



What Makes Cefpodoxime an Empiric Drug of Choice to Treat Lower Respiratory Tract Infections, including Acute Exacerbation of Chronic Obstructive Pulmonary Disease, in the Real-world Setting in India?

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Received: 08 July 2025; Accepted: 18 July 2025

ABSTRACT

Background: Acute exacerbation of chronic obstructive pulmonary disease (AECOPD) and pneumonia are challenging lower respiratory tract infections (LRTIs) commonly encountered in clinical practice. The oral extended-spectrum cephalosporin cefpodoxime proxetil is highly active against the bacterial pathogens commonly associated with LRTIs.

Aim: To assess the role of cefpodoxime in the management of infections in Indian patients with AECOPD and LRTIs in a real-world setting, based on expert opinions.

Methodology: The expert consensus meeting was convened according to an a priori protocol. Physicians were invited to participate in the discussion to frame opinion statements based on their clinical experience. A structured questionnaire was prepared regarding the role of cefpodoxime in the management of infections in patients with AECOPD and LRTIs.

Results: *Streptococcus pneumoniae* was the most common pathogen causing infections in patients with chronic bronchitis and pneumonia. Good penetration of cefpodoxime into lung tissues, high concentrations in lung tissues, and rapid resolution of symptoms make cefpodoxime the first-choice drug for treating LRTIs. Cefpodoxime is a step-down therapy of choice when switching hospitalized patients with LRTIs from parenteral antibiotics to oral antibiotics. Cefpodoxime is safe in patients with comorbid diseases and in elderly patients on polypharmacy.

Conclusion: Cefpodoxime is the preferred first-line empiric antibiotic of choice for the treatment of community-acquired LRTIs in the real-world setting in India. Cefpodoxime has been preferred by 99% of expert chest physicians to treat infections in patients with chronic obstructive pulmonary disease (COPD), considering its broad spectrum of activity. Ninety-seven percent of experts reported that cefpodoxime, as a step-down therapy, gives satisfactory patient recovery and prevents recurrent infections.

Journal of The Association of Physicians of India (2025); 10.59556/japi.73.1181

INTRODUCTION

Acute exacerbation of chronic obstructive pulmonary disease (AECOPD) and pneumonia are 2 challenging lower respiratory tract infections (LRTIs) commonly encountered in clinical practice.¹⁻⁴ It is associated with worsening respiratory symptoms and pathophysiological abnormalities such as exacerbated airway and systemic inflammation.⁵ A persistent productive cough for at least 3 months annually over 2 consecutive years characterizes chronic bronchitis in adults.⁶ The triggers are complex and commonly include respiratory viral infections, which could exacerbate bacterial LRTIs.⁷

It is noted that AECOPDs are associated with high morbidity and mortality.^{7,8} They result in loss of lung function and increase the risk of future exacerbations.^{3,6,9-12} Patients have a greater short- and long-term risk of major cardiovascular events.^{13,14} Bacterial infections are implicated as a cause of acute

exacerbation of chronic bronchitis (AECB) and pneumonia. When suspected, early initiation of antimicrobial therapy and supportive measures ensures faster recovery.^{3,15}

Increasing concerns about the emergence of penicillin-resistant strains of *Streptococcus pneumoniae* and beta-lactamase-producing strains of *Haemophilus influenzae* and *Moraxella catarrhalis* have prompted physicians to prefer third-generation cephalosporins. The oral extended-spectrum cephalosporin cefpodoxime proxetil is highly active against the bacterial pathogens commonly associated with LRTIs.¹⁶

Cefpodoxime, a third-generation cephalosporin, has inherent activity against beta-lactamase-producing pathogens, exhibiting strong antimicrobial activity against the aforementioned aerobic gram-positive and gram-negative bacteria, along with some effectiveness against anaerobic organisms. These pathogens have been implicated in causing infections in AECOPD and pneumonia.¹⁵

Hence, cefpodoxime, a broad-spectrum antibiotic, is widely used to treat LRTIs.^{4,17}

Cefpodoxime remains a drug of choice for treating LRTIs due to its high benefit-risk ratio, attributed to high efficacy balanced with good safety, driven by:

High microbial eradication rates¹⁸:

- Eradication rates of *S. pneumoniae*: 95.6% (43/45).
- Eradication rates of *H. influenzae*: 97.4% (37/38).

High clinical cure rates^{16,19}:

- Clinical efficacy of cefpodoxime in community-acquired pneumonia (CAP): 95.2%.
- Clinical efficacy of cefpodoxime in AECOPD: 97.2%.

