

Original Research Article

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Expert Opinion on the Use of Oral Antibiotics with A Special Focus on Amoxicillin-Clavulanate and Cefuroxime for the Management of Respiratory Tract Infections and Otitis Media in Indian Settings

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Respiratory tract infections (RTIs) are a major public health concern due to their high morbidity and mortality rates, and widespread distribution. Studies regarding the expert opinion on current practices, clinical observations, and experiences related to the use of oral antibiotics primarily, amoxicillin-clavulanate and cefuroxime for managing respiratory tract infections (RTIs) and otitis media in Indian settings were scarce. So, a cross-sectional, questionnaire based study was conducted to collect opinion among physicians involved in treating RTIs and otitis media across India between June 2022 and December 2022. It was observed that managing upper respiratory tract infections (URTI), majority of the experts (94.1%) preferred amoxicillin + clavulanic acid over other oral antibiotics, such as cefpodoxime, cefixime, azithromycin, cefuroxime, and cefuroxime + clavulanic acid. Furthermore, 91% of the experts opined that amoxicillin with clavulanic acid was better for URTI than other antibiotics and 88% of the respondents preferred to prescribe amoxicillin with clavulanic acid in managing acute otitis media. Additionally, majority of the clinicians (81%) reported that cefuroxime was the most commonly used oral antibiotic for managing lower respiratory tract infections (LRTIs). Nearly 62% of clinicians opined that cefuroxime has better tissue penetration compared to other broad-spectrum antibiotics. Thus, it was found that experts recommended a combination of amoxicillin with clavulanic acid and cefuroxime for the treatment of RTIs. Amoxicillin with clavulanic acid was the preferred choice for managing URTIs and acute otitis media in children, while cefuroxime was favored for lower LRTIs due to its superior tissue penetration and broad-spectrum antibiotic properties.

Introduction

Respiratory tract infections (RTIs) are a major public health concern due to their high morbidity and mortality rates, and widespread distribution (Calderaro *et al.*,

2022). RTIs are the most fatal infectious diseases, and they are the fourth major cause of death across the world. In 2019, approximately 26 lakh patients succumbed to RTIs globally. Over 567 million confirmed cases and over 6.3 million deaths have been reported globally

during the COVID-19 pandemic (Huang and Guo, 2022). India accounts for 18% of the global population with severe acute respiratory infection (SARI), which are the prominent causes of mortality in children >5 years of age (Waghmode *et al.*, 2021). Lower respiratory tract infections (LRTI) are the third leading cause of death worldwide, following cardiovascular and cerebrovascular diseases (Avendano *et al.*, 2020). However, in low-income countries, they are the prominent cause of death. In 2019, the global incidence of upper respiratory tract infections (URTI) had reached 17.2 billion, accounting for 42.83% of all cases (Xuting *et al.*, 2023).

Otitis media is a major secondary complication of URTI with significant prevalence among young children. The global incidence of acute otitis media is highest in children of 1-4 years of age, with 61 new cases per 100 children per year. According to World Health Organization (WHO) reports, otitis media is the primary cause of hearing impairment in 42 million subjects (above 3 years) globally (Santoshi *et al.*, 2016).

Nearly 80% of all antibiotics were prescribed in outpatient healthcare settings. Out of these, 50% to 70% of antibiotics prescribed in primary healthcare are used to treat RTIs (Pietrzykowska *et al.*, 2021). Amoxicillin with clavulanic acid combination is the preferred treatment for patients diagnosed with upper and lower RTIs. However, ceftriaxone is the primary choice for patients allergic to penicillin (Gessner *et al.*, 2023 and Tiwari *et al.*, 2014). The clinical success rates for amoxicillin and clavulanic acid in treating RTIs remain at 90% (White *et al.*, 2004).

Hence, it is the preferred combination for the management of URTI in pediatric outpatients (Joseph *et al.*, 2016). For the treatment of LRTI, amoxicillin and clavulanic acid at dosage 875/125 mg every 12 hours was as safe and effective as the 500/125 mg dosage given every 8 hours, and both exhibit good oral bioavailability (Calver *et al.*, 1997 and Veeraraghavan *et al.*, 2021).

