

Clinical and Sociodemographic Profiles of Patients with Chronic Otitis Media Seeking Health Care at a Tertiary Care Center of Bihar: A Prescription-based Analysis

Swati Suneha¹, Mukesh Kumar², Kranti Bhavana³

ABSTRACT

Objective: To determine the clinical and sociodemographic characteristics of patients with chronic otitis media (COM) at the Department of Otorhinolaryngology, AIIMS, Patna. To deduce the pattern of treatment provided to these patients at this center.

Materials and methods: A cross-sectional observational study was conducted on patients with COM visiting the outpatient department of Otorhinolaryngology, AIIMS, Patna, Bihar, for a period of 6 months (i.e., September 2019 to February 2020). Outpatient prescriptions were collected, and data were recorded and analyzed. Results were interpreted pictorially and through analysis tables. Chi-square test was applied to test the relationship between routes of different antibiotics administration used in the prescriptions.

Results: COM was highly prevalent in males (54.29%), 16- to 40-year age-group (64.76%), and poor to middle-class strata (90.48%). Most cases were unilateral (63.33%) and of COM mucosal subtype (64.76%). Infection (64.28%) and residual/reperforation (24.29%) were major etiological factors. Concomitant sinonasal allergy was present in 69.05% of the patients. The most common symptoms were ear discharge (77.62%) and hearing loss (75.71%). All patients were prescribed antimicrobial-steroid ear drops. Additional drugs prescribed were systemic antibiotics (64%), antihistamines (79.52%), nasal decongestants (70.95%), non-steroidal anti-inflammatory drugs (NSAIDs) (49.05%), and systemic steroids (20.48%). Beta-lactam antibiotics (52%) and cephalosporins (22%) were the most frequently prescribed. The frequency of use of topical along with oral antibiotics was highly significant ($p < 0.0001$) compared to topical with intravenous antibiotics or topical drugs alone.

Conclusion: The study revealed middle-aged males of poor or middle-class socioeconomy forming the majority of patients seeking health care for COM. These patients mostly presented with ear discharge after underlying ear infection that led to a significant hearing loss too. Therefore, topical therapy along with oral antibiotics was the most frequently prescribed on an outpatient basis for prevention and cure.

Keywords: Chronic otitis media (COM), Prescription pattern, Prevalence study.

Otorhinolaryngology Clinics: An International Journal (2022): 10.5005/jp-journals-10003-1419

INTRODUCTION

Chronic otitis media (COM) is a chronic infective cum inflammatory disorder of the middle ear causing recurrent otorrhea for at least 2–6 weeks through a tympanic membrane perforation. It causes a myriad of symptoms across all age-groups like ear discharge, hearing loss, tinnitus, and vertigo, which may be intermittent or persistent. COM has emerged as one of the most common causes of acquired hearing loss.^{1–3}

Worldwide approximately, every year 11% of the human population or 709 million cases get affected by otitis media. Intracranial complications like meningitis and brain abscess constitute the major causes of deaths related to COM. The World Health Organization (WHO) estimates indicate COM to afflict between 65 and 330 million individuals, 50% of whom suffer from hearing impairment.^{2,4} A systematic analysis done by Vos et al. revealed approximately 4.4% of the human population worldwide to be affected by chronic suppurative otitis media (CSOM).⁵

COM patients develop persistent otorrhea for at least 2–6 weeks along with a permanent perforation in the tympanic membrane. According to the WHO estimates, COM is considered to be the primary cause of hearing loss in children. Permanent conductive and/or sensorineural hearing loss has emerged as the most debilitating sequelae of CSOM among adults with recurrent COM. Every year approximately 21,000 people worldwide die as a direct or an indirect result of CSOM complications.²

^{1,3}Department of Otorhinolaryngology and Head and Neck Surgery, All India Institute of Medical Sciences, Patna, Bihar, India

²Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India

Corresponding Author: Mukesh Kumar, Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India, Phone: +91 06299836195, e-mail: mmukesh2005rims@gmail.com

How to cite this article: Suneha S, Kumar M, Bhavana K. Clinical and Sociodemographic Profiles of Patients with Chronic Otitis Media Seeking Health Care at a Tertiary Care Center of Bihar: A Prescription-based Analysis. *Int J Otorhinolaryngol Clin* 2022;14(1):7–11.

