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Original Research Article

Prescribing patterns and clinical perceptions of high-dose co-amoxiclav in upper respiratory tract infections: a nationwide study among otorhinolaryngologists

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ABSTRACT

Background: Upper respiratory tract infections (URTIs) are a leading cause of outpatient visits and antibiotic use across age groups. Amoxicillin–clavulanate (co amoxiclav) is widely prescribed due to its activity against β lactamase–producing pathogens. High dose formulations (1 g) aim to enhance pharmacodynamic target attainment and clinical efficacy, particularly against less susceptible organisms. However, real world data on otorhinolaryngologists' prescribing practices and perceptions of high dose co amoxiclav are limited.
Methods: A descriptive, questionnaire-based survey was conducted among otorhinolaryngologists attending the Annual National Conference of the Association of Otolaryngologists of India. A structured 10 item electronic questionnaire captured prescribing patterns, clinical indications, decision drivers, perceived effectiveness, safety, and patient compliance. Data was analysed using descriptive statistics.
Results: A total of 176 otorhinolaryngologists participated. Acute otitis media was the most common indication (52%), followed by acute tonsillitis (25%), sinusitis (16%), and pharyngitis (7%). Overall, 70% of respondents prescribed high dose (1g) co amoxiclav sometimes or often, with 59% using it as first line therapy. Clinical efficacy (52%) and once daily dosing convenience (21%) were the main drivers of use. Prescribing decisions were guided by clinical guidelines in 45% of cases. Satisfaction with outcomes was high (93%). Diarrhoea (66%) and nausea (21%) were the most frequently reported adverse effects. Dosing frequency was considered the key determinant of patient compliance (56%). High dose (1g) co amoxiclav was perceived as more effective than other antibiotics by 77% and safer by 87% of respondents.
Conclusion: High dose co amoxiclav (1 g) is widely accepted by otorhinolaryngologists for URTIs, supported by perceived efficacy, convenient dosing, favourable safety, and alignment with antimicrobial stewardship principles.

Keywords: High dose co amoxiclav, URTIs, ENT surgeons, Prescribing patterns, Antimicrobial stewardship

INTRODUCTION

URTIs are among the most common reasons for outpatient consultations and antibiotic prescriptions worldwide. Although a large proportion of URTIs are viral and self-limiting, antibiotics continue to be widely prescribed in both adult and paediatric practice, contributing substantially to inappropriate antibiotic use and antimicrobial resistance (AMR).[1,2] The National Institute for Health and Clinical Excellence (NICE) emphasizes judicious antibiotic prescribing for respiratory tract infections, recommending antibiotics only in selected clinical situations where bacterial infection is likely or complications are anticipated.[1] Despite such guidance, real-world prescribing patterns remain heterogeneous and are often influenced by physician experience, patient expectations, and perceived disease severity. Amoxicillin–clavulanate (co-amoxiclav)

is one of the most commonly prescribed oral antibiotics for community-acquired respiratory tract infections because of its extended antimicrobial spectrum and activity against β-lactamase–producing organisms.[3] The addition of clavulanic acid, a β-lactamase inhibitor, restores the activity of amoxicillin against resistant pathogens such as Haemophilus influenzae and Moraxella catarrhalis, which are frequently implicated in URTIs and acute otitis media.[3,4]

Over the years, the formulation of co-amoxiclav has evolved to optimize efficacy while maintaining an acceptable safety profile. Early combinations used lower ratios of amoxicillin to clavulanate, but higher-ratio formulations were later introduced to enhance amoxicillin exposure while minimizing clavulanate-related gastrointestinal adverse effects.[4]This evolution was driven by pharmacokinetic–pharmacodynamic (PK–PD) principles demonstrating that the antibacterial efficacy of β-lactam antibiotics is closely linked to the duration for which drug concentrations remain above the minimum inhibitory concentration (T>MIC).[5,6] Increasing the amoxicillin dose improves T>MIC, thereby enhancing bacterial killing, particularly against less susceptible strains of *Streptococcus pneumoniae* and other respiratory pathogens.[5]

