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A Real-World Evidence Study to Evaluate the Clinical Effectiveness and Safety of Cefixime Suspension in Managing Paediatric Infections

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Abstract

Background: Bacterial infections continue to be a significant source of morbidity and mortality in children, especially in developing countries. Cefixime, a third-generation cephalosporin, is a commonly used oral cephalosporin that has extensive activity with ease of administration.

Objective: To assess the real-world effectiveness and safety of cefixime for the treatment of bacterial infections in children in a variety of clinical centres in India.

Methods: This multicentre retrospective study assessed anonymised data from 6,768 paediatric patients (≤18 years) who were treated with cefixime 200 mg/5 mL oral suspension as a part of routine clinical practice. Clinical and microbiological effectiveness, vital signs, laboratory values, and adverse events were evaluated at baseline, end of treatment (7 days), and follow-up (14 days after treatment) based on the availability of medical information.

Results: Clinical cure was obtained at the end of therapy in 77.4% of patients, rising to 100% at follow-up. All patients were culture-positive at baseline; microbiological eradication reached 83.9% by EOT and 100% at follow-up. The most prevalent pathogen was *Salmonella typhi* (59.4%). Average treatment time was 7.7 days, with a mean duration of hospitalization of 1.32 days. Fewer than 0.05% of the patients had mild, transient side effects.

Conclusion: Cefixime has shown notable effectiveness in terms of rapid symptom resolution and a favourable safety profile in the treatment of pediatric bacterial infections. This evidence supports its continued use as a reliable therapeutic option, particularly in regions with a high prevalence of resistant bacterial strains, where standard first-line agents may be less effective.

Keywords: Cefixime, Paediatric Bacterial Infections, Antibacterial Therapy, Real-World Evidence, Clinical Cure

Introduction

Bacterial infections remain a significant global health challenge in the pediatric population, contributing substantially to childhood morbidity and mortality [1]. Common pediatric infections such as otitis media, urinary tract infections (UTIs), upper respiratory tract infections, and enteric fever are predominantly caused by bacterial pathogens [2]. The incidence of these infections is notably higher during early childhood, especially following school enrolment or entry into daycare environments [3]. Globally, an estimated 5.4 million children die before reaching the age of five, with infectious diseases responsible for over half of these deaths; fever being a frequent accompanying symptom [4]. Among these, lower respiratory tract infections remain the leading

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cause of morbidity and mortality in children under five years of age [5]. Additionally, UTIs are commonly encountered in children, with at least one episode reported in 7.8% of girls and 1.7% of boys before the age of seven [6].

Antibiotic resistance further complicates the management of pediatric bacterial infections. A comprehensive analysis by Dharmapalan et al., which reviewed 1,179 studies, reported alarmingly high resistance rates to frequently used antibiotics, including ampicillin, gentamicin, and various cephalosporins. This widespread resistance to World Health Organization-recommended first-line therapies for neonatal and pediatric bloodstream infections across India highlights the urgent need for enhanced antibiotic stewardship, strengthened infection prevention and control strategies, and critical reassessment of existing treatment protocols [7]. Third-generation cephalosporins continue to play a pivotal role in the management of diverse pediatric infections. Cefixime, introduced in Canada in 1990, remains the only orally available third-generation cephalosporin in the country. It demonstrates robust activity against *Haemophilus influenzae*, *Moraxella catarrhalis*, and penicillin-susceptible *Streptococcus pneumoniae*, although it lacks effectiveness against *Staphylococcus aureus* [8]. Importantly, cefixime shows excellent in vitro effectiveness against *Neisseria gonorrhoeae, Moraxella catarrhalis*, and beta-lactamase-producing strains of *H. influenzae*, along with several Gram-negative bacilli such as *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis,* Salmonella, and Shigella species [9-11].