Amoxicillin with clavulanic acid was also widely used and effective broad-spectrum antibiotic treatment for acute otitis media in children (Easton *et al.*, 2003). A US-based study that analyzed 165 pediatric patients treated with amoxicillin and potassium clavulanate found to be well-tolerated and effective (Chu *et al.*, 2014).

Cefuroxime is an effective antibiotic against many of the common bacterial pathogens responsible for RTIs. It is the first oral broad-spectrum cephalosporin that remains

naturally stable even in the presence of beta-lactamases. Moreover, it has been reported to be effective against *Moraxella catarrhalis*, a common respiratory tract pathogen that causes acute otitis media and sinusitis in children. Cefuroxime is the preferred treatment for RTIs in India settings because of its enhanced safety, efficacy, and pharmacokinetic properties. It was well-tolerated by diverse patient populations, including the elderly, children, pregnant women, and those with cardiac disease or diabetes (Badhwar *et al.*, 2016). However, studies regarding the expert opinion on current practices, clinical observations, and experiences related to the use of oral antibiotics in routine settings were scarce. So, the present cross-sectional survey aims to gather expert opinion on the prescription practice of antibiotics, especially amoxicillin-clavulanate and cefuroxime, for the management of respiratory tract infections in Indian settings.

Materials and Methods

We carried out a cross sectional, questionnaire based survey among clinicians specialized in managing RTIs and otitis media in the major Indian cities from June 2022 to December 2022.

Questionnaire

The questionnaire booklet titled ACE (Amoxicillin clavulanate and Cefuroxime axetil for managing infections in routine clinical practice) study was sent to the physicians who were interested to participate. The ACE study questionnaire included questions on the current practices, clinical observations, and experiences related to the use of oral antibiotics in routine settings, particularly amoxicillin-clavulanic acid and cefuroxime, for the management of RTIs and otitis media. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee which is recognized by the Indian Regulatory Authority, Drug Controller General of India.

Participants

An invitation was sent to leading doctors in managing RTIs and otitis media in the month of March 2022 for participation in this Indian survey. 1289 doctors from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. Physicians were asked to complete the questionnaire without discussing

with peers. A written informed consent was obtained from each physician prior initiation of the study.

Statistical Analysis

Descriptive statistics were used to summarize the characteristics of the study by employing frequencies and percentages. Graphical representation of data was done by using Microsoft Excel and Word, which was also used to obtain various types of graphs like bar diagram and column.

Results and Discussion

This study included 1,289 clinicians, with 34% of them reporting pharyngitis as the most common form of URTI in routine practice, followed by 26.5% on otitis media, 20% on sinusitis and 14% of them on tonsillitis. Approximately 67% of clinicians highlighted bacterial infections as the common cause of URTI, while 31% attributed it to viral causes and 33% of them reported both.

Nearly 46% of respondents noted the common occurrence of URTI in middle socioeconomic status patients whereas 24% each of them observed in upper and lower middle socioeconomic status patients. According to 78% of clinicians, URTI was prevalent in approximately 21 to 70% of adult patients and only 17.4% of them noted in less than 20% of patients.

Majority of the experts (94.1%) recommended amoxicillin + clavulanic acid over other antibiotics such as cefpodoxime, cefixime, azithromycin, cefuroxime, and cefuroxime + clavulanic acid for managing URTI infections (Table 1).

More than half of the clinicians (53.37%) preferred amoxicillin + clavulanic acid in 51 to 75% of the patients with URTI in clinical practice where 25.3% of them recommended in up to 50% and 20% of them prescribed among more than 70%. As indicated by 36% of respondents, the advantages of amoxicillin and clavulanic acid include broad-spectrum activity, favorable pharmacokinetic profile, and good bacteriological and clinical efficacy while more than 25% each recommend only for its spectrum of activity and good antimicrobial efficacy.