High-dose formulations of co-amoxiclav, including the 1g tablet, were therefore developed to provide higher systemic exposure to amoxicillin without proportionally increasing clavulanate content. This strategy offers the potential for improved clinical efficacy while maintaining tolerability.[4,7] Clinical and pharmacological evidence supports the role of high-dose co-amoxiclav in the management of respiratory tract infections, especially in settings with increasing antimicrobial resistance or higher bacterial burden.[4,7] Despite the strong pharmacological rationale and clinical evidence supporting high-dose co-amoxiclav, its real-world utilization is shaped by health care professionals' perceptions of efficacy, safety, resistance risk, dosing convenience, and patient compliance. In daily clinical practice, prescribing decisions often reflect a balance between guideline recommendations, individual clinical experience, and pragmatic considerations such as adherence and tolerability.[1,2]

Otorhinolaryngologists play a pivotal role in the management of URTIs, particularly conditions such as acute otitis media, acute bacterial sinusitis, and tonsillopharyngitis, where antibiotic therapy is frequently considered. Their prescribing behaviour therefore has a significant impact on antimicrobial utilization patterns and stewardship efforts. However, there is limited published real-world data specifically evaluating Otorhinolaryngologists' perspectives on the use of high-dose co-amoxiclav (1g) in routine clinical practice. Understanding these perspectives is essential for identifying alignment or gaps between clinical practice and guideline recommendations, supporting rational antibiotic selection, strengthening antimicrobial stewardship strategies, optimizing patient outcomes while minimizing unnecessary antibiotic exposure. Therefore, this study was conducted to systematically assess the prescribing patterns, clinical decision drivers, and perceptions of otorhinolaryngologists regarding the use of high-dose co-amoxiclav (1g) in paediatric and adult patients with upper respiratory tract infections.

METHODS

Study design

This was a descriptive, cross-sectional, questionnaire-based study conducted to assess the perspectives and opinions of practicing otorhinolaryngologists regarding the utilization of high-dose co-amoxiclav (1g) in paediatric and adult patients suffering from upper URTIs.

Study setting

The study was conducted among practicing otorhinolaryngologists who attended the Annual National Conference of the Association of Otolaryngologists of India (AOICON 2026). Participants represented diverse real-world clinical settings nationwide, including private clinics, multispecialty hospitals, and tertiary care institutions from different geographical regions of India.

Study population

The study population consisted exclusively of qualified otorhinolaryngologists who were actively involved in the management of URTIs and routinely prescribed high dose co-amoxiclav (1g) in paediatric and adult patients. Only those surgeons who consented to participate and completed the questionnaire were included in the final analysis.

Questionnaire development

A structured questionnaire comprising 10 items was used as the study instrument. The questionnaire was designed to capture information on indications for prescribing high-dose (1g) co-amoxiclav, perceived clinical efficacy, safety and tolerability concerns, considerations related to antimicrobial resistance, factors influencing antibiotic selection in URTIs

Data collection procedure

Data were collected using an electronic data capture platform. The questionnaire was administered digitally to participating otorhinolaryngologists. Responses were entered directly into the secure electronic database, minimizing transcription errors and enhancing data accuracy. Participation was voluntary, and no personal identifiers were collected. Completion of the questionnaire was considered as implied consent to participate in the study.

Ethical considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Approval was obtained from a duly constituted Independent Ethics Committee prior to initiation of the study.

As this was a non-interventional, questionnaire-based study involving only healthcare professionals and not patients, individual patient consent was not required.

Data handling and confidentiality

All data were anonymized at the point of collection. No information that could identify individual participants was recorded. Access to the study database was restricted to authorized study personnel only.

Statistical analysis

All data were analysed using descriptive statistics. Categorical variables were summarized and presented as frequencies (n) and percentages (%). The analysis was performed to describe prescribing patterns, clinical decision drivers, perceived effectiveness, safety profile, and factors influencing patient compliance among the participating otorhinolaryngologists.