Cefixime's availability in a liquid formulation and its once-daily dosing regimen offer significant advantages in pediatric care. Although amoxicillin has shown superior effectiveness against pneumococcal otitis media, cefixime is often preferred in cases involving beta-lactamase-producing *H. influenzae* strains [11]. In patients with documented baseline pathogens, cefixime demonstrated a 94% clinical cure rate compared to 68% with cefaclor, highlighting its comparable, if not superior, effectiveness with the benefit of reduced dosing frequency [12]. Additionally, a study by Leigh involving 300 children reported complete symptom resolution in over 80% of those treated with cefixime oral suspension (100–300 mg once daily) and in 90% of those receiving amoxicillin (187–750 mg daily in three divided doses) [13].

In many parts of India and other developing countries, resistance to conventional oral agents such as amoxicillin, co-trimoxazole, and macrolides has become increasingly prevalent, particularly among Salmonella and Escherichia coli isolates. Empirical first-line use of these agents is therefore often ineffective in clinical practice. Cefixime, despite belonging to the third-generation cephalosporin class, continues to demonstrate favourable susceptibility profiles against key community-acquired pathogens, including Salmonella typhi, E. coli, and Haemophilus influenzae. Its broad coverage, convenient oral dosing, and good tolerability make it a practical empirical option in pediatric infections in India, where access to parenteral therapy or susceptibility-guided treatment may be limited [14-16]. Despite these promising clinical outcomes, there remains a lack of robust, large-scale real-world evidence (RWE) evaluating the effectiveness and safety of cefixime, particularly within pediatric populations. Further high-quality research is essential to substantiate its role in routine clinical practice and to guide evidence-based treatment decisions. Against this backdrop, the present multicenter, retrospective, real-world evidence study was undertaken to assess the clinical effectiveness and safety of cefixime in the management of pediatric bacterial infections.

Methods

Study Design

This multicentre, retrospective real-world evidence (RWE) study was carried out across multiple clinical centres in India, involving paediatric patients diagnosed with bacterial infection who presented to the OPD or were admitted to the IPD and were treated with cefixime 200 mg/5ml as per routine clinical practice.

Ethical considerations

The study was carried out in accordance with the Declaration of Helsinki, Good Clinical Practice (GCP), and Indian Council of Medical Research (ICMR) principles. Independent ethics committee approval was taken. No informed consent was required as it was a retrospective analysis of medical records.

Population

Children under 18 years of age diagnosed with bacterial infections and treated with cefixime 200 mg/5 mL suspension were eligible for inclusion if their medical records documented the initiation and completion of therapy, as well as any available post-treatment follow-up outcomes. Subjects with incomplete or missing data were excluded from the analysis.

Data collection

Data was collected from patients who were admitted to IPD or who visited OPD. The study used anonymized medical data of juvenile patients (≤18 years) diagnosed with bacterial infections and treated with cefixime 200 mg/5 mL oral suspension. The duration of cefixime therapy was established at the discretion of the treating physician based on standard clinical practice. Concomitant treatments and drugs were recorded. Data were collected at three critical assessment points:

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1. Assessment 1 at the beginning of therapy, including demographics, infection type, clinical presentation, prior antibiotic use, vitals, lab results, and microbiological data
2. Assessment 2 at the end of therapy, including treatment duration, symptoms, vitals, clinical outcomes, lab results, microbiological data and adverse events during treatment, and
3. Assessment 3 (if available) during post-therapy follow-up, 7-14 days after treatment, to capture relapse, clinical outcomes, vitals, lab results, and any secondary infections or adverse events.

Data entry was done by skilled site investigators using case report forms (CRFs), as each patient was given a unique anonymised ID. Missing or incomplete data submissions were clarified with investigators wherever feasible. Since the data were retrospective and anonymised, informed consent was not necessary.

Endpoints

The primary effectiveness endpoint was to assess the clinical cure (relief of infection symptoms and signs) and microbiological cure (absence of pathogen in follow-up specimens) among patients treated with cefixime for pediatric bacterial infection. The secondary endpoint was to evaluate the safety, the frequency and types of adverse events (AEs), and serious adverse events (SAEs).

