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Multicenter, Retrospective, Real-World Evidence Study to Evaluate the Effectiveness of Cefpodoxime in the Management of Patients with Respiratory Tract Infections

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ABSTRACT

Introduction: Respiratory tract infections (RTIs) are a major cause of global morbidity and contribute significantly to healthcare burden and antibiotic utilization. Cefpodoxime proxetil, an oral third-generation cephalosporin, is widely used in clinical practice due to its broad-spectrum antibacterial activity and favorable safety profile; however, real-world evidence evaluating its effectiveness remains limited. This study aimed to assess its clinical effectiveness and outcomes in the management of RTIs in a real-world setting.

Methods: This multicenter, retrospective observational study included patients diagnosed with RTIs and treated with cefpodoxime proxetil. Data on demographics, treatment duration, clinical outcomes, inflammatory markers, and safety were collected and analyzed. The primary endpoint was clinical cure, while secondary endpoints included clinical improvement, changes in inflammatory markers, and safety outcomes.

Results: A total of 1474 patients were included, comprising 70% males and 30% females, with a mean age of 39.75 ± 14.4 years. The mean treatment duration was approximately 6 days, indicating high adherence. All patients received cefpodoxime as a twice-daily regimen. Clinical cure was achieved in 90% of patients (n=1323), while 10% (n=145) showed improvement, with no cases of worsening or mortality. Among a subset of patients, mean C-reactive protein levels decreased from 8.01 ± 4.68 mg/L to 4.14 ± 5.22 mg/L. The treatment was well tolerated, with only 20 patients reporting mild gastrointestinal adverse events managed conservatively.

Conclusion: Cefpodoxime proxetil demonstrated high clinical effectiveness, reduction in inflammatory markers, and good tolerability in RTIs, supporting its role as a reliable real-world therapeutic option.

Keywords: *C-reactive protein (CRP), Clinical cure, Treatment adherence, Inflammatory markers.*

INTRODUCTION

Respiratory tract infections (RTIs) represent a major global health burden and are among the most frequent causes of morbidity, mortality, and healthcare utilization worldwide. They account for a substantial proportion of outpatient visits, hospitalizations, and antibiotic prescriptions, particularly in low- and middle-income countries. According to global estimates, lower respiratory tract infections remain one of the leading causes of death, especially among vulnerable populations such as children, the elderly, and individuals with comorbidities **(1)**. RTIs are broadly classified into upper respiratory tract infections (URTIs)—including acute pharyngitis, tonsillitis, sinusitis, and otitis media—and lower respiratory tract infections (LRTIs) such as acute bronchitis, exacerbations of chronic obstructive pulmonary disease

(COPD), and community-acquired pneumonia (CAP). While many RTIs are viral in origin, bacterial pathogens play a significant role in moderate-to-severe disease and in cases requiring antibiotic therapy **(2).**

The most common bacterial pathogens implicated in RTIs include *Streptococcus pneumoniae*, *Hemophilus influenzae*, and *Moraxella catarrhalis***.** These organisms are responsible for a large proportion of community-acquired infections and are associated with considerable morbidity if not treated appropriately **(3).** However, the emergence of antimicrobial resistance among these pathogens has complicated empirical antibiotic selection and has become a major public health concern worldwide **(4).**

Appropriate antibiotic therapy is essential not only for clinical cure but also for preventing complications, reducing transmission, and minimizing the development of resistance. Current clinical guidelines, including those from infectious disease societies, emphasize the importance of selecting antibiotics with reliable activity against common respiratory pathogens, favorable pharmacokinetic properties, and good safety profiles **(5,6).**

Cefpodoxime proxetil is an orally administered third-generation cephalosporin that has been widely used in the treatment of RTIs. (7) It is a prodrug that is rapidly converted in vivo to its active form, cefpodoxime. The drug exhibits broad-spectrum activity against both Gram-positive and Gram-negative organisms, including β-lactamase–producing strains of *H. influenzae* and *M. catarrhalis* **(8).** Its stability against β-lactamase enzymes and its enhanced activity against *S. pneumoniae* make it a valuable option in the empirical treatment of respiratory infections. Pharmacokinetically, cefpodoxime demonstrates good oral absorption and achieves adequate concentrations in respiratory tissues, including bronchial mucosa, lung parenchyma, and epithelial lining fluid. These properties allow it to exceed the minimum inhibitory concentrations (MICs) required to inhibit common respiratory pathogens, thereby contributing to its clinical effectiveness **(9).**

Several randomized clinical trials and comparative studies have demonstrated that cefpodoxime proxetil is as effective as other commonly used antibiotics, such as amoxicillin-clavulanate and ceftriaxone, in the treatment of RTIs. Clinical success rates reported in these studies typically range from 84% to 100%, with good tolerability and a low incidence of adverse effects **(10,11).** Additionally, its twice-daily dosing regimen improves patient compliance, which is a critical factor in real-world treatment outcomes.

