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Prescribing pattern of antimicrobial agents in patients with chronic suppurative otitis media at a tertiary care hospital

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ABSTRACT

Background

Chronic Suppurative Otitis Media (CSOM) is a serious healthcare concern worldwide, especially in developing countries like India despite the advances in healthcare facilities. India's prevalence of CSOM is 7.8% which is high and this may be related to frequent upper respiratory tract infections and poor socio-economic conditions. In general practice, the therapeutic approach for ENT infections is nearly empirical and the main aim of physicians is to treat as specifically as possible, while covering the most likely pathogens. This study was undertaken to evaluate the prescribing pattern of antimicrobials in CSOM patients in a tertiary care hospital.

Materials & methods

A prospective, observational study was conducted in the patients with CSOM attending ENT outpatient department from November 2014 to November 2015. All the data regarding patient's demographics and details of antimicrobial agents were recorded in a predesigned study proforma. The data thus obtained was analyzed using descriptive statistics.

Results

Out of 500 patients, the majority of the patients belonged to 21-30 years and had a male preponderance. Oral antibiotics were prescribed to 90.8 % of patients and the remaining 9.2% patients were given ototopical antimicrobials. Most common antimicrobials being Fluoroquinolones (64%) followed by Beta lactams (36%). Other concomitant drugs like analgesics, antihistamines, decongestants anti-ulcer agents and multivitamins were prescribed.

Conclusion

The study showed that the most common antimicrobial agents prescribed was fluoroquinolone group as they have antipseudomonal activity and lack ototoxicity. Beta lactams were preferred drugs over fluoroquinolones in children as the latter is associated with tendinitis and cartilage damage.

Keywords: CSOM, Antimicrobial agents, Oral antimicrobials, Ototopical antimicrobials

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) is one of the several types of Otitis media (infection of the middle ear). The World Health Organization (WHO) defines CSOM as “a stage of ear disease in which there is chronic infection of the middle ear cleft, a non-intact tympanic membrane (i.e. perforated eardrum) and discharge (otorrhea), for at least the preceding two weeks”(WHO 1998). [1] The WHO definition requires only 2 weeks of otorrhea, but otolaryngologists tend to adopt a longer duration, i.e., more than 3 months of active disease.[2] CSOM affects 65–330 million people worldwide, mainly in developing countries. It has been estimated that there are 31 million new cases of CSOM per year, with 22.6% in children less than 5 years old.[3] The prevalence in India is 7.8% and is also the single most important cause of hearing impairment in rural population. [1]

Complications of otitis media can often result in death or severe disability, especially in low-income countries. Intracranial complications include meningitis, abscesses, hydrocephalus, or thrombosis of the lateral venous sinus. Alternatively complications may be extracranial, such as subperiosteal abscess, facial paralysis, cholesteatoma, labyrinthitis or acute mastoiditis. [4]

The most common cause of OM is bacterial infection of the middle ear. *Pseudomonas aeruginosa* and *Staphylococcus aureus* are the most common aerobic microbial isolates in patients with CSOM,

followed by *Proteus vulgaris* and *Klebsiella pneumoniae*. [5] The current primary treatment modality for CSOM is a combination of aural toilet and topical antimicrobial drops. Systemic oral or parenteral antimicrobials, although an option, are less commonly used due to the fact that topical antimicrobials in combination with aural toilet are able to achieve significantly higher tissue concentrations than systemic antimicrobials.

The present study was undertaken to evaluate the antimicrobial usage in CSOM in Department of ENT in a tertiary care hospital as it will be helpful to procure antimicrobials in our hospital formulary.

MATERIALS AND METHODS

The study was a hospital based prospective observational study. After obtaining approval from the Institutional Ethics Committee, the study was carried out in the Department of ENT at Victoria Hospital, attached to Bangalore Medical College and Research Institute, Bengaluru from November 2014 to November 2015. The patients with CSOM attending the ENT OPD were included in the study. Information regarding demographic characteristics, diagnosis, and the various classes of antibiotics and concomitant medications prescribed were noted in a pre-designed proforma from the prescriptions. The pre-designed forms were checked for completeness of data. The results were analysed using descriptive statistics.