RESULTS

In this study, females outnumbered males by a ratio of A total of 176 otorhinolaryngologists participated in the survey. Acute otitis media (AOM) was the most common indication for prescribing high-dose co-amoxiclav (1g), reported by 52% of respondents (n=90), followed by acute tonsillitis in 25% (n=43), acute bacterial sinusitis in 16% (n=28), and acute pharyngitis in 7% (n=12) (Figure 1). This shows that while AOM was the predominant indication, the drug was also widely used across other URTI conditions as well. High-dose co-amoxiclav was "frequently" prescribed in routine practice, with 36% of otorhinolaryngologists (n=62) reporting "sometimes" and 34% (n=60) reporting "often" use. Thus, 70% of respondents (n=122) indicated regular utilization of the 1 g formulation in clinical practice. Clinical efficacy was the primary reason for prescribing high-dose (1 g) co-amoxiclav in 52% of cases (n=90), followed by the convenience of the once-daily dosing schedule in 21% (n=37). Together, these two factors accounted for 73% of responses (n=127), emphasizing that effectiveness and dosing simplicity were the main drivers of prescription. Other reasons included spectrum of activity (11%, n=19), safety profile (10%, n=17), and patient preference (4%, n=7) (Figure 2). In terms of treatment positioning, 59% of otorhinolaryngologists (n=103) used high-dose (1 g) co-amoxiclav as first-line therapy, while 35% (n=61) used it as second-line and 6% (n=10) reserved it for non-responders or suspected resistant cases, indicating strong confidence in its early use for selected patients. Prescribing appropriateness was guided primarily by clinical guidelines in 45% of respondents (n=78), while the remainder relied on a combination of guidelines, empirical assessment, and microbiological testing, reflecting a balanced approach between evidence-based practice and real-world clinical judgment (Table 1).

Table 1: Assessing the appropriateness of high dose co-amoxiclav (1 gm) for a specific URTI patient.

Assessing the appropriateness of high dose co-amoxiclav (1g) for a specific URTI patient	No of responses (N)
Based on clinical guidelines	78
Empirical treatment based on symptoms	32
After culture and susceptibility testing	29
Combination of the above	34

Satisfaction with clinical outcomes was very high, with 93% of otorhinolaryngologists (n=162) reporting that they were satisfied or very satisfied with treatment results using high-dose (1 g) co-amoxiclav. Regarding safety, diarrhoea (66%, n=115) and nausea (21%, n=37) were the most commonly reported adverse effects, consistent with the known gastrointestinal profile of high-dose (1 g) co-amoxiclav. Patient compliance was most strongly influenced by dosing frequency, identified as the key factor by 56% of respondents (n=97), underscoring the advantage of the once-daily 1 g formulation (Figure 3). When compared with other antibiotics for URTIs, high-dose co-amoxiclav was perceived as more effective by 77% of otorhinolaryngologists (n=137). Similarly, its safety profile was rated as better or much better by 87% of respondents (n=152). Overall, these results demonstrate that high-dose co-amoxiclav (1 g) is widely used and highly trusted by otorhinolaryngologists across clinical practice, primarily due to its strong clinical efficacy, convenient once-daily dosing, high satisfaction with outcomes, and favourable comparative effectiveness and safety profile.

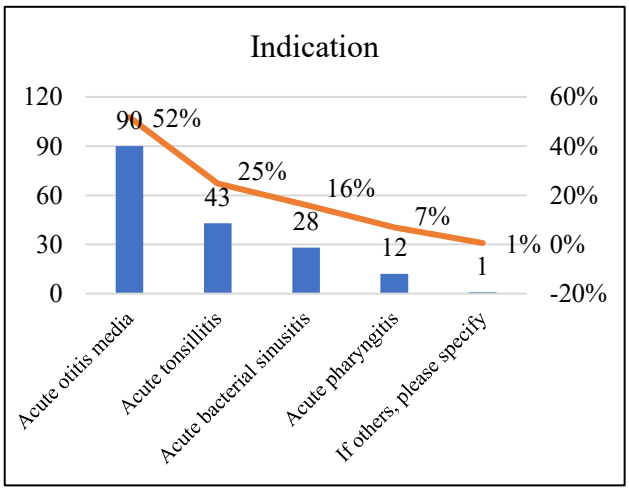

Figure 1: Top indications for prescribing high-dose amoxiclav (1 g).