Despite robust evidence from controlled clinical trials, there is a growing recognition that such studies may not fully reflect real-world clinical practice due to strict inclusion criteria, controlled environments, and limited patient diversity. Real-world evidence (RWE) studies address these gaps by evaluating the effectiveness of interventions in routine clinical settings, capturing variations in patient populations, physician prescribing behavior, adherence patterns, and comorbid conditions **(12).**

In the context of RTIs, RWE is particularly important given the heterogeneity of disease presentation, variability in antibiotic use, and the increasing burden of antimicrobial resistance. Observational studies conducted in real-world settings provide valuable insights into treatment effectiveness, safety, and outcomes across diverse populations **(13).** However, there remains a relative paucity of large-scale, multicenter real-world studies evaluating the effectiveness of cefpodoxime proxetil in the management of RTIs, particularly in the Indian clinical setting. Generating such evidence is essential to support rational antibiotic use and to guide clinicians in making informed therapeutic decisions.

Therefore, the present multicenter, retrospective real-world evidence study was undertaken to evaluate the effectiveness of cefpodoxime proxetil in patients with respiratory tract infections, with a focus on clinical outcomes including cure, improvement, worsening, and mortality in routine clinical practice.

MATERIALS & METHODS

This was a multicenter, retrospective, RWE study conducted in India. The study involved the evaluation of medical records of patients (aged ≥ 2 years) who were prescribed Cefpodoxime Proxetil tablets or syrups for the management of RTI.

Medical records were obtained from multiple participating centers. Only records containing complete and evaluable clinical information, including patient diagnosis, treatment details, and follow-up outcomes, were included in the analysis.

Data Collection

Data were retrospectively collected from qualifying medical records, and the following information was extracted for each patient: demographic details (age and sex), clinical diagnosis specifying the type of upper respiratory tract infection (such as AOM, tonsillitis, pharyngitis, laryngitis, pneumonia, bronchitis, acute sinusitis, or undifferentiated URTI), treatment details including prescribed Cefpodoxime proxetil dosage, dosing frequency (once, twice daily), prescribed and actual duration of therapy, laboratory parameters such as CRP levels (wherever data available) at baseline and follow-up, clinical outcomes assessed at the End of treatment/follow-up visit, and any adverse events reported during or after the treatment period.

Endpoints

Primary Endpoints

Clinical outcomes assessed at follow-up were categorized as:

1. **Cure:** Complete resolution of signs and symptoms
2. **Improvement:** Partial resolution of signs and symptoms without need for change in therapy
3. **Worsening:** Progression or deterioration of disease after initiation of treatment, requiring escalation of therapy
4. **Mortality:** Death during the study period attributable to the disease or its complications

Secondary Endpoints

- Change in inflammatory markers (CRP levels) from baseline to follow-up (Wherever data available)
- Safety of cefpodoxime proxetil, assessed by the reported adverse events

Statistical Analysis

All data were analyzed using descriptive statistical methods. Continuous variables, such as patient age and duration of therapy, were summarized using means and standard deviations (SD). Categorical variables, including sex, type of RTI, dosing frequency, and clinical outcomes (cure/improvement/worsening/mortality), were presented as frequencies and percentages (n, %). The normalization of laboratory parameter (CRP) at base and follow-up was also calculated.

RESULTS

Study Population and Baseline Characteristics

A total of 1474 patient medical records were evaluated and included in the final analysis, comprising 1032 males (70.0%) and 442 females (30.0%). The mean age of the participants was **39.75 ± 14.4 years**. The mean weight was **55.25 ± 17.6 kg**, reflecting the overall demographic profile of the study population. (Table 1).

The distribution of specific RTI diagnoses is as depicted in Fig. 1.

