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Expert opinion on the management of respiratory tract infections in outpatient settings with a focus on amoxicillin/clavulanate and cefuroxime/clavulanic acid

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Abstract

Objective: To gather clinicians' perspectives on the management of respiratory tract infections (RTIs), particularly with amoxicillin/clavulanate and cefuroxime/clavulanic acid in outpatient (OPD) settings in India.

Methods: This cross-sectional study was conducted among clinicians across India and included 22 questions on RTI management, focusing on antibiotic prescribing patterns, preferred therapies, treatment duration, and the use of amoxicillin/clavulanate and cefuroxime/clavulanic acid. Descriptive statistics were used to analyze the data, with categorical variables presented as percentages and visualized using pie and bar charts in Excel.

Result: Out of 1,256 study participants, nearly 68% of clinicians identified RTIs as the most common infections requiring antibiotic treatment in OPD settings. Approximately 52% of participants reported that 11-20% of upper respiratory tract infection (URTI) patients had pharyngitis, and 54% indicated that 11-20% had sinusitis. Most clinicians preferred amoxicillin-clavulanate as the first-line treatment for acute bacterial rhinosinusitis, with 56% also frequently prescribing it for skin and soft tissue infections. Around 60% of the experts highlighted the broad-spectrum activity and good efficacy of amoxicillin/clavulanate. About 51% of the participants stated diagnosing pneumonia in 11-20% of patients, with 58% prescribing cefuroxime for seven days for LRTIs.

Conclusion: RTIs are the most common infections requiring antibiotic treatment in OPD settings, with amoxicillin-clavulanate being the preferred first-line therapy for acute bacterial rhinosinusitis and skin infections. Cefuroxime is commonly prescribed for lower RTIs, with most clinicians opting for a seven-day treatment duration.

Keywords: Respiratory tract infections, antibiotic treatment, amoxicillin-clavulanate, pharyngitis, sinusitis, cefuroxime

Introduction

Respiratory tract infections (RTIs) pose a significant global health challenge due to their high morbidity and mortality. According to the 2016 Global Burden of Disease estimate, RTIs accounted for approximately 336.5 million infections and 2.4 million deaths ^[1, 2]. By 2019, the global incidence of upper respiratory tract infection (URTI) had reached 17.2 billion, comprising 42.83% of all infection cases ^[3]. In India, the National Health Portal reported 41,996,260 cases and 3,740 deaths from respiratory infections in 2018, with severe acute respiratory infections (SARI) remaining a leading cause of mortality among children under five years ^[4]. As India accounts for 18% of the global population, the burden of RTIs, especially URIs, is significant.

Effective antibiotic management is crucial in addressing this burden. Amoxicillin, a widely used antibiotic, acts by competitively inhibiting penicillin-binding proteins (PBPs) involved in bacterial cell wall synthesis, resulting in bacterial cell lysis. Its combination with clavulanic acid enhances efficacy by irreversibly binding to beta-lactamases, preventing antibiotic deactivation. This combination is particularly effective in managing complicated RTIs, otitis media, sinusitis, and urinary tract infections (UTI) ^[5-7].

Amoxicillin/clavulanate has been a cornerstone in RTI treatment for over two decades, offering broad-spectrum antibacterial activity with a favorable

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pharmacokinetic/pharmacodynamic (PK/PD) profile. It is especially effective against beta-lactamase-producing pathogens [8]. Cefuroxime, a newer parenteral beta-lactam antibiotic, offers an even broader spectrum of activity, particularly for lower RTIs, and is typically administered in a dosage of 750 mg every 8 hours. Cefuroxime acts by binding to PBPs, inhibiting bacterial cell wall synthesis, and promoting bacterial cell lysis, with potential interference with autolysin inhibitors [9, 10]. This study aims to gather expert opinion on the management of RTIs in outpatient OPD settings in India, focusing on the prescription pattern and clinical use of amoxicillin/clavulanate and cefuroxime/clavulanic acid.

