Original Article

PRESCRIPTION PATTERN OF ANTIMICROBIALS IN CHRONIC SUPPURATIVE OTITIS MEDIA AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Objective: CSOM, as defined by WHO is a chronic infection of middle ear cleft, with non-intact tympanic membrane and otorrhoea for at least two weeks. Injudicious use of antibiotics, in developing countries increases the disease burden and complications associated with the disease. Hence this study was conducted to evaluate the Prescription pattern of Antimicrobials using WHO Prescribing Indicators in patients diagnosed of CSOM in a tertiary care hospital.

Method: A prospective observational study was conducted for a period of four months. A total of 115 prescriptions of patients aged between 12-70 yrs are collected. All data regarding patient's details, demographics and details of medicines were recorded in a predesigned study proforma. The collected data was analysed and the conclusions were drawn using descriptive analysis.

Results: Of the 115 patients, majority belonged to 12-20 yrs. Left sided unilateral CSOM was more common. Penicillins (59.55%) were commonest class of antibiotics prescribed followed by fluroquinolones (27.36%). 82.35% of antibiotics were prescribed by oral route and only 17.64% by topical route. 98.5% of medicines were prescribed by generic names and other concomitant drugs like, antihistamines, decongestants, analgesics were prescribed.

Conclusion: This study is a sincere attempt to study prescription pattern of antimicrobials in CSOM patients which showed that oral antibiotics were more preferred in our set up. Timely prescription patterns analysis can enable appropriate modifications in prescribing patterns, facilitate rational utilisation of drugs and limit unnecessary use of antibiotics.

Keywords: CSOM, Antimicrobial agents, Prescription pattern, Ototopical antibiotics

INTRODUCTION

In India, ear infections are one of the common clinical problems due to which patient visit ENT OPD. Ear infections like Chronic Suppurative Otitis Media (CSOM), as like Upper Respiratory Tract Infections (URTI) are a serious cause of morbidity and debility in adults and school going children all over the world.

CSOM also known as Chronic Active Mucosal Otitis, Chronic Otomastoiditis or Chronic Tympanomastoiditis, as defined by WHO is a stage of ear disease in which there is chronic infection of middle ear cleft, a non-intact tympanic membrane (perforated eardrum) and discharge (otorrhoea) for at least preceding two weeks (WHO 1998)[1]. It was first described by Hippocrates as early as 450 B.C

Global burden of illness from CSOM involves 65-330 million individuals with draining ears, out of which 60% suffer from significant hearing loss.[2] A systemic analysis done by Anjola Onifade et al in year 2025 revealed 3.8% of human population worldwide are effected by CSOM.[3] Over 90% of disease burden is borne by countries in South-East Asia, Western Pacific Region, Africa & several other ethnic minorities in Pacific rim.[1]

India also falls under high prevalence region with prevalence rate of approximately 7.8% , which varies among different geographical locations due to a wide diversity in population density, socio- economic structure, hygiene, living conditions, knowledge about the disease etc.[19,26] Although significantly seen in rural areas and people of low socio-economic section of society with poor living conditions, it is also common in suburban and urban areas and has emerged as one of the most common causes of acquired hearing loss.[3,17,28]

CSOM is widely classified into two types, Tubo-Tympanic or Attico-Antral depending on whether the disease effects Pars Tensa or Pars Flaccid respectively. Tubo-Tympanic variety is often labelled as safe type as it is unlikely to cause severe complications like meningitis and Attico-Antral variety as unsafe type, due to higher risk of severe infections primarily due to cholesteatoma.[4]

The etiology of CSOM remains multifactorial, with demographics, genetic, environmental & other health related factors like recurrent URTI, allergy, eustachian tube dysfunction, cleft palate, adenoids hypertrophy playing a significant role as a causative factor and also in disease progression[9-11,27]

It causes a wide array of symptoms across all age groups like pain, ear discharge, hearing loss, vertigo and tinnitus.[5] The cycle of inflammation, ulceration, infection, and granulation tissue formation may eventually destroy the surrounding bony margins, ultimately leading to the various complications of CSOM.[6,7] As with the symptoms, complications can also be many, like chronic mastoiditis by contiguous spread, erosion of wall of middle ear and mastoid cavity can lead to facial nerve paralysis, lateral sinus thrombosis, labyrinthitis, meningitis and brain abscess.[8]

Injudicious use of antibiotics, poor hospital hygiene, lack of resources and trained healthcare professionals, especially in developing countries can directly increase the disease burden and complications associated with the disease.