Cefpodoxime safety²⁰⁻²²:

- Cefpodoxime safety has been demonstrated in the elderly.

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How to cite this article: Talwar D, Vora A, Tarke C, et al. What Makes Cefpodoxime an Empiric Drug of Choice to Treat Lower Respiratory Tract Infections, including Acute Exacerbation of Chronic Obstructive Pulmonary Disease, in the Real-world Setting in India? J Assoc Physicians India 2025;73(10):e55-e59.

- Elderly patients with healthy renal function do not require dose adjustment.
- Cefpodoxime does not cause QT prolongation, unlike macrolides or fluoroquinolones.
- Pseudomembranous colitis is rarely seen in postmarketing studies.

Aim

To assess the role of cefpodoxime in the management of infections in Indian patients with AECOPD and LRTIs in the real-world setting, based on expert opinions.

Methodology

The expert consensus meeting was convened according to an a priori protocol, the steps being: (1) invite the expert chest physicians to participate in the discussion to frame the consensus statements, (2) perform a systematic literature review, (3) develop the proposed consensus statements for the role of cefpodoxime in the management of infections in AECOPD, (4) develop statements for voting, and (5) analyze the poll results and develop opinion statements.

Literature Review for Framing the Opinion Statements

A rigorous literature search was performed by an information specialist for relevant publications using databases in English, including PubMed, Web of Science, Scopus, and Google Scholar. The keywords included cefpodoxime, AECOPD, antibiotic resistance, step-down therapy, and LRTIs. A structured questionnaire was prepared regarding the place of cefpodoxime in the management of

infections in patients with AECOPD. In round 1, the questionnaire was discussed with the core group members. Changes suggested by the experts were incorporated into the questionnaire, and the questionnaire was finalized. During round 2, a virtual meeting of experts was convened. The evidence of cefpodoxime was presented, followed by the poll questions. Answers that had 70% concurrence were considered positive for framing the opinion statements.

The most common pathogens implicated in infections in patients with chronic bronchitis and pneumonia.

Background

The organisms commonly implicated in causing infections in patients with AECB are *H. influenzae*, *M. catarrhalis*, *S. pneumoniae*, and *Pseudomonas aeruginosa*. Recurrent respiratory infections are attributed to a broad spectrum of microbial pathogens, encompassing both gram-positive and gram-negative organisms, including bacteria and viruses (Table 1).²³

Cefpodoxime is effective even against fastidious pathogens such as *Haemophilus* spp., *M. catarrhalis*, and beta-lactamase-producing pathogens.^{24,25} This antimicrobial activity of cefpodoxime was greater than that of cefuroxime and comparable to that of cefixime.²⁴

Cefpodoxime demonstrates stability against most plasmid-mediated beta-lactamases, making it a suitable option for empirical treatment of a broad range of community-acquired infections in both adults and pediatrics.²⁵

Expert Opinion

Sixty-three percent of experts opined that *S. pneumoniae* was the most common pathogen causing infections in patients with chronic bronchitis. However, only 21% of experts opined that *H. influenzae* caused infections in

chronic bronchitis. The less frequent pathogens were *P. aeruginosa* and *M. catarrhalis*.

Role of cefpodoxime as a first-line drug in patients with AECOPD and pneumonia.

Background

Cefpodoxime has exhibited effective penetration into the pleural fluid, with drug concentrations between 3 and 12 hours postdose reaching or exceeding the minimum inhibitory concentration required to inhibit the growth of 90% of organisms (MIC₉₀) for the majority of organisms typically associated with LRTIs.²⁶

In the multicenter randomized open study, 250 patients with secondarily infected chronic obstructive pulmonary disease (COPD) were treated with cefpodoxime proxetil 400 mg/day; 99% cure rates were observed at the end of treatment.²⁷ Cefpodoxime has exhibited a rapid bactericidal effect against *S. pneumoniae* and *H. influenzae*. The minimal regrowth and favorable time-kill curve patterns observed are attributed to its consistent maintenance of high cefpodoxime concentrations remaining above the minimum inhibitory concentration (MIC) for each isolate. Cefpodoxime has a postantibiotic effect (PAE) of up to 4 hours against pathogens such as *S. pneumoniae* (Fig. 1).²⁸

In global clinical trials, physicians rated the clinical efficacy of cefpodoxime as "very good" or "good" in 96.4% of the cases.²⁹

Expert Opinion

All experts unanimously agreed that they preferred cefpodoxime as the first-line drug to treat infections in their patients with AECOPD and CAP.

Rapid symptom resolution in AECOPD patients treated with cefpodoxime.