Table 1: Demographic characteristics

Parameter		**Number**	**Percentage**
Gender	Male	1032	70.01%
	Female	442	29.99%
Total		**1474**	**100%**
		Mean	**SD**
Age (in years)		39.75	14.4
Weight (in kg)		55.25	17.6

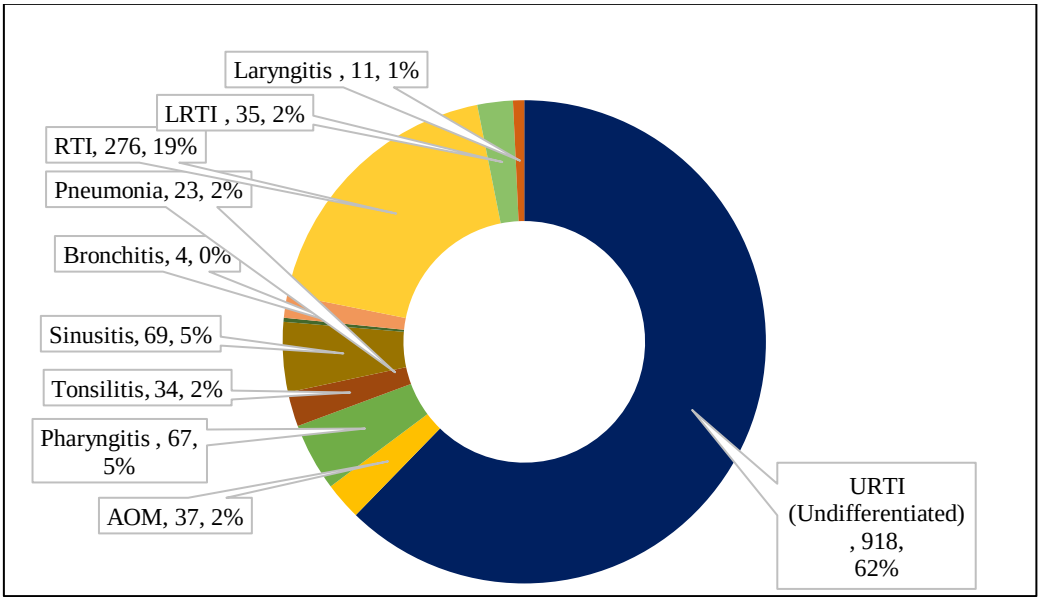

Figure 1: Indications of Cefpodoxime Proxetil

Treatment Details

The prescribed duration of cefpodoxime proxetil therapy ranged from 5 to 15 days (Mean: 5.96 days) and closely aligned with the actual duration of treatment taken by patients, which ranged from 3 to 15 days (Mean: 5.86 days), suggesting high patient adherence. All patients received cefpodoxime proxetil as a twice-daily (BD) regimen.

Clinical Effectiveness (Primary Endpoint)
Cefpodoxime demonstrated high effectiveness in the real-world setting, with all patients achieving either complete cure or clinical improvement (100%). At follow-up evaluation, the clinical outcomes were as follows: Cure (complete resolution of signs and symptoms): n=1323 (90%), and Improvement (partial resolution of signs and symptoms): n=145 (10%). Notably, no cases of Worsening (progression or deterioration of disease after initiation of treatment, requiring escalation of therapy): n=0% were observed during the study period. Furthermore, there were no reported cases of Mortality (death of a patient during the study period, attributable to the disease or its complications): n=0%. These findings highlight the strong clinical effectiveness of cefpodoxime in the management of respiratory tract infections in real-world practice. Clinical outcomes at the follow-up evaluation were as the following (Fig. 2):