According to WHO, antibiotics used against many diseases are loosing their effectiveness due to their overuse or misuse. In light of the aforementioned context, the objective of this investigation is to conduct an in-depth analysis of the prescription patterns and drug utilisation within the ENT department of our tertiary care teaching hospital using WHO Prescribing Indicators and International Network for Rational Use of Drugs (INRUD) guidelines in patients diagnosed of Chronic Suppurative Otitis Media.

MATERIALS AND METHODS
Study Design: This study is a tertiary care hospital based, prospective, observational type of study.

Study period: Study was conducted for a period of 4 months from July 2025 to October 2025

Inclusion Criteria
 The patients diagnosed of CSOM aged between 12 to 70 years, of either sex, visiting the ENT Out Patient Department (OPD) and willing to give informed consent were included in the study.

Exclusion Criteria
Patients below 12yrs and above 70yrs, along with pregnant and lactating women were excluded from the study.

Sample Size
The sample size was calculated by using the Daniel's formula:
$$N= [Z^2 p (1-p)]/ d^2$$
Here, Z value is 1.96 for confidence level of 95%,
Prevalence of Chronic Suppurative Otitis Media in India is 7.8%.[12-13] So, p is 0.078. So for our study, a sample size of 115 was taken.

Methodology
After taking approval of the Institutional Ethics Committee, the study was carried out in ENT Out Patient Department (OPD) of Silchar Medical College and Hospital

Convenience sampling method was employed and after taking informed consent, prescriptions were collected on thrice weekly basis.

The prescription of the patients satisfying the inclusion criteria were duly analysed for demographic characteristics, age, sex, diagnosis, antibiotic drug data (group, route of administration, dosage and duration), concomitant medications and associated co-morbidities based on WHO core prescribing indicators and noted in a pre-designed proforma.

Statistical Analysis

The pre-designed proforma were checked for completeness of data and the results were analysed using Microsoft excel 2021. Results on categorical measurements were presented as number and percentage and after proper analysis of data, tables were generated.

Parameters for evaluation

According to the World Health Organization (WHO), core drug prescribing indicators such as the average number of drugs per prescription (total number of drugs/total number of prescriptions), average number of antibiotics per prescription (total number of antibiotics/total number of prescriptions), average duration of antibiotic drug treatment (number of antibiotics for a particular duration/total number of antibiotics), and percentage of antibiotics prescribed by generic name (antibiotics prescribed with generic name/total number of antibiotics prescribed ×100) were evaluated.[23]

RESULTS

A total of 115 prescriptions of patients diagnosed of CSOM were collected and analysed from ENT OPD. Out of which 79 (68.69%) were males and 36 (31.30%) were females. Based on age group classification, maximum number of patients (33.91%) belonged to 12-20yrs of age group followed by 40-50yrs (22.6%) (Table1).

TABLE1: Age and Gender wise distribution of CSOM patients

AGE (In yrs)	MALE (n)	FEMALE (n)	TOTAL	NTAGE (%)
12-20	24	15	39	33.91
20-30	13	10	23	20
30-40	15	4	19	16.52
40-50	19	7	26	22.60
50-60	6	0	6	5.21
60-70	2	0	2	1.73
TOTAL	79	36	115	100