Background

A study treated 126 patients with LRTI of bacterial origin [59 with AECOPD, 32 with

Table 1: Prevalence of pathogens in recurrent LRTIs, including chronic obstructive pulmonary disease (COPD) patients²³

Gram staining and culture isolates in LRTI	n (%)
Gram-positive cocci (Gram staining in 75 episodes)	Showed gram-positive cocci in 57 (76%)
Total culture done in 102 episodes	Positive cultures: 57 (55.88%)
<i>P. aeruginosa</i>	27 (26.47%)
<i>Klebsiella pneumoniae</i>	18 (17.64%)
<i>Escherichia coli</i>	5 (4.9%)
<i>S. pneumoniae</i>	3 (2.94%)
<i>Acinetobacter baumannii</i>	2 (1.96%)
<i>Staphylococcus aureus</i>	1 (0.98%)
<i>Serratia marcescens</i>	1 (0.98%)
Negative cultures	45 (44.12%)

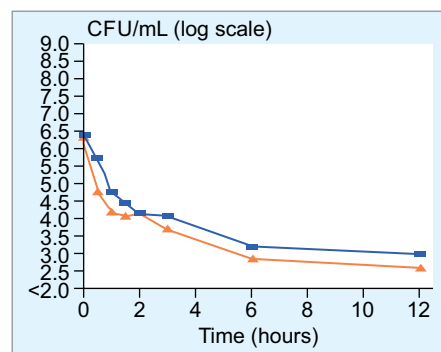


Fig. 1: Bacterial time-kill curves for *H. influenzae* for cefpodoxime 200 mg once daily (OD) (■) and cefpodoxime 400 mg OD (▲); CFU: colony-forming unit; adapted from Garrison MW et al.²⁸

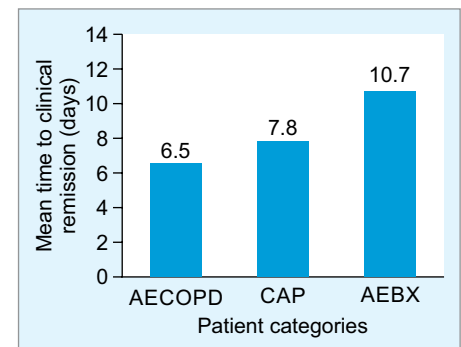


Fig. 2: Mean time to clinical remission after treatment with cefpodoxime⁴

CAP, and 35 with acute exacerbation of bronchiectasis (AEBX)] with cefpodoxime. The mean time to clinical remission in AECOPD patients was 6.5 days. The results support the use of cefpodoxime in bacterial LRTI treatment due to its high efficacy and good tolerability (Fig. 2).⁴

Expert Opinion

Cefpodoxime was observed to be associated with rapid symptom resolution after day 2 by 42% of experts, while another 42% of experts reported symptom resolution after day 3 of treatment. Another opinion given by experts was that the response to therapy was often gauged clinically, not by symptom resolution or defervescence, but rather by observing “no worsening of symptoms” in the patient. The experts opined that the absence of clinical worsening was a more practical way to assess response to antibiotics since the time to defervescence may be prolonged in some patients.

Prescription of cefpodoxime as a step-down therapy at the time of discharge in patients with AECOPD.

Background

Cefpodoxime can be a preferred treatment option for step-down therapy after hospitalization for LRTIs since it has a broad

spectrum of activity that encompasses the common respiratory pathogens *S. pneumoniae*, *H. influenzae*, and *Streptococcus pyogenes*, has favorable pharmacokinetics, and has been proven to be an effective treatment option to replace parenteral therapy, especially ceftriaxone.³⁰ In an Indian survey, cefpodoxime was the preferred antibiotic by Indian physicians to treat their patients with LRTIs (Fig. 3).³¹

Expert Opinion

In hospitalized patients, parenteral antibiotics are the preferred mode of treatment, considering the morbidity and the clinical condition of the patient. However, when the patient can take oral therapy, the patients are switched to oral antibiotics as part of the “step-down” therapy protocol. Ninety-nine percent of experts opined that they preferred to prescribe cefpodoxime as the step-down therapy in hospitalized patients with AECOPD.

Outcomes when cefpodoxime is prescribed as step-down therapy after discharge.

Background

Cefpodoxime has the lowest failure rates in patients not responding to other antibiotics.³² No pseudomembranous colitis-related

diarrhea has been observed during clinical trials. Common reactions have been noted with a similar frequency to that seen with other beta-lactam antibiotics.²²

Expert Opinion

Ninety-eight percent of experts opined that when cefpodoxime is prescribed as step-down therapy, they observed either satisfactory patient recovery, no recurrent infection, or both.

