ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1616

An Observational Study to Compare Antibiotic Resistance and Microbiological Organism Relation in Cases of CSOM

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Publication Date: 2026/07/03

Abstract:

- ***Background:***

Chronic Suppurative Otitis Media (CSOM) is an inflammatory disease of the middle ear that is chronic, which is characterized by persistent ear discharge due to a perforated tympanic membrane. The dynamic bacteriological paradigm and the growing antimicrobial resistance of causative organisms are the reasons to appraise local microbial tendencies and susceptible to antibiotics on a periodical basis.

- ***Methods:***

This was a prospective observational study, carried out in the Department of Otorhinolaryngology, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India. Eightythree patients with CSOM and active ear discharge were enrolled. The ear discharge samples were taken using aseptic precautions and subjected to microbiological culture and identification. Kirby Bauer disc diffusion method was used to perform antibiotic susceptibility test, and results interpreted by CLSI guidelines.

- ***Results:***

most of the patients fell within the age bracket of less than 30 years and the male population was slightly predominant (51.8%). The most frequent presenting complaint was ear discharge (79.5%) and then ear pain (53.0) and decreased hearing (72.3). The commonly isolated pathogen was Staphylococcus aureus (40.96%), Pseudomonas aeruginosa (34.94), and Klebsiella pneumoniae (13.25). Testing of antibiotic susceptibility showed that the amikacin was the most sensitive (79.52%), ciprofloxacin (67.47%), and gentamicin (62.65%) was the least sensitive. Cefoxitin (86.75), cefixime (84.34), cefuroxime (66.27) and azithromycin (65.06) had high resistance rates.

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➢ ***Conclusion:***

Staphylococcus aureus and Pseudomonas aeruginosa are the two main pathogens related to CSOM. The isolating organisms had been found to show the greatest antimicrobial activity of Amikacin and also a high resistance was noted to a variety of antibiotics commonly administered.

Keywords: *Chronic Suppurative Otitis Media; Staphylococcus Aureus; Pseudomonas Aeruginosa; Antibiotic Susceptibility.*

How to Cite: Dr. Ayushi Agrawal; Dr. Navin Agrawal; Dr. Sidra Khan; Dr. Prachi Goyal; Dr. Samiksha Sharma; Dr. Chhavi Agrawal (2026) An Observational Study to Compare Antibiotic Resistance and Microbiological Organism Relation in Cases of CSOM. *International Journal of Innovative Science and Research Technology*, 11(6), 2301-2306. https://doi.org/10.38124/ijisrt/26jun1616

I. INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) is a chronic inflammatory disease of the middle ear cleft which occurs with persistent or recurrent ear discharge through a perforated tympanic membrane in the duration of at least 12 weeks as defined by the World Health Organization [1]. It is one of the leading causes of preventable hearing impairment in the world and it has been an extremely important public health issue, especially in the developing countries [2].

The international burden of CSOM is enormous an estimated 65-330 million people are affected by the condition of which a sizeable number experiences hearing loss of different severities [2]. The disease is mostly common in children and in groups residing in resource constrained areas where overcrowding, inadequate sanitation, malnutrition & recurrent infections of the upper respiratory system is prevalent[3].Microbiological profile of CSOM is quite varied and depends on geographic location, environmental factors and antibiotic prescribing patterns. Pseudomonas aeruginosa, Staphylococcus aureus and other species of the Enterobacteriaceae family are the most commonly isolated organisms [4]. Such pathogens have a wide array of virulence factors such as biofilm formation, toxin production and antimicrobial resistance, which cause chronic infection and failure of treatment [5].

The effective determination of causative microorganisms and their antimicrobial susceptibility profile is critical in choosing the correct therapy, complications, and avoiding development of antibiotic resistance. [8,9]

II. MATERIAL AND METHODS

It was a prospective observational study carried out in the Department of Otorhinolaryngology, Index Medical College Hospital and Research Centre, Indore, Madhya Pradesh, India, with the permission of the Institutional Ethics Committee. Eligible patients, male and female and of any age with a diagnosis of CSOM with active ear discharge were recruited with written informed consent. The sample was determined with the formula n = Z 2 p(1-p)/d 2 taking into account the prevalence, 6, the confidence interval that must be 95% (Z = 1.96) and the permissible error of 5 percent.

➢ *Inclusion Criteria*

All patients who had CSOM and reported with active ear discharge and consented to take part in the study were used.

➢ *Exclusion Criteria*

Otomycosis, cholesteatoma, acute otitis externa, topical/systemic antibiotics within 1 week prior to sample collection (excluding culture-negative cases), and patients who have not given their informed consent were excluded.

III. METHODOLOGY

All participants were asked to provide a detailed clinical history, such as age, sex, place of residence, occupation, presenting symptoms, duration of ear discharge and medical history. A complete otorhinolaryngological investigation was conducted, including an otoscopic examination of the canal and tympanum of the ear. A structured case record proforma was used to record demographic and clinical data.