Majority of the experts (91%) reported that amoxicillin with clavulanic acid has the best clinical cure rates for

managing URTI over other antibiotics (Figure 1). About 38% of clinicians reported the incidence of acute otitis media in pediatric patients as 21 to 50%, followed by nearly 30% of them as 0 to 20% and 26% of them as 51 to 70%.

Almost 68% of clinicians reported the common occurrence of acute otitis media in both urban and rural pediatric subjects and 20% of them highlighted in rural children along with only 12% pointed in urban children. Around 47% of experts noted its increased prevalence in middle socioeconomic status population whereas nearly 25% and 20% recorded in lower and upper socioeconomic status people. Approximately 88% of respondents preferred prescribing amoxicillin with clavulanic acid to manage acute otitis media (Figure 2).

About 40% of the clinicians favored using amoxicillin + clavulanic acid in 51 to 75% of the children with acute otitis media (Figure 3). Approximately 43% of the experts stated that 61 to 90% of the patients were compliant to the prescribed antibiotic course and 35.3% of them reported that 31 to 60%, followed by nearly 17% on more than 90% of adherence.

Approximately 33% of respondents noted that individuals aged 31 to 45 years were commonly affected by LRTIs, in line with 27.7% of them on age less than 18 and approximately 23% on people aged 19 to 30. About 47% reported that 26-50% of patients present with LRTIs in routine practice, then nearly 31% of them on 51 to 75% and finally 16.3% of physicians on less than 25%. According to 71% of participants, LRTIs were common in both urban and rural population and nearly 20% of the clinicians opined on rural population. Acute bronchitis and pneumonia are the most common LRTIs, as noted by 42% and 31% of clinicians, respectively where only 22.2% of them opined on chronic obstructive pulmonary disease (COPD) acute exacerbations.

Majority of the clinicians (81%) reported cefuroxime as the most commonly used oral antibiotic for managing LRTIs (Table 2). The average duration of prescribing cefuroxime for LRTIs was 6 to 10 days, as reported by nearly 67% of experts, since less than 5 days were followed by approximately 26% of clinicians.

Nearly 62% of clinicians opined that cefuroxime has better tissue penetration among broad-spectrum antibiotics followed by 25% of them highlighted its favorable pharmacokinetic profile and only 10% of them reported both. Approximately 58% of participants

preferred a treatment course of 6 to 10 days for cefuroxime, while 34% favored a 5-day prescription and nearly 6% of clinicians prescribed for more than 10 days. Approximately 61% of participants reported a clinical success rate of 92 to 97% with cefuroxime in managing LRTIs followed by 10% of them pointed more than 97% whereas only 29% of them reported less than 90% success rate.

This study finding provide valuable insights into the antibiotic choices made by clinicians when treating RTIs. It highlighted the potential benefits of prescribing amoxicillin plus clavulanic acid combination and cefuroxime for effectively managing the symptoms of RTIs and otitis media in Indian population.

As per the current survey, amoxicillin with clavulanic acid is the most frequently prescribed medication for URTIs in clinical practice. This result was consistent with the study conducted by [Baillie et al., \(2022\)](#) which also found that the combination of amoxicillin and clavulanic acid was the most commonly prescribed antibiotic for treating URTIs. URTIs were the most prevalent infections in the pediatric population and [Tiwari et al., \(2014\)](#) reported that the combination of amoxicillin and clavulanic acid was the most commonly prescribed antibiotic for children >5 years of age with URTIs. Similarly, [Malo et al., \(2015\)](#) reported that 70% of all prescriptions for treating RTIs in children involved amoxicillin with clavulanic acid. [Das et al., \(2006\)](#) and [Hotwani et al., \(2023\)](#) noted that amoxicillin with clavulanic acid was the commonly used antibiotic for treating URTIs in pediatric subjects. [Zulqarnain et al., \(2021\)](#) found that the combination was prescribed commonly for patients with URTIs, including pharyngitis, sinusitis, and otitis media.