In our study, 81.73% study population was from rural areas and 18.26% were from urban areas. (Figure 1)
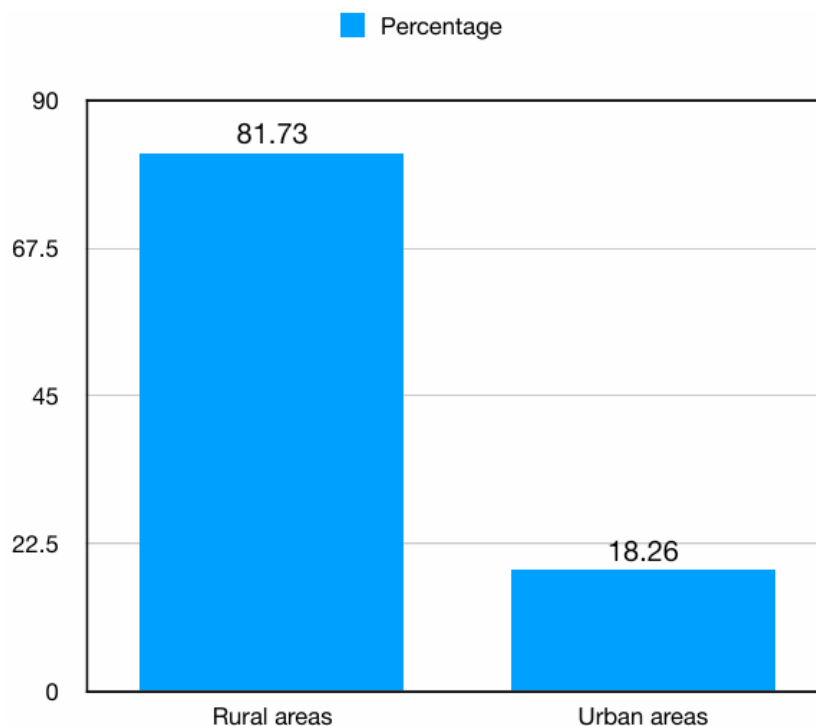

FIGURE 1: Percentage distribution of Rural vs Urban population

Unilateral CSOM was most frequently seen and 57 (49.56%) were suffering from left sided CSOM, 32 (27.8%) from right sided and 26 (22.6%) from bilateral CSOM (Figure2).
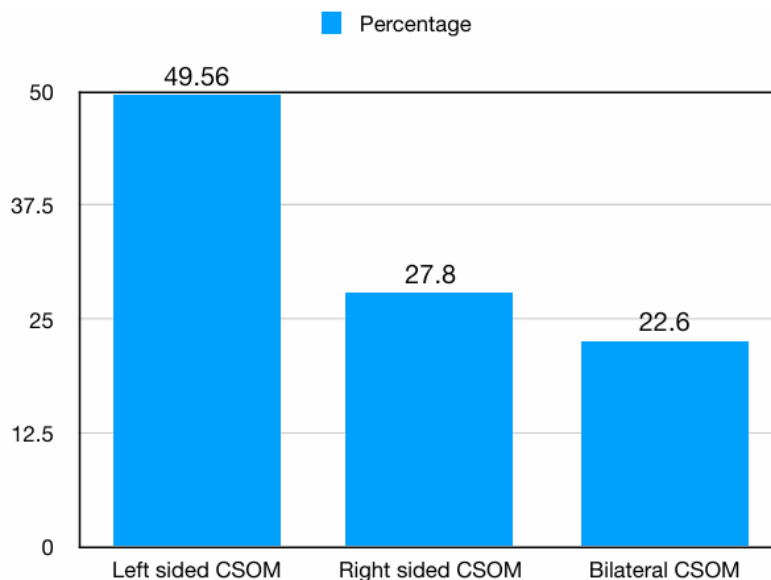
FIGURE 2: Percentage distribution of side of ear involved at the time of presentation

Otorrhoea was the most common symptom (93.91%) followed by hearing loss (44.34%) and 20% of patients were suffering from otorrhoea for more than five years (Table2).

TABLE 2: Percentage Distribution of Associated Symptoms in CSOM Patients

ASSOCIATED SYMPTOMS	PERCENTAGE (%)
Otorrhoea	93.91
Hearing Impairment	44.34
Nasal symptoms	20.89
Ear ache	19.1
Pruritis	6.9
Headache	18.2
Tinnitus	3.4
Fever	4.2