➢ *Sample Collection and Microbiological Analysis*

Aseptic precautions were observed while collecting ear discharges samples in sterile cotton swabs of the affected ear avoiding the outer ear canal contamination. The samples obtained were taken to the Department of Microbiology and handled within 30 minutes of receipt.

Samples were grown in suitable microbiological media under usual laboratory conditions. The isolated isolates were documented and examined and the antibiotic susceptibility was conducted according to the Kirby-Bauer disc diffusion technique on the agar of Mueller-Hinton. The isolated organisms were tested on a panel of regularly prescribed antibiotics against CSOM. The zone diameters were taken and interpreted as per Clinical and Laboratory Standards Institute (CLSI) guidelines.

IV. STATISTICAL ANALYSIS

The data were typed in Microsoft Excel and subject of analysis by AD-Statistic Package of Social Sciences (SPSS) version 21.0 (IBM Corp., Armonk, NY, USA). Mean, standard deviation, frequencies and percentages were used to describe continuous and categorical variables respectively. Where necessary, appropriate statistical tests were used to evaluate the associations between variables.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1616

The p-value of below 0.05 was taken as significant. The findings were in-table and graphical displays.

➢ *Ethical Considerations*

The protocol of the study was reviewed and approved by Institutional Ethics Committee of Index Medical College Hospital and Research Centre, Indore. All were enrolled through written informed consent, or through legal guardians. The research was carried out against the ethical guidelines of the Declaration of Helsinki and the confidentiality of patient data throughout the research was ensured.

V. RESULTS

The study included 83 patients who were diagnosed with the chronic suppurative otitis media (CSOM) and appeared with active ear discharge. The demographic profile of the patients is shown in Table 1. Most of the patients were of younger age groups with 22.9% of the patient population being aged 0-10 years and 21.7% of the population being aged 11-20 years and 21-30 years respectively. The study population was 51.8% male and 48.2% female. The rural/urban population was almost equally balanced. [Table 1]

Table 1. Demographic Characteristics of Study Participants (n=83)

Variable	Frequency	Percentage (%)
Gender		
Male	43	51.8
Female	40	48.2
Residence		
Rural	42	50.6
Urban	41	49.4
Age Group (Years)		
0–10	19	22.9
11–20	18	21.7
21–30	18	21.7
31–40	13	15.7
41–50	7	8.4
51–60	6	7.2
>60	2	2.4

Most frequent presenting complaint was ear discharge (79.5% reported), then there were decreased hearing (72.3%), and ear pain (53.0%). In 49.4% of patients, there was an involvement of left ear, 47.0% had a right ear involvement, and bilateral disease (3.6). [Table 2]

Table 2. Clinical Presentation and Ear Involvement

Variable	Frequency	Percentage (%)
Chief Complaints		
Ear Discharge	66	79.5
Decreased Hearing	60	72.3
Ear Pain	44	53.0
Ear Fullness	17	20.5
Itching	15	18.1
Tinnitus	12	14.5
Ear Involved		
Right Ear	39	47.0
Left Ear	41	49.4
Bilateral	3	3.6

The length of the disease among participants of the study was different. The highest percentage of patients (36.1) were represented within six months of the symptoms onset where 18.1% of patients showed a period between six months and one year of disease. [Table 3]

Table 3. Duration of Disease

Duration of Disease	Frequency	Percentage (%)
<6 Months	30	36.1
6 Months–1 Year	15	18.1
1–2 Years	12	14.5
2–5 Years	12	14.5
>5 Years	12	14.5

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1616

Does Not Remember	2	2.4
Total	**83**	**100**

The microbiological examination indicated that Staphylococcus aureus was the most predominant pathogen (40.96%), Pseudomonas aeruginosa (34.94%). Klebsiella pneumoniae made up 13.25% of the isolates with other organisms being less frequently isolated. [Table 4]

Table 4. Bacteriological Profile of CSOM

Organism Isolated	Frequency	Percentage (%)
Staphylococcus aureus	34	40.96
Pseudomonas aeruginosa	29	34.94
Klebsiella pneumoniae	11	13.25
Proteus mirabilis	3	3.61
Haemophilus influenzae	3	3.61
Moraxella catarrhalis	1	1.20
No Growth	2	2.41
Total	**83**	**100**

An antibiotic susceptibility test revealed that amikacin had the best sensitivity rate (79.52%), ciprofloxacin (67.47%) and gentamicin (62.65%). Rates of highest resistance were noted to be cefoxitin (86.75%) and cefixime (84.34%). [Table 5]