Source of support: Nil

Conflict of interest: None

COM is more prevalent in developing countries where a higher population percentage belongs to the lower socioeconomic strata. These patients suffer from poor hygiene and nutrition and high population density associated with poor housing conditions. This often results in recurrent upper respiratory tract infections. These countries are frequently beset with infrequent and inadequate health care service measures for their vast population.⁶ WHO under its Child and Adolescent Health and Development Prevention of Blindness and Deafness program has categorized India as one with a high prevalence of COM (>4%),

thus underscoring the need for urgent attention to deal with this massive public health issue.⁷

The etiology of COM remains multifactorial, with demographics, genetic, environmental, and other health-related factors like infections, trauma, allergy, asthma, Eustachian tube dysfunction, cleft palate, and adenoid hypertrophy, etc playing a role in its onset and progression. Despite COM being a disease with a high medical and socioeconomic burden, it often fails to get due attention because of insidious onset and chronic course.⁸

An understanding of the prevalence, symptoms, diagnostic measures, and routine treatment protocols including antibiotic prescription patterns followed for its management would help in refining our approach to this disease. Therefore, this study was conducted to determine the prevalence and associated factors of COM and to analyze the management protocol of these patients visiting our hospital.

MATERIALS AND METHODS

Study Design

It was a cross-sectional observational study conducted on patients clinically diagnosed with COM who visited the outpatient Department of Otolaryngology, AIIMS Patna, for a period of 6 months (i.e., September 2019 to February 2020). These patients underwent routine otoscopic and oto-endoscopic evaluation and were managed accordingly. Outpatient prescriptions of these patients were then collected after obtaining a well-informed consent. Relevant clinical data were recorded and analyzed to demonstrate the prescription pattern. Data were entered on Microsoft Excel Sheet version 2007, and statistical analysis was done. Results were interpreted pictorially and through analysis tables. Chi-square test was applied to test the relationship among routes of administration of the prescribed antibiotics using GraphPad prism QuickCalcs online software.

Inclusion Criteria

- Patients diagnosed with COM.
- Patients seeking treatment on an outpatient basis.
- Patients residing in the state of Bihar.
- Patients who gave consent for data collection.

Exclusion Criteria

- Patients with a diagnosis other than COM.
- Patients whose prescription lacked the data required for analysis.
- Prescriptions referred from another department/concerned with other associated diseases.
- Patients refusing to give consent.

Sample Size

Prescriptions of 210 COM patients were thus analyzed.

Statistical Analysis

Descriptive data were tabulated on Microsoft Excel sheet version 2007, and the relevant results were depicted as percentages, bar graphs, and pie charts. Chi-square test (using WinPepi Version 11.65 software) was applied to analyze the test of significance among different routes of administration of antibiotics or its combination prescribed in COM treatment.

RESULTS

We analyzed the prescription of 210 patients. Our study demonstrated the sociodemographic profile, clinical picture, and

treatment modalities of the patients diagnosed with COM. The results are depicted below:

COM was slightly more prevalent in males (54.29%) and commonly seen in middle socioeconomic classes (49.05%). Both males and females presented frequently in the age-group of 16–30 years (Table 1).

Table 2 demonstrates the clinical profile of these patients. Mucosal type of COM was more common, and patients frequently had unilateral disease. Infection was the most common identifiable cause (64.28%). The majority had a large tympanic membrane perforation (53.81%) with mucopurulent ear discharge (57.05%). Hearing loss (75.71%) and tinnitus (56.67%) were the most common associated symptoms. Concomitant allergy was found to be present in about 69% of patients.

About 65% of these cases received systemic antibiotics with penicillin and cephalosporin groups being most frequently administered. Approximately 80% of patients were prescribed antihistamines for symptomatic relief. About 70% of patients were also treated with nasal decongestants to manage concomitant nasal allergy (70.95%). All patients received topical therapy, with antibiotic-steroid-antifungal therapy being the most common (Figs 1 to 3).