Most of the respondents stated that the combination of amoxicillin with clavulanic acid has the best clinical rates for treating URTIs. Consistent with the present survey, [Mishra et al., \(2022\)](#) reported that the combination of amoxicillin and clavulanic acid was the preferred treatment (52.6%) for effectively managing URTIs in children. A randomized trial by [Ferreira et al., \(2006\)](#) observed that the cure rates were significantly higher (61.7% to 93.2%) with the use of amoxicillin and clavulanic acid in treating URTIs. Similarly, a retrospective cohort study by [Chu et al., \(2014\)](#) noted that high-dose amoxicillin with clavulanic acid was recommended in clinical practice for treating acute otitis media, as opposed to conventional doses in children.

According to this study, the clinicians preferred the combination of amoxicillin plus clavulanic acid in treating acute otitis media, especially in children. In line with these findings, [Casey et al., \(2012\)](#) found that amoxicillin-clavulanic acid (80 mg/kg per day for 10 days) was more effective than cefdinir (14 mg/kg per day for 5 days) in treating acute otitis media in 330 children aged 6 to 24 months.

The amoxicillin-clavulanic acid group demonstrated a significantly higher cure rate (86.5%), when compared to cefdinir group (71%, P=0.001) ([Sakulchit et al., 2017](#)). [Hoberman et al., \(2011\)](#) evaluated the effectiveness of amoxicillin with clavulanic acid as a treatment for acute otitis media in children. The study found that approximately 35% experienced initial resolution of symptoms by day 2, 61% by day 4, and 80% by day 7.

Similarly, a retrospective cohort study by [Chu et al., \(2014\)](#) noted that high-dose amoxicillin with clavulanic acid was recommended in clinical practice for treating acute otitis media, as opposed to conventional doses in children.

Majority of the current respondents preferred cefuroxime among the commonly prescribed oral antibiotics for treating LRTIs due to its superior tissue penetration and a treatment course of 6-8 days. Likewise, [Bax et al., \(1979\)](#) concluded that administering 750 mg of cefuroxime every 8 hours was effective in treating LRTIs and may offer advantages over other antibiotics.

Similarly, in a clinical study involving 23 in-patients, [Samanta et al., \(1980\)](#) observed that cefuroxime sodium appears to be an effective and well-tolerated drug for treating patients with severe LRTIs. [Adam et al., \(2000\)](#) noted that short-course (5-day) cefuroxime axetil was as effective as the standard 10-day oral penicillin V regimen for the management of tonsillopharyngitis.

The current survey provides valuable insights for clinicians and policymakers in optimizing antibiotic treatments for respiratory infections. Understanding these trends was crucial for promoting evidence-based and effective antibiotic prescribing practices. One of the major strengths of the current survey was the utilization of a meticulously crafted and validated questionnaire for data collection among clinicians. However, it was important to acknowledge certain limitations of the survey.

Table.1 Distribution of response on common antibiotics prescribed for URTIs in routine clinical practice

Antibiotics	Response (n = 1289)
Amoxicillin + clavulanic acid	94.10%
Cefpodoxime	3.72%
Cefixime	0.47%
Azithromycin	0.23%
Cefuroxime	0.54%
Cefuroxime+ clavulanic acid	0.08%
Not attempted	0.62%

Table.2 Distribution of responses on the preference of the most common oral antibiotics for managing LRTIs in clinical practice

Oral antibiotics	Response rate (n = 1289)
Cefuroxime	80.68%
Ceftriaxone	8.92%
Cefotaxime	2.64%
Amoxicillin + clavulanic acid	2.72%
Cefixime	0.47%
Cefpodoxime	0.47%
Cephalexin	0.08%
Clarithromycin	0.31%
Co-amoxiclav	1.32%
Moxifloxacin with cefixime	0.08%
Not attempted	1.55%

Figure.1 Distribution of responses among antibiotics providing the best clinical cure rates for treating URTIs