RESULTS

Demographic profile

Table 1: Demographic profile of CSOM patients

AGE	MALES	FEMALES	TOTAL	PERCENTAGE (%)
1-10	24	15	39	8
11-20	37	46	83	17
21-30	97	73	170	34
31-40	69	44	113	23
41-50	32	36	68	14
51-60	7	7	14	3
61-70	8	5	13	3
GRAND TOTAL	279	221	500	100

A total of 500 patients with CSOM were enrolled in our study. A maximum number of patients

belonged to the 21-30 years of age group (34%) followed by 31-40 years (23%). 55.8% of the study

patients were males and 44.2% were females. 55.2% of the study population was from rural areas and 44.8% were from urban areas.

Unilateral CSOM was most frequent occurrence accounting for 363 ears (72.6%). CSOM

tubotympanic type was found in 558 ears (87.4%) and CSOM atticointral type was found in 79 ears (12.6%).

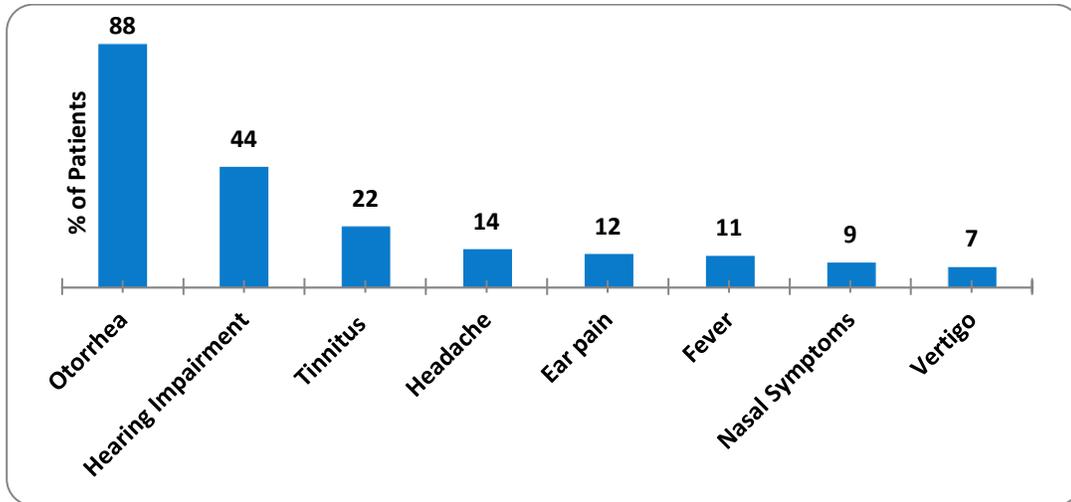


Figure 1: Symptoms in patients with CSOM

Otorrhea was the most common diagnostic symptom (88%) followed by hearing loss (44%) and 60.8% of patients had duration of otorrhea for atleast 5 years.