Patient populations in whom cefpodoxime is effective and safe.

Background

The spectrum of comorbid diseases associated with COPD ranges from cardiac disease, diabetes mellitus, hypertension, osteoporosis, and obstructive sleep apnea to psychological disorders.¹ Comorbidities are associated with increased hospitalizations in patients with COPD.³³ Cefpodoxime can be used to safely treat LRTIs in patients with comorbid diseases such as arthritis, diabetes, hypertension, and ischemic heart disease (Table 2). Cefpodoxime is also safe in elderly patients.^{20,34}

In a study comparing the incidence of diarrhea with cefpodoxime vs amoxicillin-clavulanic acid, no diarrhea was reported in the cefpodoxime-treated patients, as compared to 11% in amoxicillin-clavulanic acid-treated patients.³⁵

Expert Opinion

Ninety percent of experts opined that cefpodoxime is effective and safe in patients with comorbid diseases such as diabetes, hypertension, and ischemic heart disease. Cefpodoxime is also preferred in smokers.

Presence of extended-spectrum β -lactamase (ESBL) producing pathogens in patients with AECOPD and CAP in the real-world setting.

Background

Cefpodoxime demonstrated strong efficacy against the fastidious organisms most frequently linked to respiratory infections,

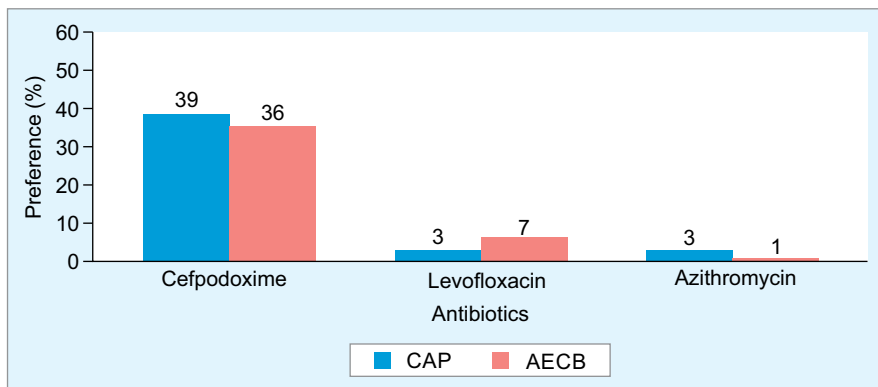


Fig. 3: Antibiotic preferred by Indian physicians to treat LRTIs³¹

Table 2: Chronic obstructive pulmonary disease and comorbid diseases^{1,20,36,37}

Comorbid disease	Mechanistic pathways	Impact of COPD on the comorbid disease	Impact of cefpodoxime when prescribed to manage infections
Cardiovascular disease (CVD)	C-reactive protein (CRP) Tumor necrosis factor (TNF)	Arrhythmias can be triggered by exacerbations of COPD Hyperinflation in COPD could have a compressive effect on the heart and increase the risk of myocardial infarction	No QT prolongation No arrhythmias No drug interactions with cardiac drugs
Diabetes	Interleukin-6 (IL-6) TNF Adipokines	In patients with diabetes mellitus, corticosteroids impair glycemic control	No adverse effect on glycemic control
Gastroesophageal reflux disease (GERD)	Aspiration		No increased reflux

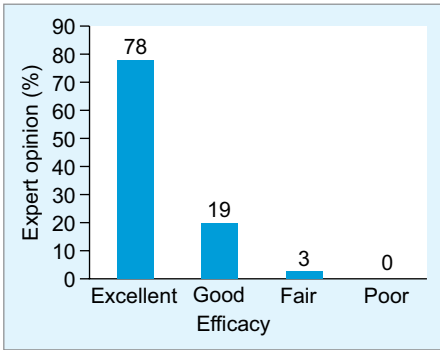


Fig. 4: Efficacy of cefpodoxime to treat infections in AECOPD patients

such as *S. pneumoniae* (MIC₉₀, 0.12 µg/mL), *H. influenzae* (MIC₉₀, 0.12 µg/mL), and *M. catarrhalis* (MIC₉₀, 1 µg/mL).³⁸ Cefpodoxime is also found to be effective against beta-lactamase-producing pathogens. It was active at ≤1 mg/L against 50% of the members of beta-lactamase-producing pathogens.³⁹

Expert Opinion

Sixty-seven percent of experts opined that they do come across infections in AECOPD patients caused by ESBL-producing pathogens.

The most commonly preferred antibiotic for AECOPD patients.