Methodology

This cross-sectional study was conducted among clinicians specialized in managing RTIs in Indian settings from June 2024 to December 2024. The study was performed after obtaining approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India. An invitation was sent to clinical experts across India based on their expertise and experience in treating RTIs in the month of March 2024 for participation in this survey. About 1256 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. Clinicians had the discretion to skip questions they did not wish to answer. Written informed consent was obtained from all participants, who were required to independently complete the questionnaire without consulting peers. Unanswered questions were treated as non-attempts. The questionnaire booklet titled SMART (Experts' Opinion on the Management of Routine Infections in Clinical Practice) study was sent to the doctors who were interested in participating in this study. The study questionnaire comprised 22 questions designed to gather feedback, clinical insights, and experiences related to RTI management, with a focus on antibiotic prescriptions, preferred therapies, treatment duration, and the use of amoxicillin/clavulanate and cefuroxime/clavulanic acid.

Statistical analysis: Descriptive statistics were performed to analyze the data, with categorical variables expressed as percentages to show their distribution. The frequency and percentage of each variable were calculated, and pie and bar charts were created using Microsoft Excel 2013 (version 16.0.13901.20400) to visually represent the results.

Results

Out of 1,256 survey participants, more than half (67.67%) reported that RTIs are the most common infections in adults requiring antibiotic treatment in OPD clinical practice (Table 1). The majority (75%) of the clinicians identified bacterial infection as the most common etiology of URTIs. Around 38% of experts recognized pharyngitis as the most common presenting URTI in clinical practice. Approximately 52% of participants indicated that 11-20% of patients presenting with URTI have pharyngitis (Table 2).

Table 1: Distribution of responses to the most common infections in adults requiring antibiotic treatment in OPD clinical practice

Most common infection	Response rate (n=1256)
Respiratory tract infections	68%
Skin and soft tissue infections	18%
Urinary tract infections	9%
Dental infections	3%

Table 2: Distribution of responses regarding the proportion of patients with URTI and pharyngitis

Proportion of patients with URTI and pharyngitis	Response rate (n=1256)
<10	15%
11-20	52%
21-30	29%
Not answered	4%

More than half of the experts (54%) reported that 11-20% of patients presenting with URTI have sinusitis (Fig. 1). The majority (84%) of participants preferred amoxicillin-clavulanate as the first-line antibiotic therapy for acute bacterial rhinosinusitis (Fig. 2). About 56% reported that amoxicillin-clavulanate is frequently prescribed for skin and soft tissue infections (Table 3).

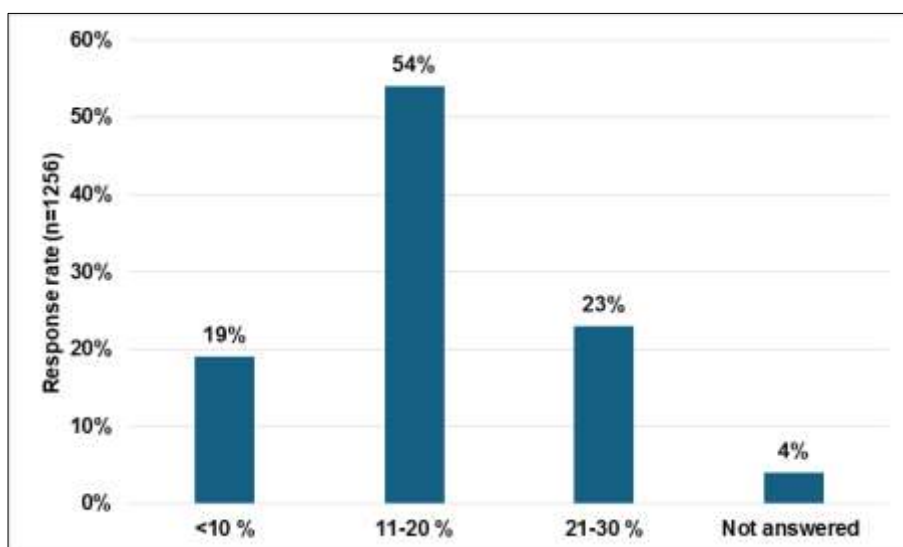


Fig 1: Distribution of responses regarding the proportion of patients with URTI and sinusitis