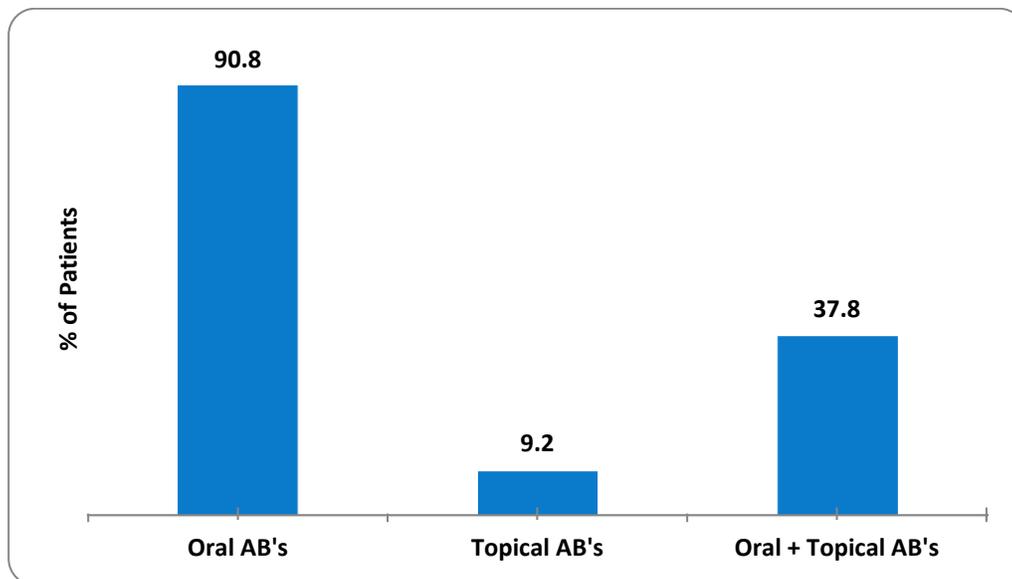


Figure 2: Prescribing pattern of Antimicrobials

90.8% patients were prescribed oral antimicrobials and only 9.2% patients were prescribed topical antimicrobials alone. 37.8% cases were given a combination of oral and topical

antimicrobials. Fluoroquinolones (64%) and betalactams (36%) were the common classes of antimicrobials prescribed in CSOM.

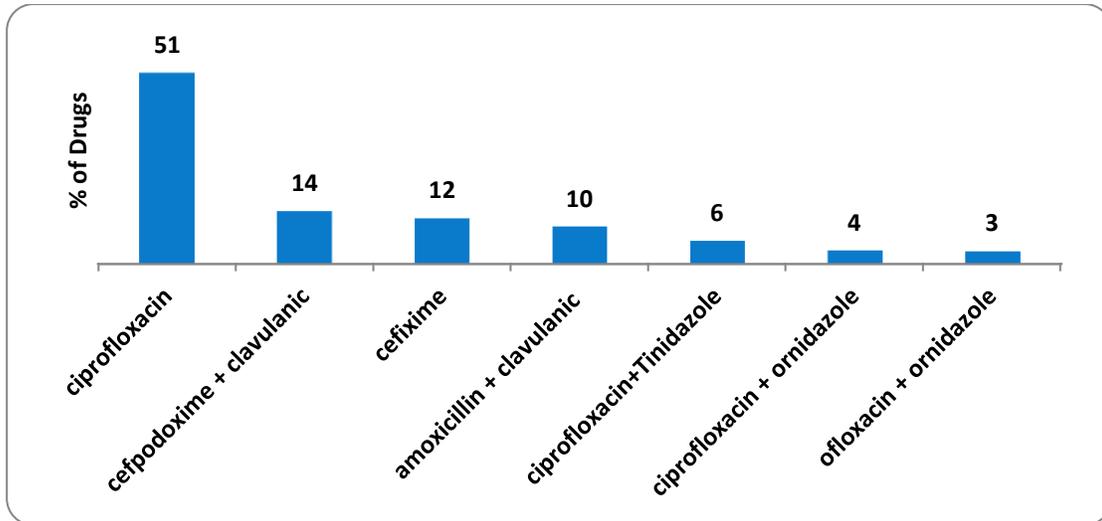


Figure 3: Prescribing frequency of Antimicrobial drugs

Ciprofloxacin was the most common drug prescribed (51%) and the least common being ofloxacin with ornidazole.

