible complications. Therefore early bacteriological diagnosis by culture of the cases will help to give appropriate and accurate effective therapy.[6]

In our study females were more affected (53.3%). The result is quite similar to the study done by Prakash et al, where the prevalence among females (53.92%) was also more. [3]. A study by Gopal Kiran et al reported higher prevalence among males. [7]. The proportion of individuals affected with CSOM differed from researches, where maximum cases were observed in the age group of 0–20 years(51%),21 to 30 years (25.5%)21-30(57.05%) respectively.[3,9,10,]

In our study there were (4,3.3%) patient from the lower socio economic group,(80,65.6%) were from the lower middle class,(38,31.1%)were from the upper middle class. Our study differs from the study by Shyam et al done in Telengana where they found maximum cases from the lower class. In their study(80 ,53.3 %) cases were from the the lower class (45 ,30 %) cases were from the lower middle class ,(15 ,10%) cases were from the upper middle class and(10 ,6.6 %) cases were from the Upper class.(11)In another study by Thakur et al found highest no of cases belonged to lower class . They reported (53 ,51.96%) cases were from lower class, (37 ,36.27%) and (12 ,11.76%) cases were from upper lower,and lower middle class respectively.(12)

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In our study 27.86% people had history of pond bathing and 72.14% has no history of pond bathing, and we did not find any association (x^2=.14, and p value=.708) between pond bathing and culture positive CSOM. The study conducted by Thakur et al reported higher no of people have history of pond bathing associated with(55 ,53.92) than no history (47 ,46.08%) of (12)

In this study it had been found that people with frequent upper respiratory tract infection had higher incidence of culture positive CSOM(p value .019)which was at per with the study by Kesari et al. where they also found that increased the risk of development of CSOM was associated with frequent upper respiratory tract infection including nasal and throat problems and GERD .(10) Muftah et al. also reported recurrent respiratory tract infections of more than three times per year was itself an independent risk factor of CSOM. (13)

In a study by Rana et al reported both Pond/river bath (32.5%), and URTI (30.6%) were among the other major possible factors associated with CSOM.(14)

In this study mucosal variety 108 (88.5%)which was previously known as tubotympanic type were more common than Squamosa(l14 ,11.5) or atticoantraltype.Our study was in accordance with the study by Kumar et al and Basak et al where tubotympanic type was more common than Atticoantral types and respective percentages of tubotympanic type were (66.13%), and(86.02%) (15,16).Our study differ from the study byKumari et al. conducted in Hyderabad, Telanganashowed high prevalence of squamosal disease (47.3%)when compared to mucosal type (18.5%).[17]

In our study Unilateral infection 95(77.9%) was more common compared to bilateral infection (22.1%)which is almost similar to study by Hiremath et al where also unilateral infection (77.5%) was more common compared to bilateral infection (22.5%).[6]

In our study 27 % people had the history of Diabetes mellitus(DM) while 73% people did not have the history of Diabetes mellitus. But we had found an association between culture positive CSOM and DM (chi square =3.90,p value=.048).In a study by Gopal et al found that in their study about 75% of the patients above 45 years had a history of DM but they did not performe any further test of association.

In the present study we got culture positivity rate around(62.29%)but the study by Prakash et aL and Rana et al found much higher culture positive cases of CSOM and the rates are (91.18%)and (91.7%)respectively.[3,14].In our study monomicrobial growth was seen in (73 ,96%) cases and polymicrobial growth was seen in 3 (4%).A study by Rangaiah el found single bacterium isolates from 108 cases(80%), multiple bacterial isolates from 7 samples, 5.2%. No growth was seen in 20 cases (14.81%).(2)

In an analysis by Prakash et al found that among total 204 cases mono-microbial growth was seen in 118 (57.84%)samples, 68 (33.33%) samples revealed polymicrobial growth, whereas, 18 (8.82%) samples showed no growth. [3] Another study in chaina by Jianghong et al also found higher monomircobial growth than polymicrobial growth where single microbial isolates were seen in 211 cases (94.6%), and multiple bacteria were found in 12 cases (5.4%).(18)