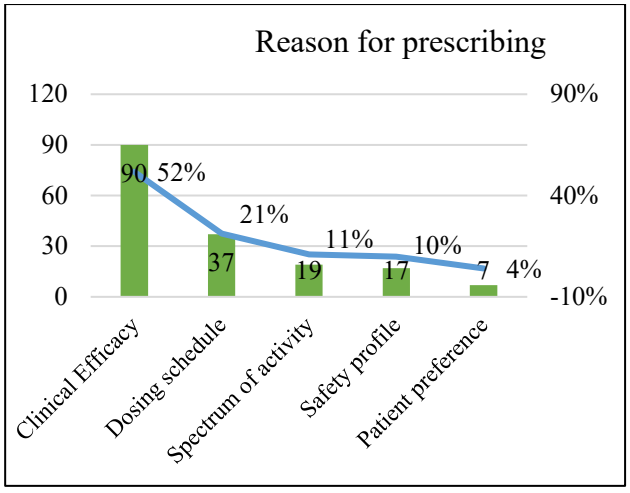

Figure 2: Reasons for prescribing high-dose amoxiclav (1 g).

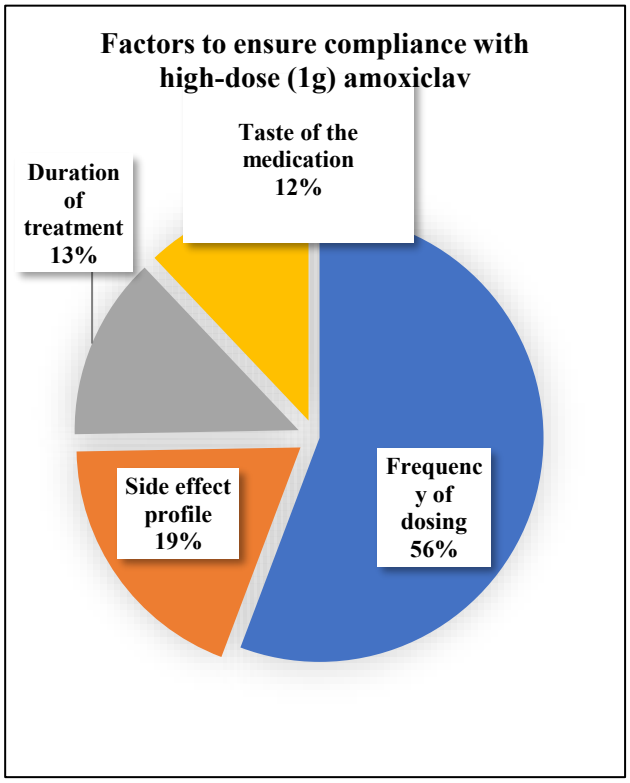

Figure 3: Important factors to ensure patient compliance with high-dose (1 g) amoxiclav.

DISCUSSION

Upper respiratory tract infections are among the most common reasons for antibiotic prescribing in routine clinical practice, despite many being self-limiting conditions.[1] Inappropriate antibiotic use contributes significantly to antimicrobial resistance, a major global public health concern.[2] In this context, understanding clinician's perspectives on commonly prescribed antibiotics is crucial for aligning real-world practice with evidence-based stewardship. Co-amoxiclav combines amoxicillin with clavulanic acid, extending antimicrobial coverage against β-lactamase–producing organisms.[3] Its continued clinical development has been driven by the need to enhance efficacy while maintaining an acceptable safety profile.[4] The pharmacokinetic and pharmacodynamic rationale for higher doses of amoxicillin is well established, as β-lactam efficacy is closely linked to the time that drug concentrations remain above the minimum inhibitory concentration (T>MIC).[5,6] High-dose formulations therefore provide improved bacterial eradication, particularly in infections caused by less susceptible pathogens.