Most common associated clinical feature was tonsillitis (13.91%) followed by hypertension (10.41%) (Figure 3).
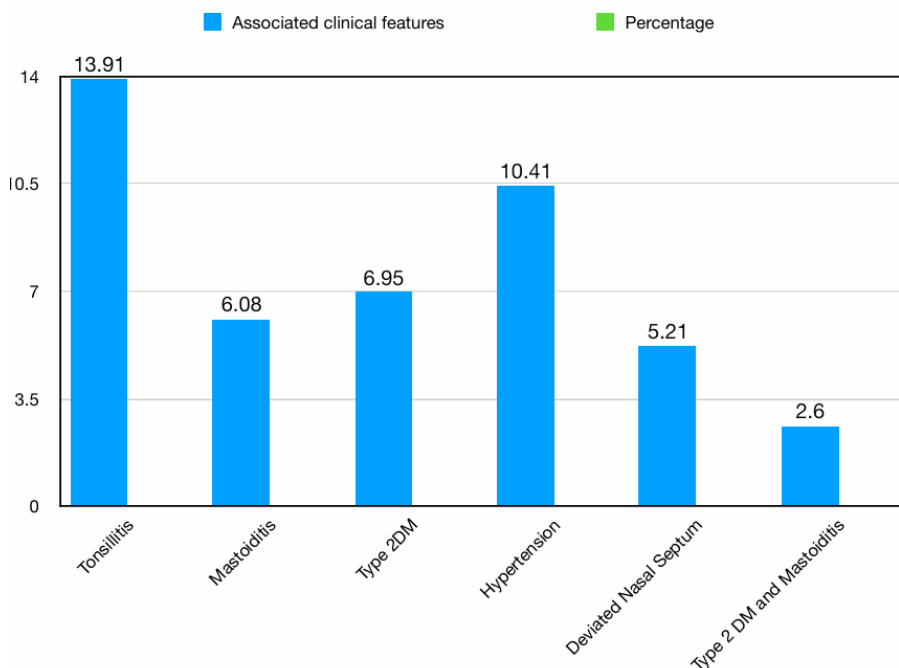

FIGURE 3: Percentage Distribution of Associated clinical features in CSOM Patients

Total 390 medicines were prescribed and most of them, 136 (34.87%) were antibiotics followed by antihistaminics (26.15%)(Table3).

TABLE 3: Types of drugs prescribed for CSOM

Class of drugs	Percentage (%)
Antibiotics	34.87
Antihistaminics	26.15
Proton pump inhibitors	10.76
NSAIDS	3.07
H2 blockers	0.51
Nasal decongestants	20.05
Paracetamol	0.76
Steroid ear drops	1.53
Miscellaneous	2.30
*Miscellaneous- steroid nasal spray, ear wax solvent	

In our study, no other antimicrobials like antifungals were prescribed. Out of 115 prescriptions, 62 (53.91%) had three drugs per prescription followed by four drugs (26.95%) with an average of 3.38 (Figure 4).
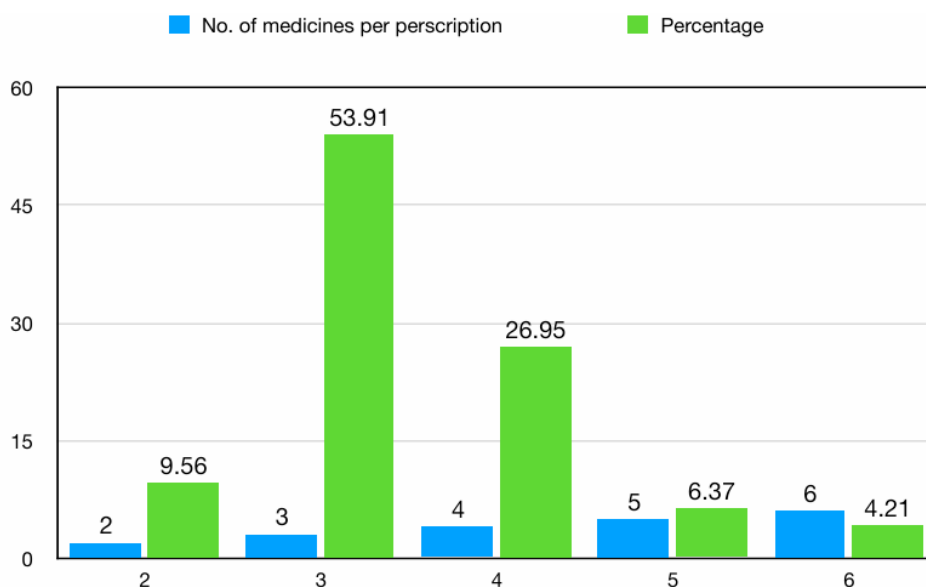

FIGURE 4: Number of medicines prescribed per prescription

98.5% of medicines were prescribed by generic name and only 1.5% of medicines were prescribed by brand name (Table 4).