Various routes of administration of a combination of antibiotics or its fixed-dose combination preparations were compared using Chi-square test. Oral + topical route was the most commonly prescribed route (64.28%) and was found highly significant ($p < 0.0001^*$, $\chi^2 = 186.814$, $df = 2$) than other routes prescribed routinely (Table 3).

DISCUSSION

COM is a preventable cause of acquired hearing loss. Its early detection and timely management are essential to avoid its debilitating but treatable sequelae and complications. Though this disease is highly prevalent across the globe, its exact regional prevalence, disease pattern, and treatment challenges often remain underreported and analyzed. This hinders the formulation of an effective treatment strategy at the regional level.

This study showed that the majority of hospital attendance for COM belonged to the middle-aged group of 16–40 years (64.76%) and had a male preponderance with a sex ratio of 1.2:1. Chandra et al. had similar findings with young adults being most frequently afflicted with the disease and males reporting more (55%).⁹

Table 1: Sociodemographic profile of COM cases

Demographic data	No. of COM cases (%) (n = 210)	
Sex distribution		
Male (M)	n = 114 (54.29%)	
Female (F)	n = 96 (45.71%)	
Age distribution	Male	Female
0–15 years	n = 8 (3.81%)	n = 10 (4.76%)
16–30 years	n = 37 (17.62%)	n = 44 (20.96%)
31–40 years	n = 24 (11.43%)	n = 31 (14.76%)
41–60 years	n = 18 (8.57%)	n = 21 (10%)
>60 years	n = 9 (4.28%)	n = 8 (3.81%)
Socioeconomic strata		
Poor	n = 87 (41.43%)	
Middle class	n = 103 (49.05%)	
Above middle	n = 20 (9.52%)	

Poor and middle-class people were found to have a high prevalence of COM, corresponding to 90.48% of all prescriptions

under analysis. Shaheen et al. found that 71.4% of their COM population under study belonged to the low socioeconomic groups.¹⁰

Table 2: Clinical profile of COM cases

I. COM subtype (n = 210)	
Mucosal	<i>n = 136 (64.76%)</i>
Squamous	<i>n = 74 (35.24%)</i>
II. Ear involved	
Unilateral	<i>n = 133 (63.33%)</i>
Bilateral	<i>n = 77 (36.67%)</i>
III. Etiology	
Infection	<i>n = 135 (64.28%)</i>
Residual/reperforation	<i>n = 51 (24.29%)</i>
Trauma	<i>n = 16 (7.62%)</i>
Cause not identifiable	<i>n = 8 (3.81%)</i>
IV. Concomitant sinonasal allergy	
Present	<i>n = 145 (69.05%)</i>
Absent	<i>n = 65 (30.95%)</i>
V. Clinical features on presentation	
Ear discharge	<i>n = 163 (77.62%)</i>
<i>Seromucinous</i>	<i>n = 19 (11.66%)</i>
<i>Mucopurulent</i>	<i>n = 93 (57.05%)</i>
<i>Purulent</i>	<i>n = 51 (24.26%)</i>
Granulation	<i>n = 69 (32.86%)</i>
Vertigo	<i>n = 60 (28.57%)</i>
Hearing loss	<i>n = 159 (75.71%)</i>
Earache	<i>n = 96 (45.71%)</i>
Tinnitus	<i>n = 119 (56.67%)</i>
VI. Tympanic membrane perforation size	
Small	<i>n = 26 (12.38%)</i>
Medium	<i>n = 71 (33.81%)</i>
Large	<i>n = 113 (53.81%)</i>

The figures in italics show that mucopurulent and purulent secretions are a common finding in COM patients, which is a clinical indication of most cases of ear discharge having an underlying bacterial infection. So they require antibiotic sensitivity-directed antimicrobial treatment