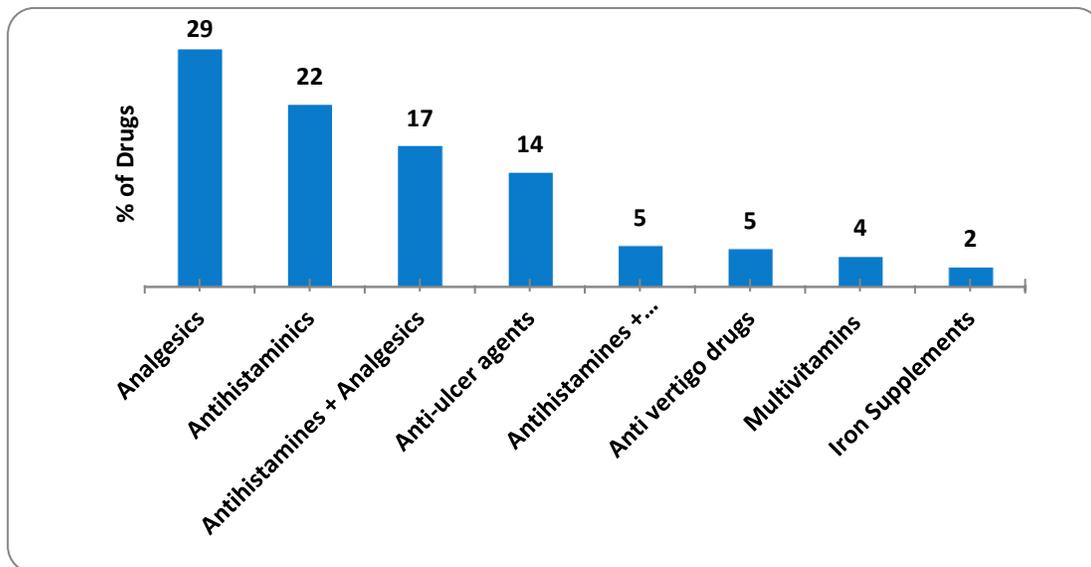


Figure 4: Concomitant medications for CSOM

Among the concomitant drugs prescribed Analgesics (29%) were the most common followed by Antihistamines (22%)

DISCUSSION

CSOM is a persistent disease of the middle ear, which is capable of causing severe destruction and sequelae with the manifestation of deafness, discharge and perforation [6]. It usually presents with otorrhea, hearing loss and otalgia, causing psychological trauma and a financial burden to the

society [7]. Most common organisms found in CSOM are *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *E. coli*, *Aspergillus* and *Candida albicans*. However, due to increased and irrational use of wide-spectrum antimicrobials, the resistance in the bacterial isolates has become very common along

with the emergence of multiple strains of bacteria [8].

In the present study, demographic data showed that a maximum number of patients (34%; 170/500) belonged to the 21-30 years age group. The mean age was 29 ± 13.3 years. This is consistent with the results obtained in other studies. [7,9,10] However, in other Indian studies conducted by Agarwal *et al.*, in Agra and Ghosh *et al.*, in Uttar Pradesh showed that more than half of the study population belonged to the age group of less than ten years. [11,12] As compared to studies in India, a Nigerian study by Abubakar *et al.*, reported that 60.6% cases were children aged less than ten years. [13] This shows the presence of slight variation in the prevalence of CSOM in different age groups in different regions of the world. However, it tends to occur more in the early decades of life and it decreases with the progression of age. [7]

In the current study, male patients were more in number than female patients with a male female ratio of 1.2:1 (males 55.8%, females 44.2%). This result was in consistent with a study conducted by Bansal Sulabhet *et al.*, which reported male, female distribution as 62.1% and 37.9% respectively. [14] However, this is in contrast to few other researches which showed a female preponderance of CSOM infection. [7, 15] Indeed, in this study increased prevalence of CSOM in males might just be a simple reflection of overall high male attendance in a hospital and females being more reluctant to seek treatment as they do not prioritize their health and most of them are dependent on other family members for hospital visits for treatment and follow up.

In the present study, more than half of the patients were from rural background. This is comparable to the other studies done in India. [7, 16] Prevalence of CSOM is more in low socioeconomic groups worldwide due to various risk factors like malnutrition, overcrowding, poor hygienic condition, passive smoking, ignorance regarding ear disease and lack of medical facilities.