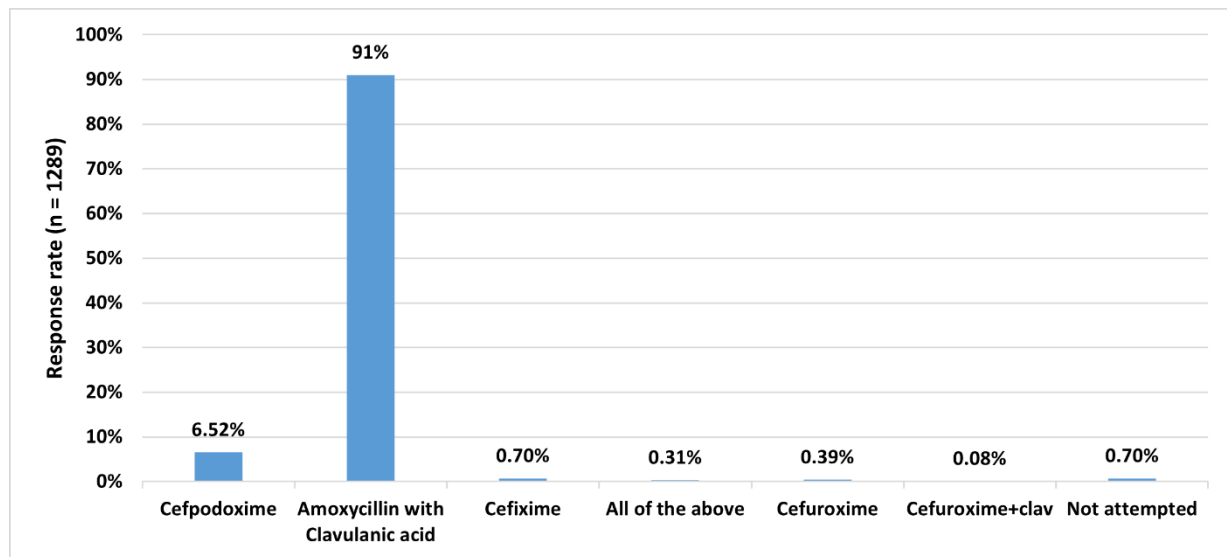


Figure.2 Distribution of responses on the preferred antibiotics for managing acute otitis media in clinical practice