In the present study, acute otitis media was the most common indication for high-dose co-amoxiclav, reported by 52% of otorhinolaryngologists. This is clinically appropriate, as AOM is frequently associated with β-lactamase–producing organisms such as Haemophilus influenzae and Moraxella catarrhalis.[8,9] The frequent use of high-dose co-amoxiclav in AOM reflects rational antimicrobial selection based on pathogen coverage and pharmacodynamic advantage. Nearly 60% of respondents positioned high-dose co-amoxiclav as first-line therapy in selected URTI patients. This finding indicates a strong level of confidence in the formulation, not merely as a rescue option but as an initial therapeutic choice. Such practice is consistent with PK–PD principles showing superior efficacy with optimized amoxicillin exposure.[5,6]

Clinical efficacy and dosing convenience emerged as the dominant drivers for prescription. The importance of simplified dosing regimens is well documented. Systematic reviews and clinical studies have consistently shown that reduced dosing frequency significantly improves medication adherence, particularly in outpatient and paediatric settings.[10,11] This is strongly supported by the present finding, where more than half of the respondent's identified frequency of dosing as the most important determinant of patient compliance.

A very high proportion of otorhinolaryngologists (93%) expressed satisfaction with clinical outcomes using high-dose co-amoxiclav. This aligns with published clinical evidence demonstrating reliable effectiveness of high-dose co-amoxiclav in respiratory tract infections.[4,7] Such consistency between real-world experience and published literature strengthens the external validity of these findings. Gastrointestinal adverse effects, particularly diarrhoea and nausea, were commonly reported, which is consistent with the known safety profile of clavulanate-containing regimens. A large meta-analysis has shown that amoxicillin–clavulanate is associated with a higher incidence of gastrointestinal adverse events compared with amoxicillin alone.[12] However, despite this, 87% of respondents still perceived the overall safety profile to be better than that of alternative antibiotics, suggesting a favourable benefit–risk balance in real-world practice. Notably, 45% of otorhinolaryngologists reported relying primarily on clinical guidelines to assess appropriateness of therapy. This reflects partial alignment with evidence-

based prescribing practices. At the same time, the use of empirical clinical judgment by the remaining physicians highlights the complexity of URTI management, where microbiological confirmation is often impractical. From an antimicrobial stewardship perspective, the rational selection of antibiotics is emphasized in international frameworks such as the WHO AWaRe classification, which promotes responsible antibiotic use and monitoring.[13] The high level of confidence in high-dose co-amoxiclav observed in this study suggests that, when appropriately prescribed, it remains a valuable component of the therapeutic armamentarium for URTIs. Overall, these findings demonstrate that high-dose co-amoxiclav (1g) is widely perceived by otorhinolaryngologists as an effective, convenient, and clinically reliable option for managing URTIs, supported both by pharmacological rationale and real-world experience.

CONCLUSION

This nationwide cross-sectional survey among 176 otorhinolaryngologists demonstrated a high level of confidence in the use of high-dose co-amoxiclav (1 g) for the treatment of upper respiratory tract infections. The formulation was frequently prescribed, commonly positioned as first-line therapy, and strongly valued for its clinical efficacy and convenient once-daily dosing schedule. Acute otitis media emerged as the most common indication, and simplified dosing was identified as the key determinant of patient compliance. Although gastrointestinal adverse effects were frequently encountered, the overall safety profile was perceived as favourable compared with alternative antibiotics. These findings support the continued rational use of high-dose co-amoxiclav (1 g) in clinical practice and reinforce its role as an effective and practical therapeutic option within evidence-based and antimicrobial stewardship-oriented frameworks for the management of URTIs.

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