Table 5. Antibiotic Sensitivity Pattern of Isolated Organisms

Antibiotic Tested	Sensitive (%)	Intermediate (%)	Resistant (%)
Amoxicillin + Clavulanic Acid	52.41	0.00	47.59
Cefuroxime	32.53	1.20	66.27
Ceftazidime	25.30	15.66	59.04
Cefixime	15.66	0.00	84.34
Cefoxitin	13.25	0.00	86.75
Azithromycin	33.73	1.20	65.06
Gentamicin	62.65	1.20	36.14
Amikacin	79.52	1.20	19.28
Ciprofloxacin	67.47	0.00	32.53
Clindamycin	34.94	14.46	50.60

Sensitivity rates were obtained relative to amikacin, which had the highest overall susceptibility, to compare an overall effect or relative efficacy of antibiotics. The rest of the antibiotics were much lower in sensitivity than amikacin. [Table 6]

Table 6. Comparison of Antibiotic Sensitivity with Amikacin

Antibiotic Tested	p-value
Amoxicillin + Clavulanic Acid	<0.001*
Cefuroxime	<0.001*
Ceftazidime	<0.001*
Cefixime	<0.001*
Cefoxitin	<0.001*
Azithromycin	<0.001*
Gentamicin	NS
Ciprofloxacin	0.01*
Clindamycin	<0.001*

*Statistically significant; NS = Not significant

Table 7. Summary of Statistical Findings

Parameter	Key Finding	p-value
Age Group vs Sex	No significant association	0.42
Residence Distribution	No significant difference	0.85
Ear Involvement	No significant difference between ears	0.67
Ear Discharge	Significant association with CSOM	<0.001*
Decreased Hearing	Significant association with CSOM	<0.001*
Ear Pain	Significant association with CSOM	0.02*
Disease Duration vs Age	No significant association	0.21

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26jun1616

Disease Duration vs Sex	No significant association	0.38

Comprehensively, the paper has shown that the most common pathogens that caused CSOM were Staphylococcus aureus and Pseudomonas aeruginosa. Amikacin was the most sensitive of all antibiotics tested with ciprofloxacin and gentamicin ranking the third and fourth. This data proof the significance of regular culture and sensitivity analysis in the effective management of CSOM and the selection of antibiotics.

VI. DISCUSSION

Chronic suppurative otitis media (CSOM) is a longstanding issue in the realm of public health and among the causes of hearing loss which can and should be prevented, especially in the developing world. In the current study, most patients were younger with 44.6% of the cases falling below the age of 20 years. Kumar et al. [10], Deb et al. [11], Poore et al. [12], and Saraswati et al. [13] also reported similar observations and a greater occurrence of CSOM in children and adolescents.

Ear discharge which was the most prevalent presenting complaint, amongst hearing loss and ear pain. Unilateral disease was much more frequent as opposed to bilateral, which was consistent with the results on the same study by Deb et al. [11], Sharma et al. [14], and Hiremath et al. [15].

Microbiological analysis showed that Staphylococcus aureus (40.96%) dominated followed by Pseudomonas aeruginosa (34.94%). The most commonly isolated was Pseudomonas aeruginosa with prevalence differing within the 32.2 to 79. Nevertheless, the similarity of the organism dominating in the current research is in line with the research study by Prakash et al. [18], where the aforementioned organism was reported as the leading causative agent of CSOM.[17]

Other than the major isolates, Klebsiella pneumoniae, Proteus mirabilis, Haemophilus influenzae and Moraxella catarrhalis were also isolated. Kumar et al. [10], Sharma et al. [14], Vishwanath et al. [16], and Hiremath et al. [15] have reported similar bacteriological profiles that prove polymicrobial nature of CSOM and the significance of microbiological investigation prior to the initiation of treatment.

Antibiotic susceptibility testing showed the greatest sensitivity of amikacin (79.52%), ciprofloxacin (67.47%) and gentamicin (62.65%). These reports show that there has been a growing tendency towards antimicrobial resistance of CSOM pathogens. Previous investigators have reported similar variances in patterns of susceptibility. Vishwanath et al. [16] reported high sensitivity of Staphylococcus aureus to erythromycin and cotrimoxazole. However, Sharma et al. [19] have achieved better sensitivity of Staphylococcus aureus to ciprofloxacin showing some regional variation in antimicrobial susceptibility patterns. On the whole, the results of the current research prove that Staphylococcus aureus and Pseudomonas aeruginosa are still the most significant pathogenic agents that cause CSOM. The sensitivity observed with amikacin, ciprofloxacin, and gentamicin is high and contributes to the therapeutic value of these antibiotics, but the increasing resistance to a number of widely used antibiotics points at the escalating problem of antimicrobial resistance.

VII. CONCLUSION

This current work demonstrates the dynamics of an antibiotic susceptibility and bacteriological range in chronic suppurative otitis media used in a tertiary care hospital. Staphylococcus aureus and Pseudomonas aeruginosa were the most common organisms, and the amikacin showed the best performance in antimicrobial activity against the identified organisms.

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