Ninety-four percent of experts opined that they preferred to prescribe cefpodoxime in patients with AECOPD.

Efficacy of cefpodoxime to treat infections in AECOPD patients.

Ninety-seven percent of experts rated the efficacy of cefpodoxime as excellent to good (Fig. 4).

Benefits of cefpodoxime sustained release.

Eighty-two percent of experts opined that the sustained-release formulation of cefpodoxime is associated with several advantages, such as improved adherence to treatment due to reduced dosing frequency. This could lead to the resolution of infection and improved treatment outcomes.

DISCUSSION

Pneumonia and COPD are the leading causes of morbidity and mortality globally, including middle-income countries like India.^{1,40} Both gram-positive and gram-negative pathogens are implicated in causing infections in COPD patients.¹⁵ The rising prevalence of resistance of respiratory pathogens to common antibiotics poses a challenge to clinicians treating AECOPD patients with infections.¹⁶

COPD and CVD significantly impact morbidity and mortality, with many

COPD patients commonly experiencing cardiovascular comorbidities such as coronary heart disease and stroke.² Patients with COPD have other comorbid diseases such as diabetes and arthritis. Hence, choosing an antibiotic requires due consideration to balance efficacy with the safety of the antibiotic in this challenging patient population.³⁴

Cefpodoxime is a broad-spectrum antibiotic that covers the pathogens that cause LRTIs. Cefpodoxime has been associated with high sensitivity and low resistance rates against pathogens implicated in causing LRTIs.^{4,17}

Evidence from clinical trials has already proven high clinical cure rates with cefpodoxime (99%).²⁷ In the current consensus meeting, all experts unanimously agreed that they preferred cefpodoxime as the first-line antibiotic to treat infections in their patients with AECOPD. The findings of the expert consensus group corroborate the evidence published in clinical trials.

Rapid resolution of symptoms after treatment with cefpodoxime was proven in the study.⁴ Indian experts concurred that cefpodoxime is associated with no worsening of symptoms, and patients have an uneventful recovery. Ninety-nine percent of Indian experts opined that they prefer to prescribe cefpodoxime as a “step-down” therapy in hospitalized patients. They prefer to switch patients from parenteral cephalosporins to oral cefpodoxime and have reported no loss of efficacy or relapse of infection.

Cefpodoxime has been reported to be effective and safe across a spectrum of patients with or without comorbid disease. Cefpodoxime is safe in patients with CVD or diabetes. Cefpodoxime does not adversely affect glycemic control.^{1,20,34} Ninety percent of experts concurred that they perceive cefpodoxime to be safe across the range of comorbid disorders observed in patients with COPD. Ninety-seven percent of experts rated the efficacy of cefpodoxime as excellent to good.

The extended-release formulation of cefpodoxime is now available in India. Eighty-two percent of experts opined that the sustained-release formulation of cefpodoxime is associated with several advantages, such as improved adherence to treatment due to reduced dosing frequency. This could lead to the resolution of infection and improved treatment outcomes.

The current expert meeting corroborated the multiple benefits of cefpodoxime observed in clinical trials. The experts concurred that cefpodoxime effectively balances efficacy and safety and is considered the empiric antibiotic of first choice for the treatment of

lower respiratory tract community-acquired infections. The low risk of resistance to pathogens implicated in LRTI makes the continued use of cefpodoxime a preferred way to treat LRTI in the real-world setting.

Experts across India concurred that they have observed continued susceptibility of pathogens implicated in causing community-acquired LRTI to cefpodoxime.

CONCLUSION

Cefpodoxime is the preferred first-line empiric antibiotic of choice for the treatment of community-acquired LRTIs, including infections in patients with AECOPD in the real-world setting in India.⁴ Cefpodoxime has been preferred by 99% of expert chest physicians to treat infections in patients with COPD, considering its broad spectrum of activity that encompasses both gram-positive and gram-negative bacteria. Ninety-seven percent of experts opined that when cefpodoxime is prescribed as a step-down therapy, they have observed satisfactory patient recovery, with no cases of recurrent infection. Cefpodoxime can be used to safely treat LRTIs in patients with comorbid diseases such as arthritis, diabetes, hypertension, and ischemic heart disease. Cefpodoxime is safe for elderly patients.

Cefpodoxime continues to be the antibiotic of first choice to treat community-acquired LRTIs in India.⁴

ACKNOWLEDGMENT

Medical writing assistance was provided by Hansa Medcell (a division of R K Swamy Ltd.), Mumbai.

FUNDING STATEMENT

This initiative was funded by Aristo Pharmaceuticals.

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