Otological antimicrobials in combination with aural toilet are the first line therapy for CSOM whereas second line therapy being oral antimicrobials. Systemic therapy has not been as effective as topical antimicrobials due to the inability to achieve effective concentrations in the infected tissues of the middle ear. [1] As far as topical preparation is concerned in the treatment of CSOM,

the otolaryngologist has either quinolones or aminoglycosides in their armory. However, in our study only 9.2% patients were prescribed with otological antimicrobials alone and 37.8% patients received a combination of topical and oral antimicrobials. Though our finding deviates from the WHO standard of otological antimicrobials as the mainstay of treatment, it may be attributed to the fact that oral antimicrobials are free of cost and readily available in our hospital formulary and since it is a tertiary care hospital, most of the patients are referred after failure of primary modality of treatment. The main cause of failure of treatment with otological antimicrobials in CSOM is inadequate aural toileting. [1] Moreover, due to the high risk of concomitant fungal infections with the usage of topical antimicrobials, the physicians prefer to prescribe oral antimicrobials.

In the present study, fluoroquinolones and beta lactams were the most common class of antimicrobials prescribed. In a study by Kadar AA *et al.*, [17] it was shown that quinolones give better results compared to topical aminoglycosides. Similar findings were also shown by other researchers indicating the effectiveness of topical quinolones particularly against *Pseudomonas aeruginosa* and *Staphylococcus aureus*. [18] This is in strong agreement with our physicians who prescribe fluoroquinolone antimicrobials as the only choice of topical agents.

Oral antimicrobials were prescribed to 90.8% of patients, the most common being Fluoroquinolones followed by Beta lactams. The above results were consistent with the previous studies. [13, 16] The preference for quinolones could be due to the fact that in CSOM more than 90% cultures yield two or more isolates consisting of both aerobic and anaerobic bacteria with the most common pathogens being *Pseudomonas aeruginosa* and *Staph. aureus*. [1] Since, fluoroquinolones have antipseudomonal activity and lack of ototoxic side effects; it is the preferred drug of choice over the beta lactam which has limited efficacy due to narrow spectrum activity. However, beta lactams are the preferred drugs since fluoroquinolones are avoided in children as their use is associated with tendonitis and cartilage damage. In our study, ciprofloxacin was the most commonly prescribed fluoroquinolone (61%), either alone or in combination with tinidazole or ornidazole. It has also been shown

that ciprofloxacin concentrations within the structures of the middle ear exceed the minimum inhibitory concentration for the micro-organisms responsible for CSOM. [18]

Different group of concomitant drugs are employed in the management of ear infection like analgesics, antihistamines and decongestants. In our study, 16% (245/1508) of the total drugs prescribed were analgesics followed by antihistamines (12%) and analgesic-antihistamine combinations (10%). Among the analgesics, paracetamol was the most common drug prescribed. The least common prescribed drugs were decongestants, anti-ulcer agents and multivitamins. These findings were in tandem with the pattern of drugs prescribed in the studies conducted by Goud S K, et al., and Abubakar K et al., [16,13]

The present study gives an insight of disease profile and antimicrobial usage in CSOM. The knowledge about the prevalent local microorganisms causing CSOM helps the clinician to assess the rationality of the antimicrobials prescribed. Hence, this study is useful to generate data for good evidence based practice and facilitate appropriateness of usage of antimicrobials in CSOM. The limitation of this study was that it was conducted in a government tertiary care health center, therefore limits the extrapolation and generalizability of the findings to the population at large. Also, due to the emerging

problem of antibiotic resistance, the evaluation of microbiological profile and antibiotic sensitivity pattern of the bacterial isolates could have been helpful in prescribing empirical therapy for successful treatment and prevent emergence of resistant strains.

CONCLUSION

Prevalence of CSOM is still high in rural areas and is commonly found in younger age groups. Though topical antimicrobials with aural toileting are the first line of treatment, our study depicted a maximum use of oral formulations. This may be attributed to the failure of therapy with ototopical antimicrobials due to inadequate aural toileting which led to an increased use of systemic antimicrobials. Most commonly prescribed class of antimicrobials was the quinolones and amongst them ciprofloxacin was prescribed in more than half of the patients. Other commonly prescribed concomitant drugs were analgesics and antihistamines.