TABLE 4: Number and percentage of medicines prescribed by generic and brand names

	Number (n)	Percentage (%)
ibed by generic names	384	98.5
ibed by brand names	6	1.5

Analysis of antibiotic prescriptions

A total of 136 antibiotics were prescribed and in most of the prescriptions, 94 (81.73%) single antimicrobial agent (AMA) was prescribed and in 21 (18.26%) prescriptions two AMA were prescribed. Average number of antibiotics prescribed per encounter was 1.18 (Figure 5)
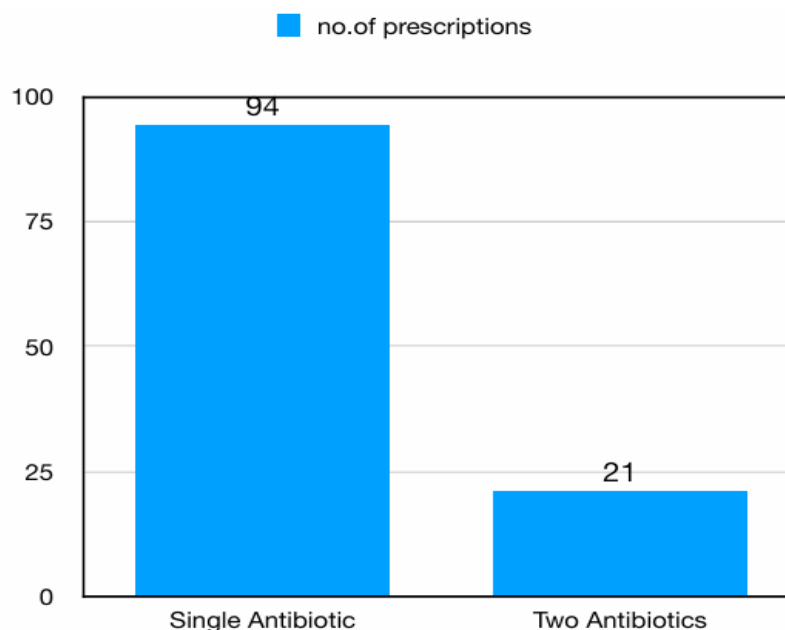
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FIGURE 5: Number of antibiotics used per prescription

82.35% of patients were prescribed oral antibiotics, 17.64% were prescribed topical antibiotics and no injectables were prescribed (Figure 6).
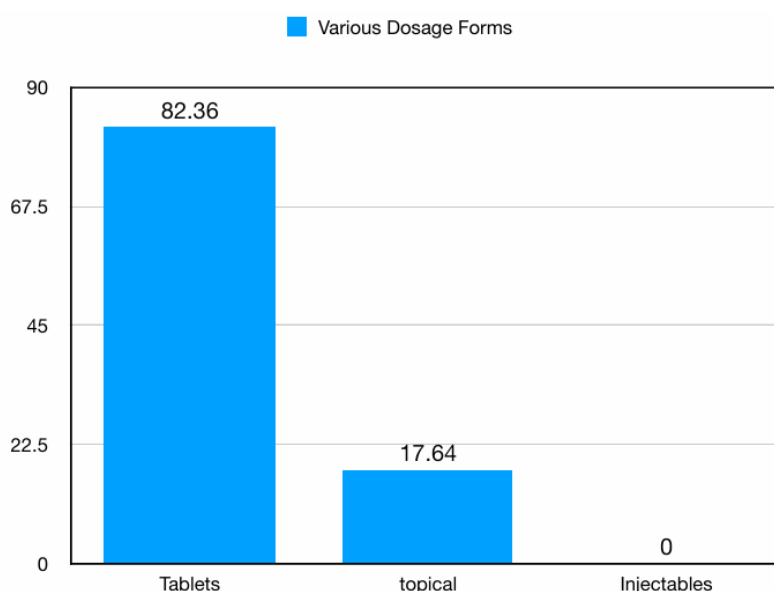

FIGURE 6: Percentage distribution of various dosage forms of antibiotics prescribed

18.26% of cases were given a combination of oral and topical antibiotics. 100% of the antibiotics were prescribed by generic names.

In our study, Penicillins (59.55%) were the most common class of antibiotic prescribed followed by Fluroquinolones (27.36%) and Cephalosporins (12.04%)(Table 6).