Statistical Analysis

Statistical analysis results were reported as mean ± standard deviation (SD) or standard error (SE) for continuous variables and as frequencies or percentages for categorical variables. A p-value of <0.05 was considered statistically significant. Statistical analyses included Chi-square tests for comparing clinical cure rates (between Assessments 1 and 2) and for trend in microbiological cure rates (across three assessments). One-way ANOVA followed by Tukey's HSD post-hoc test (for $p < 0.05$) was used to compare group means. Safety outcomes (AEs/SAEs) were descriptively summarized due to low event frequency. Analyses were conducted using MS Excel 2019 and SPSS V20.

Results

Demographic Characteristics

A total of 6,768 pediatric patients were enrolled in this study. The mean age was 9.0 (3.4) years, with a clear male predominance (70.1%) compared to females (29.9%). The mean body weight and height were 27.02 (11.3) kg and 114.24 (23.1) cm, respectively. The median Body Mass Index (BMI) was 22.69 (14.6) kg/m². A detailed summary of demographic characteristics is provided in Table 1.

Table 1: Demographic characteristics of the patients

Parameters	Number of patients Mean (SD)
Age (years)	9.0 ± 3.4
Sex	
Male	4746 (70.1)
Female	2022 (29.8)
Height (cm)	114.2 ± 23.1
Weight (kg)	27.0 ± 11.3
BMI (In Kg/m²)	22.6 ± 14.6

Clinical Presentation

The most commonly reported presenting symptom was fever, observed in 91.8% of patients, followed by cough (11.7%), pain (9.6%), diarrhea (5.2%), vomiting (3.5%), headache (2.3%), and nausea (0.9%). These findings are illustrated in Figure 1. The symptoms often overlapped, with multiple symptoms present in individual patients.

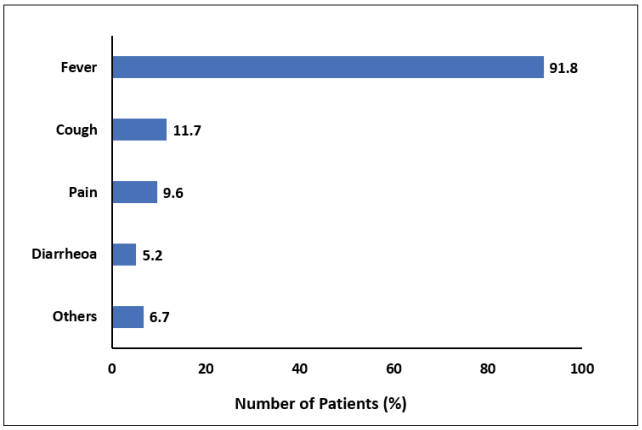

Figure 1: Symptomatic presentation of the patients
Others* Vomiting, Headache, Nausea

Microbiological Findings at Baseline

Microbiological culture results confirmed a range of bacterial pathogens at baseline. In this study, the most commonly diagnosed bacterial condition was typhoid fever (caused by *Salmonella typhi/paratyphi*), accounting for 59.4% of cases (n = 4,020). This was followed by gastroenteritis (e.g., *E. coli*, *Shigella*) at 16.9% (n = 1,145), bacterial bronchitis at 11.7% (n = 789), lower respiratory tract infections (LRTIs) at 5.9% (n = 402), otitis media at 3.5% (n = 234), and urinary tract infections (UTIs) at 2.6% (n = 178). Further distribution details are provided in Table 2.