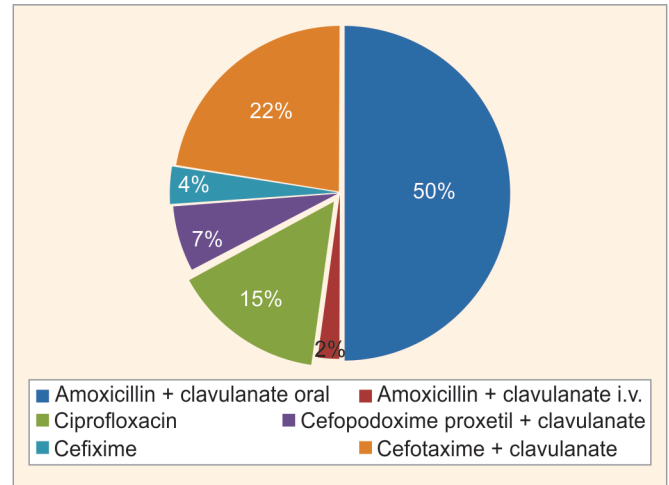


Fig. 2: Categorization of systemic antibiotics prescribed in COM

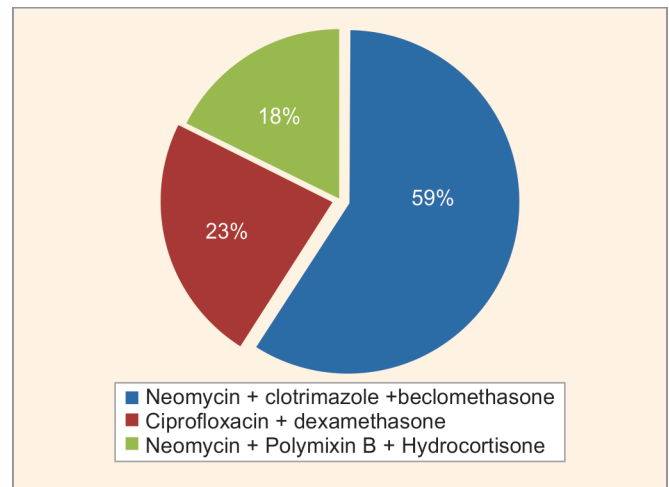


Fig. 3: Percentage of prescribed topical ear drops (antimicrobial + steroids)

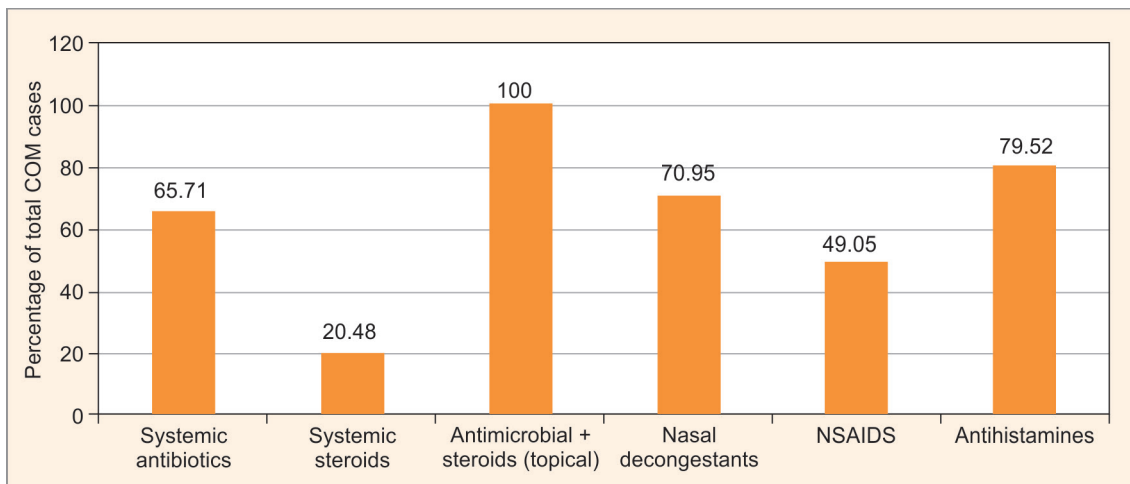


Fig. 1: Drug prescription pattern in COM patients (n = 210)