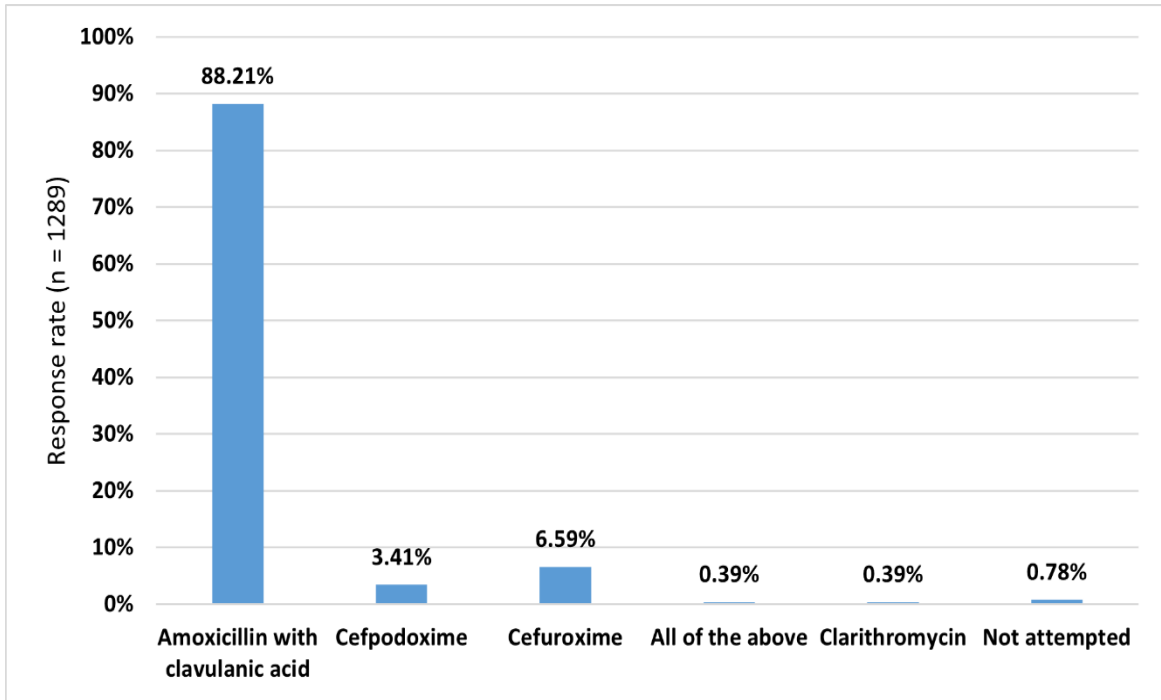
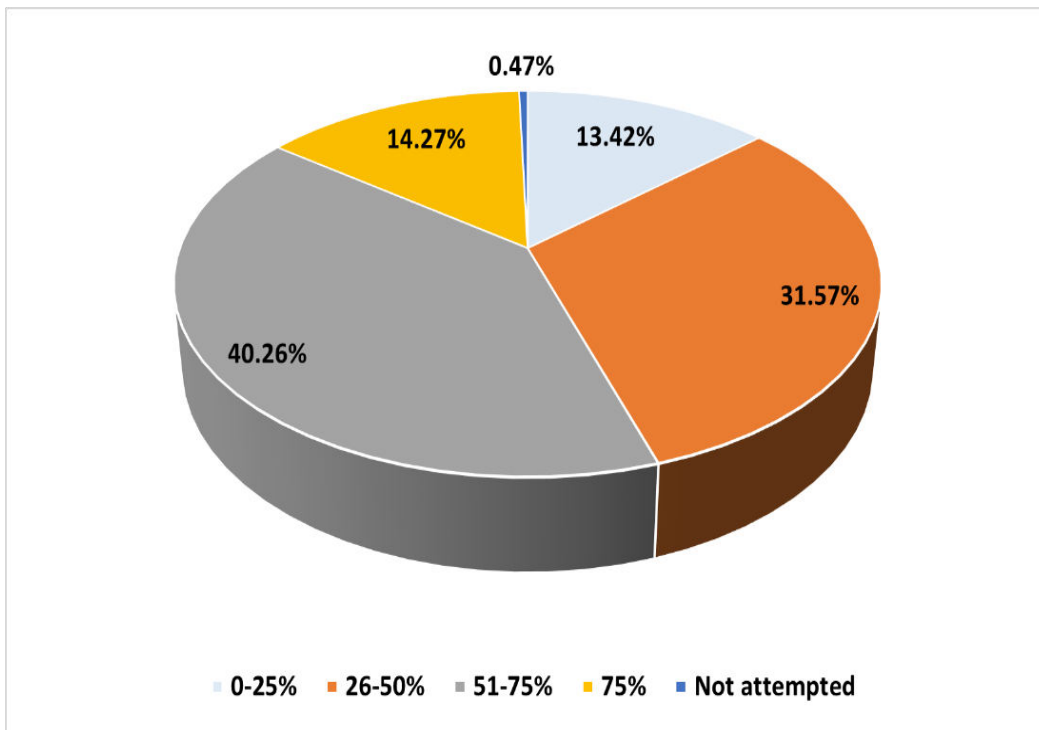


Figure.3 Distribution of responses on the preference of amoxicillin + clavulanic acid in children with acute otitis media



The reliance on expert judgment introduces the possibility of bias, as divergent perspectives and preferences may have impacted the reported results. It was essential to consider these limitations when interpreting the findings and to conduct further research to validate and expand upon the conclusions.

In the treatment of RTIs, experts endorsed a combination of amoxicillin and clavulanic acid as well as cefuroxime. The majority of specialists opted for amoxicillin with clavulanic acid when managing URTIs and acute otitis media in children, while cefuroxime was the preferred option for lower LRTIs due to its superior tissue penetration and broad-spectrum antibiotic properties.

Reporting Standards Statement

The authors pledge adherence to recognized reporting standards (STROBE for observational studies).

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Author Contribution

Dr. Manjula S, contributed Conceived the original idea and designed the model and wrote the manuscript. Dr Krishna Kumar M, designed the model and the computational framework and analysed the data.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

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Consent to Participate: Not applicable.

Consent to Publish: Not applicable.

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