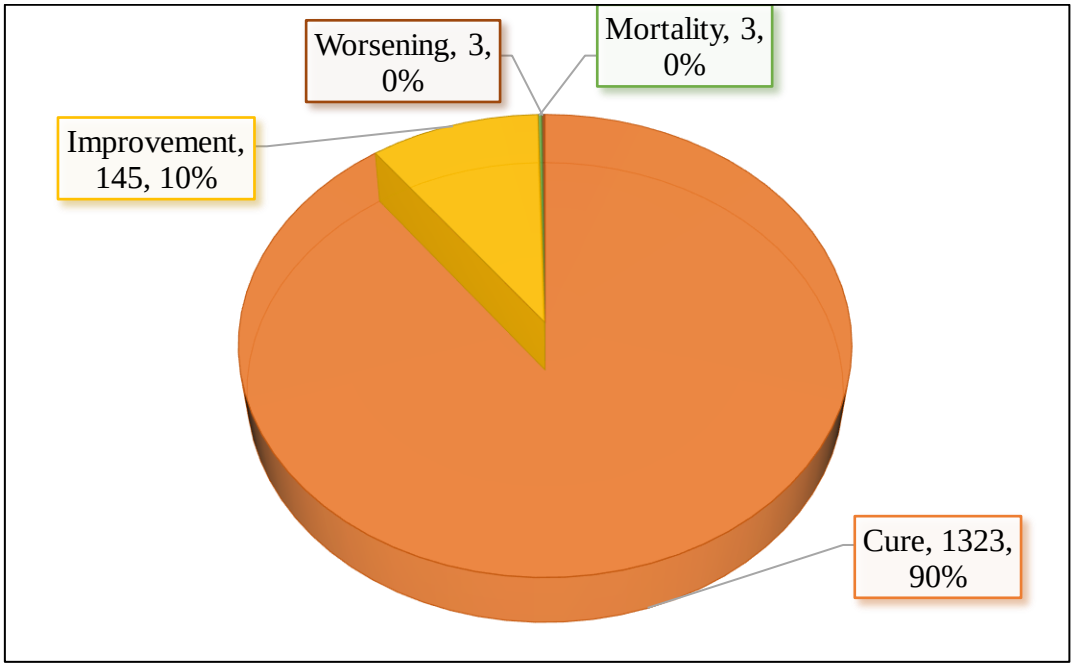

Figure 2: Clinical effectiveness in terms of outcomes

Impact on Inflammatory Markers (Secondary Endpoint)
Data on inflammatory markers were available for a subset of participants, enabling an analysis of the treatment's impact (Table 2):

C-reactive protein (CRP): Baseline CRP levels were available for 39 patients, with a mean ± SD of **8.01 ± 4.68 mg/L**. At follow-up, CRP data were available for 45 patients, with a mean ± SD of **4.14 ± 5.22 mg/L**, indicating a reduction in inflammatory markers following treatment.

Table 2: Inflammatory Marker Changes

	Baseline	**Follow-up**
Parameter	(n=39) Mean ± SD	(n=45) Mean ± SD
CRP (mg/L)	8.01 ± 4.68	4.14 ± 5.22

Safety and Tolerability (Secondary Endpoint)
Cefpodoxime proxetil was well tolerated across the study population. No major adverse events were reported during or after the treatment period. Total 22 patients experienced mild gastrointestinal disturbances, mainly including diarrhea and nausea, which were managed conservatively without the need for treatment discontinuation.

DISCUSSION
The present multicenter real-world evidence (RWE) study provides robust insights into the clinical effectiveness and safety of cefpodoxime proxetil in the management of respiratory tract infections (RTIs). The findings demonstrate a high rate of clinical cure and improvement, with no cases of worsening or mortality reported, thereby reinforcing the therapeutic value of cefpodoxime in routine clinical practice. These outcomes are consistent with previously published literature, which has established cefpodoxime as an effective oral third-generation cephalosporin for the treatment of both upper and lower RTIs (6,13,20).

The high clinical success rate observed in this study aligns closely with earlier randomized controlled trials and multicenter comparative studies, where cefpodoxime proxetil demonstrated efficacy comparable to commonly used antibiotics such as amoxicillin-clavulanate and ceftriaxone (9,10). These studies have consistently reported clinical success rates exceeding 90%, indicating that cefpodoxime is a reliable alternative in the empirical treatment of RTIs (10,13). The concordance between controlled trial data and the present real-world findings strengthens the evidence base supporting its use across diverse clinical settings.

An important finding of the current study is the observed reduction in C-reactive protein (CRP) levels following treatment. CRP is a sensitive and widely accepted biomarker of systemic inflammation and is frequently used to monitor response to antimicrobial therapy in bacterial infections. A decline in CRP levels typically reflects effective bacterial clearance and resolution of the inflammatory response (19). The reduction in CRP observed in this study supports the clinical outcomes and further validates the effectiveness of cefpodoxime proxetil in managing RTIs.

The antimicrobial efficacy of cefpodoxime can be attributed to its favorable microbiological profile. It exhibits potent activity against key respiratory pathogens such as *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*, which are among the most commonly implicated organisms in RTIs (3). Additionally, cefpodoxime demonstrates stability against β-lactamase enzymes, enabling it to retain activity against β-lactamase–producing strains, particularly *H. influenzae* and *M. catarrhalis* (8,16). This characteristic is particularly important in the current era of increasing antimicrobial resistance. Clinical studies have reported bacteriological eradication rates ranging from approximately 78% to 96%, further highlighting its effectiveness in eliminating causative pathogens (16).