In our study Pseudomonas aeruginosa was the most common aerobic Gram negative organism29 (23.8%) followed by Staphylococuss 25(20.5%) of which 23 cases were MSSA rest were MRSA .Our study was at per with the study by Herminth et al and Rana et al. whileHerminth et al found Pseudomonas aeruginosa(38.79%) as the most predominant organism followed by Staphylococcus(32.75%) ,Rana et al repoted*P. aeruginosa* (28.5%), *S. aureus* (22.9%) and Klebsiella species (14.6%) being the most common etiological agents for CSOM.[6,14].Same findings were seen in the studies by Kiran Gopal and Kombade et al where they found Pseudomonas aeruginosa(31.4%) as the most common organism followed by Staphylococcus (28%)and Pseudomonas aeruginosa (55.8%) followed by Staphylococcus aureus (27.5%) respectively..[7,9]

Increased resistance to even more potent antibiotics,opportunistic extracellular pathogen,thrives well in the warm damp external auditory meatus were the reasons that made Pseudomonas as one of the most common casusative organism of CSOM.(14)

A study by Prakash et al. reported staphylococcus aureus (41.25%) as the predominant isolate.[3] Our study also differs from the study by Jianghong et al and by Uddén et al where Staphylococcus aureus (44.9%)was the most commonly found microorganism identified in the cultured specimens followed by Pseudomonas aeruginosa accounting for (16.9%)(19).and Proteus spp. (14.7%), P. aeruginosa (13.2%) and Enterococcus spp. (8.8%) were most commonly isolated organisms respectively.[1]

In our study Pseudomonas aeruginosa was most sensitive to Meropenem27(93.10%),followed by%),Ceftazidim(25,86.2%),Amikacin(21,72.4%),levofloxacin and Ciprofloxacin(20,68.9).

The study by Hiremath et al where Pseudomonas aeruginosa showed maximum sensitivity to piperacillin (91.11%), followed by amikacin (71.11%) gentamicin (71.11%), , moderate sensitivity to ceftazidime (51.11%), and resistance to carbpenicillin (60%).[6]In a study by kombade found that P. aeruginosa showed 100% susceptibility to ceftazidime and colistin followed by piperacillin tazobactam (95.5%), ceftazidime-tazobactam (92.9%) and cefepime (81.8%). Moderate sensitivity to aztreonam, fluoroquinolones ,aminoglycosides, and imipenem was seen.[9]

In our study among the 25 staphylococcus are sensitive to vancomycin (100%), cefoxitin(92%) Linezolid(88%), Amoxcillinclavunilicacid(68%), Cefuroxime(68%),cefotaxime(68%) .

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In a study Xu et al found that Staphylococcus aurous isolates were highly susceptible to vancomycin (100%), gentamicin (98.1%), rifampicin (97.2%), moxifloxacin (97.1%), and sulfamethoxazole and trimethoprim (96.2%)levofloxacin(76%)and ofloxacin (79%)were and. isolates identified in this study were highly resistant to penicillin (61.3%) and erythromycin (50%).[18]

In an another study by Prakash et al found Fluoroquinolones and Cephalosporin'swere the Most sensitive antibiotic groups in which Cephalosporin's and fluoroquinolones showed maximum sensitivity with 97%& 100% and 76%, 83% sensitivity for Pseudomonas spp. and Staphylococcus aureus respectivelyand Penicillin's and Macrolides wereleast effective[19]

CONCLUSION

The study helped us understand the different socio-demographic factors associated with CSOM. Nowadays, the irrational use of antibiotics, without knowing the causative organisms and sensitivity patterns, leads to antibiotic resistance. Therefore, it is essential to study each case of CSOM bacteriologically to determine local prevalence, which in our study is primarily Pseudomonas aeruginosa and Staphylococcus spp. Additionally, we aim to devise an antibiotic policy for the appropriate use of antibiotics to reduce the development of antibiotic resistance.

Confidentiality:

Confidentiality of the patients were maintained.

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