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REFERENCES

- [1]. Acuin J Chronic suppurative otitis media - Burden of Illness and Management Options. Geneva: World Health Organization 2004.
- [2]. Goycoolea MV, Hueb MM, Ruah C. Definitions and terminology. *Otolaryngol Clin North America*, 24(4), 1991, 757-761.
- [3]. Monasta L, Ronfani L, Marchetti F, Montico M, Vecchi Brumatti L, Bavcar A et al., Burden of disease caused by otitis media: systematic review and global estimates. *PLoS One* 7, 2012, 36226.
- [4]. Dhingra PL. Chronic suppurative otitis media. In: *Diseases of ear, nose and throat*. 6, 2014, 68-74
- [5]. Sattar A, Alamgir A, Hussain Z, Sarfraz S, Nasir J, Badar-e-Alam. Bacterial spectrum and their sensitivity pattern in patients of chronic suppurative otitis media. *J Coll Physicians Surg Pak* 22, 2012, 128-129.
- [6]. Altuntas A, Aslam A, Eren A. Susceptibility of microorganisms isolated from CSOM to Ciprofloxacin. *Eur Arch Otorhino Laryngology* 3, 1996, 64 -6.
- [7]. Basak B, Gayen GC, Das M, Dhar G, Ray R, Das Ak. Demographic profile of CSOM in a rural tertiary care hospital. *IOSR-JOP* 4(6), 2014, 43-46.
- [8]. Sabella C. Management of otorrhea in infants and children. *Paed infectious dis J* 12(1), 2000, 1007-8.
- [9]. Kumar R, Srivastava P, Sharma M, Rishi S, Nirwan PS, Hemwani K et al., Isolation and antimicrobial sensitivity profile of bacterial agents in chronic suppurative otitis media patients at NIMS hospital, Jaipur. *IJPBS* 3(4), 2013, 265-269
- [10]. RenukanandaGS, Santosh UP, George NM. Topical vs Combination Ciprofloxacin in the Management of Discharging Chronic Suppurative Otitis Media. *J Clin Diagn Res* 8(6), 2014, KC01-KC04.

- [11]. Agrawal A, Kumar D, Goyal A, Goyal S, Singh N, Khandelwal G. Microbiological profile and their antimicrobial sensitivity pattern in patients of otitis media with ear discharge. *Indian J* 19, 2013, 5-8.
- [12]. Ghosh A, Rana A, Prasad S. Risk Factors and Microbiology of Chronic Suppurative Otitis Media and its Clinical Significance in a Tertiary Care Setup in Western Uttar Pradesh, India. *IJCMAAS* 6(3), 2015, 177-183.
- [13]. Abubakar K, Abdulkadir R, Abubakar MR, Ugwah-Oguejiofor JC, Abubakar SB. Pattern of Drug Utilization in the Treatment of Chronic Suppurative Otitis Media in a Tertiary Health Institution in Kaduna, Nigeria. *J Health Sci* 4(1), 2014, 7-10.
- [14]. Hirapure PV, Pote MK. Microbial Profile and Antibiograms of Active Patients of Chronic Suppurative Otitis Media in Latur, Maharashtra, India. *Int Res J Medical Sci* 2(5), 2014, 6-9.
- [15]. Sulabh B, Tarun O, Suresh K, Amit S, Pratibha V. Changing microbiological trends in cases of chronic suppurative otitis media patients. *Int J Cur Res Rev* 05(15), 2013, 76-81.
- [16]. Goud SKT, Kumar R, Patil VG, Bhusal A, Rajlakshmi KH, Senpaty S et al., Incidence & Drug Use in Chronic Suppurative Otitis Media (CSOM) In Opd E.N.T at Tertiary Care Teaching Hospital. *IOSR-JDMS* 13(4), 2014, 13-19.
- [17]. Kardar AA, Usman M, Tirmizi S. Topical quinolone versus topical aminoglycosides in the medical management of chronic suppurative otitis media; A comparative trial. *J Surg Pak* 8(4), 2003, 6-9.
- [18]. Sanjana RK, Singh Y, Reddy NS. Aerobic bacteriology of Chronic Suppurative Otitis Media (CSOM) in a tertiary care hospital: A retrospective study. *Journal of College of Medical Sciences* 7(2), 2011, 1-8.