TABLE 6: Percentage distribution of different classes of antibiotics prescribed

Classes of Antibiotics Prescribed	Percentage (%)
Penicillins	59.55
Fluroquinolones	27.36
Cephalosporins	12.04
Tetracyclins	1.05

Amoxicillin(59.55%) was the most common antibiotic prescribed followed by Ciprofloxacin (27.94%) (Figure 6). Amoxicillin with clavulanic acid was the most common FDC prescribed followed by Cefpodoxime with Clavulanic acid. Most of the antibiotics (94.85%) were prescribed for 7days and rest 5.14% were prescribed for 5 days.
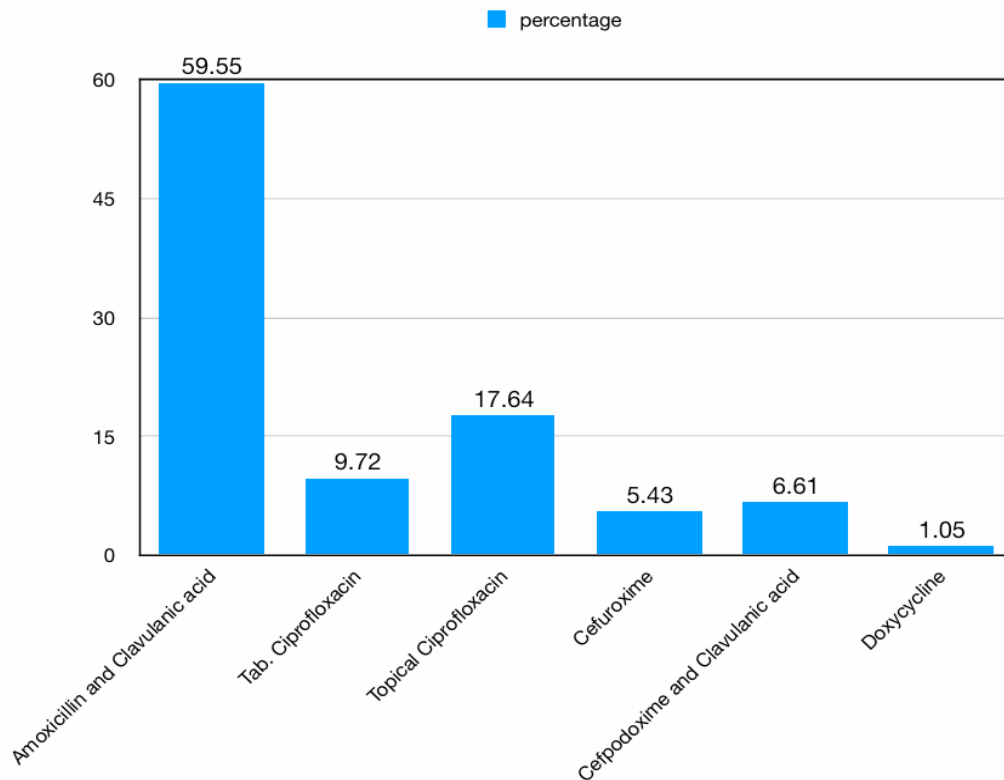
FIGURE 6: Percentage Distribution of Different Antimicrobial Agents Prescribed

Analysis of adjuvant drug prescriptions

In adjuvant group, antihistaminics (26.15%) were the most common medication prescribed followed by nasal decongestants (20%) and proton pump inhibitors (PPI) (10.76%) (Figure 7). Levoceterizine and montelukast (25.12%) was the most common FDC used followed by Aceclofenac with Paracetamol (2.05%).