Another notable aspect of this study is its real-world design, which enhances the external validity and generalizability of the findings. Unlike randomized controlled trials that often involve highly selected patient populations under controlled conditions, real-world studies capture a broader and more heterogeneous population, including variations in age, comorbidities, disease severity, and treatment adherence. This allows for a more accurate reflection of routine clinical practice and provides valuable insights into treatment effectiveness outside the constraints of controlled environments (11).

The inclusion of a large sample size across multiple centers further strengthens the reliability of the findings.
From a clinical perspective, cefpodoxime proxetil offers several practical advantages that contribute to its effectiveness in routine practice. Its convenient twice-daily dosing regimen is associated with improved patient adherence, which is a critical determinant of therapeutic success in infectious diseases (15). Poor adherence is a well-recognized factor contributing to treatment failure and the development of antimicrobial resistance. Therefore, antibiotics with simpler dosing schedules, such as cefpodoxime, may offer an advantage in real-world settings. Furthermore, cefpodoxime is generally well tolerated, with a low incidence of adverse effects, primarily mild gastrointestinal disturbances, which rarely necessitate discontinuation of therapy (6,20). The favorable safety profile observed in this study is consistent with previous reports and supports its use in a wide range of patients.

The growing challenge of antimicrobial resistance represents a significant concern in the management of RTIs. Resistance to commonly used antibiotics, including penicillins and macrolides, has been increasingly reported among respiratory pathogens, complicating empirical treatment strategies (4). In this context, cefpodoxime proxetil serves as a valuable therapeutic option due to its retained activity against many resistant strains. Its broad-spectrum coverage and stability against β-lactamases make it particularly useful in regions with high resistance rates, including parts of India. The findings of this study support its continued use as an effective empirical therapy in such settings.

In addition to its clinical and microbiological advantages, the findings of this study contribute to the growing body of real-world evidence supporting the use of cefpodoxime proxetil. Real-world data play an increasingly important role in informing clinical decision-making, as they complement evidence from randomized controlled trials by providing insights into effectiveness in routine practice. Such data are particularly valuable in heterogeneous populations and resource-variable healthcare settings, where treatment patterns and patient characteristics may differ significantly from those in controlled trial environments (11).

Despite these strengths, certain limitations of the study must be acknowledged. The retrospective design inherently limits the ability to establish causal relationships and is subject to potential biases related to data collection and documentation. The absence of a comparator or control group restricts the ability to directly compare the effectiveness of cefpodoxime with other antibiotic therapies. Additionally, the possibility of selection bias cannot be excluded, as only patients with available and sufficiently complete medical records were included in the analysis.

Another important limitation relates to missing or incomplete data. Certain laboratory parameters, particularly CRP values, were available only for a subset of patients, which may have limited the robustness of the analysis of inflammatory markers. Cases with missing data were excluded from specific analyses, which could introduce bias and affect the generalizability of these findings. Furthermore, the lack of microbiological confirmation in most cases precluded pathogen-specific analysis and assessment of antimicrobial susceptibility patterns.

Variability in clinical practice across participating centers, including differences in treatment duration, dosing patterns, and use of adjunctive therapies, represents another potential limitation. Additionally, confounding factors such as comorbidities, concomitant medications, and baseline disease severity were not uniformly controlled or adjusted for, which may have influenced treatment outcomes. The study also did not assess patient adherence using objective measures, although indirect indicators such as treatment duration suggested good compliance.

Finally, the relatively short follow-up period limited the ability to assess long-term outcomes, recurrence rates, and delayed adverse events. Future prospective studies with standardized protocols, microbiological confirmation, and longer follow-up durations are warranted to address these limitations and further validate the findings.

Limitations of the study:

The retrospective design of this study limits the ability to establish strong causal relationships. There is also a possibility of selection bias, along with missing or incomplete data, such as CRP values being available for a smaller number of patients. Additionally, the lack of microbiological confirmation limits pathogen-specific conclusions. Variability in treatment practices, duration of therapy, and supportive therapy, while uncontrolled confounding factors such as comorbidities and concomitant medications may have influenced the observed outcomes.

CONCLUSION

Cefpodoxime proxetil is an effective, safe, and well-tolerated antibiotic for the management of respiratory tract infections in real-world clinical practice. The high clinical cure rate and low incidence of adverse outcomes support its continued use in RTIs.

Declaration by Authors

- **Ethical Approval:** Ethical approval was taken before the commencement of study.
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- **Conflict of Interest:** Author no. 3, 5, & 6 are full-time employee of Alkem laboratories. The authors declare that there are no other conflicts of interest related to this study.

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