Table 3: Routes of drug administration of antibiotics

Various routes	No. of patients prescribed	No. of patients not prescribed	Significance status*
Oral + Topical	n = 135 (64.28%)	n = 75 (36.72%)	p < 0.0001*, $\chi^2 = 186.814$, df = 2
IV + Topical	n = 3 (1.43%)	n = 207 (98.57%)	
Topical alone	n = 72 (34.29%)	n = 138 (65.72%)	

Mucosal type of CSOM (64.76%) was more frequent than squamous type (35.24%). Shrestha et al. in their comparative study on the clinical presentation of mucosal vs squamous COM found the mucosal type of CSOM to be more common (60%) than squamous type (40%).¹¹ In the present study, unilateral COM (63.33%) was more prevalent than bilateral cases. Chandra et al. also reported unilateral ear disease (78.75%) to be more common.⁹

Infection (64.28%) and residual perforation (24.29%) were the common etiological factors associated with COM. Worldwide, infection has been considered one of the strongest factors associated with COM.^{1,5} Additionally, coexisting sinonasal allergic symptoms were present in 69.05% of our study population. Ear discharge (77.62%), hearing loss (75.71%), and tinnitus (56.67%) were the most common presenting complaints of patients at this center. Otorrhea was mostly mucopurulent (57.05%). Shrestha et al. also found a similar pattern of symptom distribution among their study population.¹¹

Topical therapy in the form of antifungal-antibiotic-steroid eardrops with or without oral broad-spectrum antibiotics was found to be the mainstay of treatment protocol being followed at our center. Additionally, prescribing antihistamines (79.52%), nasal decongestants (70.95%), and NSAIDs (49.05%) in these patients point toward the presence of associated symptoms of allergy, nasal congestion, and earache in COM patients. In about one-fifth (20.48%) of patients, systemic steroids were also prescribed for coexisting severe inflammatory and granular changes in the middle ear. This study approach to COM management is as per the current treatment protocols being followed at the majority of centers worldwide. Mittal et al. concluded in their review of the current concepts of COM management that ototopical therapy was the primary effective therapy, followed by oral antibiotics on non-resolution of ear discharge. IV antibiotics and steroids were prescribed for recurrent COM cases.¹²

Amoxicillin + clavulanate (52%) was the most frequently prescribed antibiotic formulation for infective COM, with its antimicrobial profile covering gram-positive cocci, including staphylococci, streptococci, methicillin resistant *Staphylococcus aureus* (MRSA), and other β -lactamase-producing bacteria. It was followed by cefotaxime + clavulanate (22%) and other third-generation cephalosporins in case of moderate-to-severe infection caused by resistant gram-positive bacteria and gram-negative bacilli, including *Pseudomonas aeruginosa*. Vishwanath et al. found a similar antibiotic sensitivity pattern in COM patients, with piperacillin and ceftazidime for *P. aeruginosa* and amoxicillin + clavulanic acid and cephalosporins for *S. aureus* to be the most sensitive antibiotics based on antibiotic sensitivity testing reports.¹³

Cochrane database systematic reviews on the effectiveness of topical antibiotics and antibiotics vs topical antiseptics done by Johns et al. and Head et al., respectively, have been conducted. It has been suggested that topical antibiotics alone are frequently prescribed. There is evidence to suggest that topical antibiotics might be useful either alone or with oral antibiotics.^{14,15} The present

study found that the use of both oral antibiotics and topical drugs was significantly high ($p < 0.0001$, $\chi^2 = 186.814$, df = 2) for COM patients. This indicated that treatment with topical therapy alone and a combined topical and oral antibiotics approach was preferred at our center, presumably as a result of improved patient compliance with better treatment outcomes.

This study was limited by the fact that it only considered patients seeking treatment at this center. Given that the access to medical facilities remains poor, especially among the lower sections of the society, most of the patients who would have been unable to avail of the services were excluded. Thus, it becomes somewhat difficult to get the real sociodemographic picture and treatment assessment on the ground level. Conducting a multicentric study with a much larger sample size would help overcome these shortcomings.