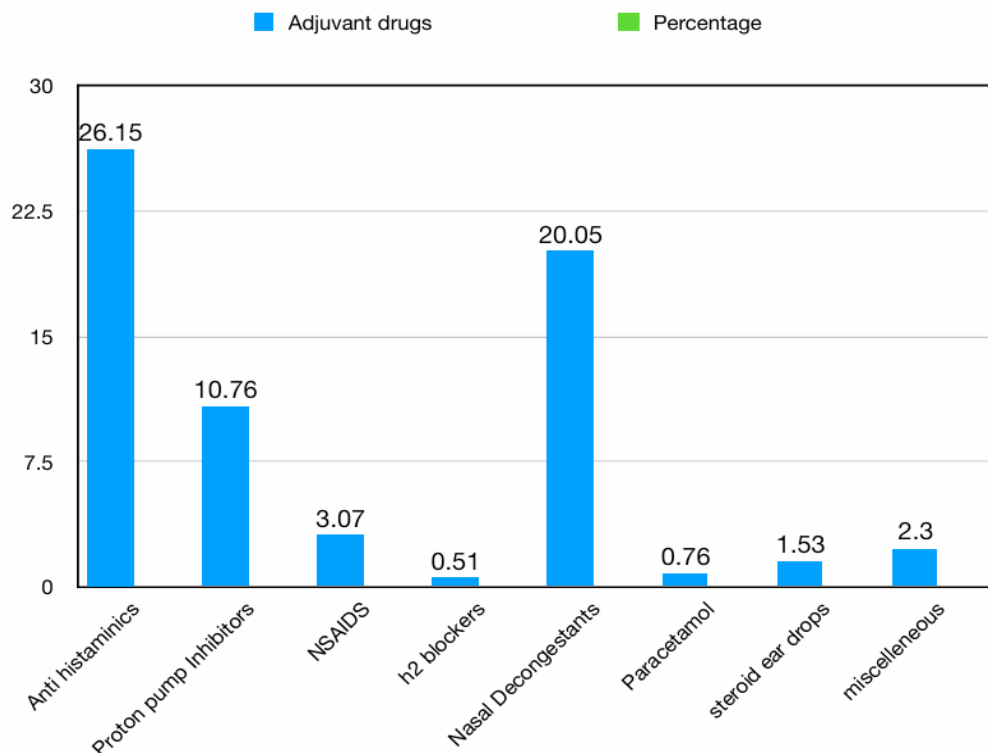**FIGURE 7 : Percentage Distribution of Adjuvant Medicines Prescribed**

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Discussion

This is an prospective, observational study conducted in the ENT OPD of a tertiary care hospital of Silchar. CSOM is a major health problem with high prevalence rate in India and still its disease pattern, and treatment challenges often remain underreported and analyzed. A study done by Naveen, *et al* observed CSOM to be the most common infection for which patients visited ENT OPD.[25] As it is a persistent disease with greater risk of irreversible complications, timely diagnosis and management can save the patients from its debilitating sequele and complications. In our study, analysis of prescriptions of CSOM cases was done in various categories.

On analysing the demographic profile it was found that, number of male patients (68.69%) was markedly higher than female patients (31.30%) with a sex ratio of 2.19 which was similar to studies by Chandra et al and Bansal Sulabhet *et al* where there was male preponderance (55%).[14,15] As males constitute the majority of working population in India, chances of exposure to environmental pollutants and allergens are more and neglect by women of their health could be some of the reasons for more number of male patients.

Most of the patients (81.73%), were from rural areas and only 18.26% were from urban areas which was also observed in a study by Surajit Basumatari *et al* in FAAMCH Barpeta where 84.44% patients were from rural areas.[16] The reason for higher incidence in the rural area could be due to lower standard of living, poor hygiene, malnutrition, illiteracy, and lack of proper medical facilities.

On analysing the age group, most patients 33.91% belonged to 12-20yrs which is in accordance with the study by Gupta and Mittal where 36.59% of patients belonged to this age category.[17] Probably, the habit of swimming in polluted water in a pond or river regularly may be a factor responsible for discharging ear. However there are many studies like Divya R *et al,* Swati Suneha *et al,* done all over in India where more patients belonged to the age group of 20-40 yrs.[13,18] In our study the second peak was seen in age group of 40-50yrs (22.6%) which could be due to chronic nature of the disease and negligence on the part of patients to seek medical help.