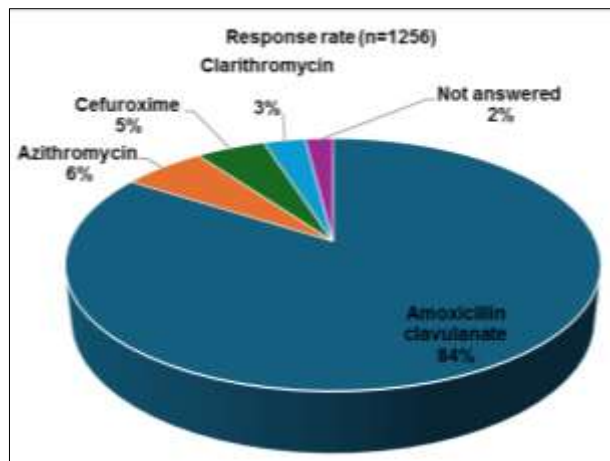


Fig 2: Distribution of responses to preferred first-line antibiotic therapy for acute bacterial rhinosinusitis in adults

Table 3: Distribution of responses to the duration of amoxicillin prescription for skin and soft tissue infections

Frequency	Response rate (n=1256)
Frequently	56%
Occasionally	30%
Rarely	9%
Never	2%
Not answered	3%

Approximately 39% of clinicians stated that co-amoxiclav is prescribed based on the nature of the infection. Around 40% reported that RTIs are the most common bacterial infections treated with amoxicillin 500 mg + clavulanic acid 125 mg tablets. About 60% of survey participants highlighted the advantages of amoxicillin-clavulanic acid, including broad-spectrum activity, good bacteriological and clinical efficacy, and a favorable tolerability profile (Table 4).

Table 4: Distribution of responses to the advantages of amoxicillin + clavulanic acid

Advantages	Response rate (n=1256)
Favorable tolerability profile	6%
Broad-spectrum activity	21%
Good bacteriological and clinical efficacy	11%
All of the above	60%
Not answered	1%

According to 37% of participants, antibiotic resistance is the reason for switching a patient from co-amoxiclav to a different antibiotic. About 37% stated that acute bronchitis is the most common lower RTI seen in clinical practice. Half (50.95%) of the participants reported that 11-20% of their patients are diagnosed with pneumonia (Fig. 3).

Around 35% of experts indicated that the 40–60-year age group is most commonly affected by pneumonia. About 38% of experts reported that cefuroxime + clavulanic acid is preferred for 26-50% of their patients. Approximately 58% of clinicians stated 7 days was the recommended average duration of cefuroxime prescription for lower RTIs (Fig. 4).

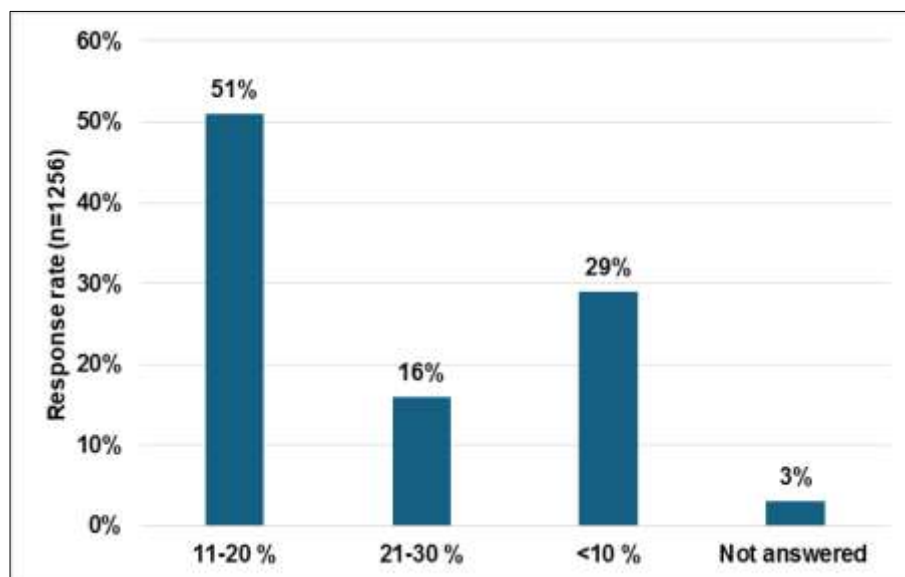


Fig 3: Distribution of responses to the proportion of patients diagnosed with pneumonia in clinical practice