CONCLUSION

COM is an important preventable cause of hearing impairment and other deleterious symptoms. Evaluating the regional socioeconomic and clinical profile of these patients provides a framework for formulating locally efficient management policies. Young adults belonging to middle and poor socioeconomic strata of both genders were most commonly affected. Patients frequently present with ear discharge, hearing loss, and tinnitus. Topical antibiotic-steroid-antifungal combination along with systemic antibiotics and antihistamines forms the backbone of the treatment protocol. Therefore, antimicrobial drug selection after culture sensitivity test and rational multidrug therapy must be assured to minimize bacterial resistance, refractory disease, and its prevalence.

Compliance with Ethical Standards

All procedures contributing to this study have been conducted complying with the Helsinki Declaration of 1975 institutional guidelines.

ORCID

Swati Suneha  <https://orcid.org/0000-0003-0711-4935>

REFERENCES

1. World Health Organization. Chronic Suppurative Otitis Media—Burden of Illness and Management Options. World Health Organization; 2004. p. 9. Available from: https://www.who.int/pbd/publications/Chronic_suppurative_otitis_media.pdf.
2. Acuin J. Global burden of disease due to chronic suppurative otitis media: disease, deafness, deaths and DALYs chronic suppurative otitis media—burden of illness and management options. Geneva: World Health Organisation; 2004. p. 9–23.
3. Qureishi A, Lee Y, Belfield K, et al. Update on otitis media—prevention and treatment. *Infect Drug Resist* 2014;7:15–24. DOI: 10.2147/IDR.S39637.
4. Monasta L, Ronfani L, Marchetti F, et al. Burden of disease caused by otitis media: systematic review and global estimates. *PLoS One* 2012;7(4):e36226. DOI: 10.1371/journal.pone.0036226.

5. Global Burden of Disease Study 2013 Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;386(9995):743–800. DOI: 10.1016/S0140-6736(15)60692-4.
6. Gupta R, Mittal M. A study on clinical and epidemiological profile of chronic suppurative otitis media (CSOM) at a tertiary care center. *Int J Med Sci Public Health* 2016;5(5):1021–1024. DOI: 10.5455/ijmsph.2016.18022016360.
7. Chronic suppurative otitis media—burden of illness and management options. World Health Organization; 2004. p. 14.
8. Manche SK, Jangala M, Koralla RM, et al. Prevalence of otitis media and its hearing loss in children of South Indian population. 17th International Congress on Infectious Diseases. *Int J Infect Dis* 2016;45S:1–477. DOI: 10.1016/j.ijid.2016.02.723.
9. Chandra S, Mohan C, Rahman A. Pattern of hearing impairment in adolescent patients with otitis media. *Int J Adv Integ Med Sci* 2019;4(2):28–30.
10. Shaheen M, Raquib A, Ahmad M. Chronic suppurative otitis media and its association with socioeconomic factors among rural primary school going children of Bangladesh. *Indian J Otolaryngol Head Neck Surg* 2012;64(1):36–41. DOI: 10.1007/s12070-011-0150-9.
11. Shrestha BL, Shrestha I, Amatya RC. Comparison of clinical presentation between Chronic Otitis Media Mucosal with Squamous. *Kathmandu Univ Med J* 2010;9(32):387–391. DOI: 10.3126/kumj.v8i4.6237.
12. Mittal R, Christopher V Lisi, Gerring R, et al. Current concepts in the pathogenesis and treatment of chronic suppurative otitis media. *J Med Microbiol* 2015;64(Pt 10):1103–1116. DOI: 10.1099/jmm.0.000155.
13. Vishwanath S, Mukhopadhyay C, Prakash R, et al. Chronic suppurative otitis media: optimizing initial antibiotic therapy in a tertiary care setup. *Indian J Otolaryngol Head Neck Surg* 2012;64(3):285–289. DOI: 10.1007/s12070-011-0287-6.
14. Brennan-Jones CG, Head K, Chong LY, et al. Topical antibiotics for chronic suppurative otitis media. *Cochrane Database Syst Rev* 2018;2018(6):CD013051. DOI: 10.1002/14651858.CD01.3051.
15. Head K, Chong LY, Bhutta MF, et al. Antibiotics versus topical antiseptics for chronic suppurative otitis media. *Cochrane Database Syst Rev* 2020;1(1):CD013056. DOI: 10.1002/14651858.CD013056.pub2.