Maximum number of patients suffered from left sided CSOM (49.56%), 27.8% from right sided and only 22.6% suffered from bilateral CSOM, similar observations were seen in study by Surajit Basumatari *et al* where left sided CSOM was found to be 48%. However no explanation has been given for involvement of left ear more than right ear. But in study done by G. Rachana *et al* right sided CSOM was more observed (66.6%).[19]

In our study, otorrhoea was found to be the most common symptom seen in (93.91%) of cases followed by hearing loss (44.34%). Kumar *et al* observed that otorrhoea was the commonest complaint with which 81.25% patients presented to hospital, followed by hearing impairment in 62.50%.[20]

Tonsillitis was present in 13.91% of cases and was most common associated clinical feature. The proximity of the tonsils to the Eustachian tube and middle ear, shared risk factors, and frequent co- existence of upper respiratory infections explain why tonsillitis is commonly associated with CSOM. Children with recurrent tonsillitis have an increased risk of developing CSOM due to their more reactive lymphoid tissue and frequent upper respiratory tract infection.[31]

For CSOM, Ototopical antimicrobials in combination with aural toilet are the first line therapy and oral antibiotics are the second line of therapy. But in our study topical antibiotics were prescribed to only 17.64% of patients and 82.36% of patients were prescribed oral antibiotics whereas 18.26% received both topical and oral antibiotics. Though our finding deviates from the WHO standard of ototopical antimicrobials as mainstay of treatment, it could be due to ease of availability of oral antibiotics in Govt. Hospitals and since it is a chronic disease most patients visit hospitals after failure of primary treatment or due to recurrence of disease. Similar results were observed by Divya *et al* where 90.8% patients received oral antibiotics.[13] 81.73% prescriptions had single antibiotic and in 18.26% prescriptions two antibiotics were prescribed with an average number of antibiotic per prescription of 1.18. total no. medicines ?

Penicillins (59.55%) , fluroquinolones (27.36%) and cephalosporins (12.04%) were commonly prescribed empirical antibiotics and in the FDC, amoxicillin with clavulanic acid was the commonest followed by cefpodoxime with clavulanic acid. A study by Gupta, *et al.* on microbiological review for 20 yrs of causative organisms of CSOM and S. Vishwanath *et al* showed Pseudomonas aeruginosa and Staphylococcus aureus to be the most common bacterial isolates.[21,29] Amoxicillin + clavulanate due to its antimicrobial profile covering gram-positive cocci, including staphylococci, streptococci, methicillin resistant Staphylococcus aureus (MRSA), and other β- lactamase- producing bacteria could be the reason for its preference as empirical antibiotic. The above result is consistent with study Swati Suneha *et al* where Amoxicillin + clavulanate (52%) was most common oral antibiotic prescribed but in some other studies by Abubakar K *et al*, Divya *et al* fluroquinolones were more preferred.[22,13]

In our study, 97.89% of medicines and 100% of the antibiotics were prescribed by generic names and prescribing

generic medicines in government hospitals leads to significant cost savings, making healthcare more affordable and accessible for patients and the public sector.

Average number of medicines per prescription was found to be 3.38 which shows decreased chances of adverse reactions due to drug-drug interaction and polypharmacy.

In adjuvant group, antihistaminics (26.15%) were the most commonly prescribed followed by nasal decongestants (20.05%) which point towards the presence of associated symptoms of allergy and nasal congestion, in CSOM patients.
In our study, 62.14% of medicines were prescribed from national list of essential medicines (NLEM) and 71.92% of medicines were prescribed from EDL whereas WHO recommendation is 100% prescription of drugs from the essential drug list (EDL) which shows there is significant scope of improvement to increase the availability and accessibility of medicines to the patients.[24]

Limitations
This study was conducted for a period of 4 months only, hence seasonal variations were not taken into account. This was a single centre study and all the antibiotics prescribed were empirical. Since convenience sampling was used, it becomes somewhat difficult to get the real sociodemographic picture and treatment assessment on the ground level.

Conclusion
CSOM is one of the oldest diseases and continue to affect a significant percentage of population worldwide especially India which falls under high prevalence zone. With an increase in antibiotic resistance throughout the world, time to time prescription patterns analysis can enable appropriate modifications in prescribing patterns which can lead to increased therapeutic efficacy, facilitate rational utilization of drugs and limit unnecessary use of antibiotics. This study was a sincere attempt to study prescription pattern of antimicrobials in CSOM patients. In our study oral antibiotics were more prescribed and most medicines were prescribed by generic names which pointed towards an attempt by our physicians to make healthcare affordable and lower the cost of medical burden for the patients. Increase in prescription of medicines from NLEM and EDL is required which will increase the overall availability and affordability. Overall, more of public awareness about the disease especially in rural areas , maintainance of hygiene, early diagnosis and treatment can decrease the disease burden and the debilitating complications associated with CSOM.

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