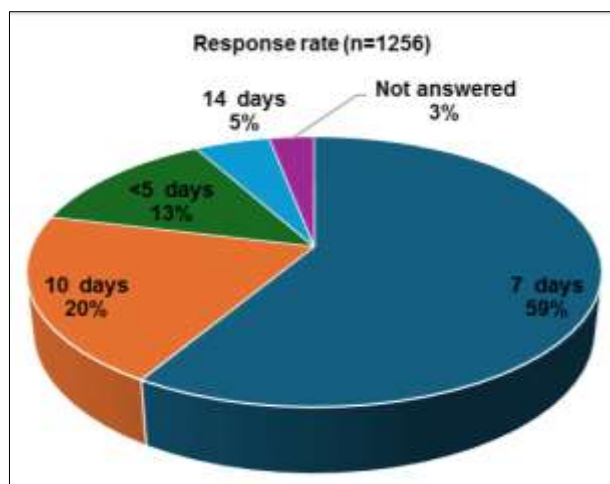


Fig 4: Distribution of responses to the average duration of cefuroxime prescription for lower RTIs

According to 39% of participants, 11-20% of patients with suspected methicillin-resistant *Staphylococcus aureus* infections visit routine practice. Additionally, 37% reported that 11-25% of UTI patients were prescribed cefuroxime + clavulanic acid. About 37% of clinicians stated that 11-20% of patients suspected of having pseudomonal infections are prescribed cefuroxime + clavulanic acid as the initial therapy. Around 26% of participants preferred prescribing cefuroxime + clavulanic acid for UTI cases. About 38% of respondents noted that patients discontinue or stop antibiotic treatment before completing the prescribed course due to a lack of counseling. Nearly 42% of participants indicated that culture sensitivity tests are occasionally used in clinical practice before prescribing antibiotics.

Discussion

The present survey findings underscore the importance of evidence-based antibiotic selection, resistance surveillance, and enhanced antibiotic stewardship for effective RTI management. Over half of the respondents identified RTIs as the most common infections in adults requiring antibiotics in OPD settings. Harris *et al.* reported that acute RTIs, including bronchitis, pharyngitis, rhinosinusitis, and the common cold, are major drivers of OPD visits and antibiotic prescriptions in adults [11]. Similarly, Havers *et al.* highlighted that, despite the widespread use of antibiotics for ARIs, over-prescription remains a concern, even among patients with confirmed viral infections. Improved antibiotic stewardship efforts aim to reduce unnecessary antibiotic use for viral upper respiratory infections and promote adherence to treatment guidelines for bacterial conditions like pharyngitis and sinusitis [12].

Many participants reported that 11-20% of patients with URTIs are diagnosed with pharyngitis. Guibas and Papadopoulos noted that RTIs commonly affect the upper respiratory tract, often presenting with rhinitis and pharyngitis, sometimes accompanied by conjunctival and ear complications. In infants, URTIs are frequently linked to fever, resulting in lethargy and poor feeding [13]. Additionally, Thomas and Bomar found that bacterial infections account for approximately 15% of cases of sudden-onset pharyngitis [14]. More than half of the current clinicians reported that 11-20% of patients presenting with URTI are diagnosed with sinusitis. According to Marom *et al.*, acute bacterial sinusitis is a frequent complication of

viral URTI [15]. Additionally, Graham Worrall found that approximately 0.5% of all URTIs are complicated by sinusitis [16].

The majority of survey participants favored amoxicillin-clavulanate as the first-line antibiotic therapy for acute bacterial rhinosinusitis. The 2015 updated guidelines from the American Academy of Otolaryngology recommend amoxicillin with or without clavulanate as the first-line treatment for most adults, typically for a duration of 5 to 10 days [17]. Additionally, the Infectious Diseases Society of America (IDSA) also recommends amoxicillin-clavulanate as the preferred first-line therapy for acute bacterial rhinosinusitis, emphasizing its enhanced efficacy against beta-lactamase-producing pathogens [18]. Similarly, Seggev *et al.* found that administering amoxicillin and clavulanate every 12 hours is equally effective and safe as giving it every 8 hours for treating acute bacterial maxillary sinusitis [19].

Many of the participants reported frequently prescribing amoxicillin-clavulanate for skin and soft tissue infections. According to Fleisher *et al.*, this combination effectively treats impetigo and cellulitis, with all children in their study responding positively to therapy, and 86% achieving a cure [20]. Similarly, Kar *et al.* highlighted that amoxicillin-clavulanate provides good coverage against *Staphylococcus aureus* and *Streptococcus* species, making it suitable for managing mild skin and soft tissue infections in children or as an oral step-down therapy following intravenous antibiotics in moderate to severe cases [21].

Most of the respondents highlighted the broad-spectrum activity, excellent bacteriological and clinical efficacy, and favorable tolerability profile of amoxicillin-clavulanate as key advantages. Bucher *et al.* reported that amoxicillin-clavulanate exhibits strong activity against *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*, which are the most common bacteria responsible for upper RTIs and acute bacterial rhinosinusitis [22]. Additionally, Beeuwkes and Rutgers found good clinical success in 17 patients, with notable improvement in eight others. They noted that while 20 out of 22 *Haemophilus influenzae* strains were resistant to amoxicillin, they remained sensitive to the amoxicillin/clavulanic acid combination, highlighting its effectiveness in treating amoxicillin-resistant respiratory infections [23].

Nearly half of the clinicians surveyed indicated that 11-20% of patients with upper RTIs in clinical practice are diagnosed with pneumonia. Thomas and Bomar reported that while URTIs are typically mild and occur most often during the winter season, they can significantly impact quality of life for several weeks. In some cases, complications such as pneumonia, meningitis, sepsis, and bronchitis may develop [14]. Garibaldi highlighted that URTIs are the most prevalent infectious diseases among adults. In younger adults, atypical pneumonia, primarily caused by *Mycoplasma pneumoniae*, is the most commonly observed clinical presentation [24].

Many participants reported 7 days as the typical duration for prescribing cefuroxime for lower RTIs. Omole *et al.* recommended a dosage of 125 to 250 mg orally every 12 hours for 7 to 10 days [25]. Similarly, Sécurité and Santé reported that while treatment duration is generally 7–10 days (Grade C), cefuroxime-axetil and cefpodoxime-proxetil have demonstrated effectiveness in as few as 5 days. In a previous study by the current authors, nearly 67% of

clinicians prescribed cefuroxime for 6 to 10 days for lower RTIs, while approximately 26% prescribed it for less than 5 days ^[26].

The study's strengths include its broad participant base, comprising experts managing RTIs across Indian clinical settings, ensuring diverse insights. The structured 22-question format effectively captured data on antibiotic prescribing practices, treatment preferences, and clinical management trends. However, limitations include the self-reported nature of responses, which introduces the possibility of recall bias. As the survey relied on clinician opinions rather than direct patient data, findings may not fully align with real-world clinical outcomes. Furthermore, its findings may not be universally applicable due to regional variations in prescribing practices and healthcare systems.

Conclusion

The study highlights that RTIs are the most common infections requiring antibiotic treatment in OPD settings, with amoxicillin-clavulanate being the preferred first-line therapy for conditions such as acute bacterial rhinosinusitis and skin infections. A significant number of participants reported that bacterial infections are the primary cause of URTIs, with pharyngitis and sinusitis being common presentations. Cefuroxime-clavulanic acid is frequently prescribed for lower RTIs, particularly pneumonia and bronchitis. Additionally, broad-spectrum activity, clinical efficacy, and tolerability are key reasons for choosing amoxicillin-clavulanate.

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