Significant clinical improvement was observed over the course of treatment. The mean pulse rate decreased from 104.3 (11.8) beats per minute (bpm) at baseline to 91.2 (8.6) bpm by Assessment 2, and further to 84.7 (7.2) bpm by Assessment

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Table 2: Diagnosed Bacterial Conditions

Diagnosed Bacterial Condition	N	%
Typhoid Fever	4020	59.40%
Gastroenteritis	1145	16.90%
Bronchitis	789	11.70%
Lower Respiratory Tract Infection (LRTI)	402	5.90%
Otitis Media	234	3.50%
Urinary Tract Infection (UTI)	178	2.60%

Improvement in Vital Signs and Laboratory Parameters

3 (P < 0.0001). Similarly, the respiratory rate declined from 31.4 (6.5) breaths per minute at baseline to 23.6 (4.2) bpm at Assessment 2, and 19.8 (3.5) bpm at the final assessment (P < 0.0001). Body temperature also showed a significant reduction, decreasing from 102.2 (1.6) °F at Assessment 1 to 99.1 (0.8) °F by Assessment 2, and reaching 98.4 (0.6) °F at Assessment 3 (P < 0.0001). Oxygen saturation (SpO_2) improved from a baseline mean of 92.4% (4.3) to 95.8% (2.6) at Assessment 2, and further to 97.1% (1.8) by Assessment 3 (P < 0.0001), reflecting improved respiratory function and clinical recovery (Table 3).

Table 3: Vitals Data

Vital Sign	Mean	SD	LS Mean	95% CI	P Value (ANOVA)
Pulse (bpm)					
Assessment 1	104.3	11.8	104.2	103.9 – 104.5	–
Assessment 2	91.2	8.6	91	90.8 – 91.3	<0.0001*
Assessment 3	84.7	7.2	84.6	84.4 – 84.9	<0.0001*
Respiratory Rate (bpm)					
Assessment 1	31.4	6.5	31.3	31.0 – 31.6	–
Assessment 2	23.6	4.2	23.5	23.3 – 23.7	<0.0001*
Assessment 3	19.8	3.5	19.7	19.6 – 19.9	<0.0001*
Temperature (°F)					
Assessment 1	102.2	1.6	102.2	102.1 – 102.3	–
Assessment 2	99.1	0.8	99.1	99.0 – 99.2	<0.0001*
Assessment 3	98.4	0.6	98.4	98.3 – 98.5	<0.0001*
SpO_2 (%)					
Assessment 1	92.4	4.3	92.3	92.1 – 92.5	–
Assessment 2	95.8	2.6	95.7	95.6 – 95.9	<0.0001*
Assessment 3	97.1	1.8	97.1	97.0 – 97.2	<0.0001*

*- statistically significant as compared to assessment 1 in Tukey HSD Post-hoc Test

The mean white blood cell (WBC) count declined significantly from 14200 (3500.0) cells/µL at baseline to 9800 (2100.0) cells/µL by Assessment 2, and 7200 (1,400.0) cells/µL by Assessment 3 (P < 0.0001). C-reactive protein (CRP) levels, an indicator of systemic inflammation, showed a substantial decrease from 32.5 (14.7) mg/L at baseline to 14.2 (9.3) mg/L at Assessment 2, and 3.1 (2.4) mg/L by Assessment 3 (P < 0.0001). Elevated liver enzymes (SGPT and SGOT), noted at baseline, progressively normalized as treatment continued (Table 4).

Table 4: Laboratory Parameters

Parameter	Assessment 1 Mean (SD)	Assessment 2 Mean (SD)	Assessment 3 Mean (SD)	P Value (ANOVA)
WBC (cells/µL)	14200 (3500.0)	9800 (2100.0)	7200 (1400.0)	<0.0001
CRP (mg/L)	32.5 (14.7)	14.2 (9.3)	3.1 (2.4)	<0.0001
SGPT (U/L)	42.8 (16.1)	33.2 (12.9)	27.5 (10.6)	<0.0001
SGOT (U/L)	39.4 (14.2)	30.8 (11.1)	25.7 (9.4)	<0.0001
Serum Creatinine (mg/dL)	0.6 (0.2)	0.5 (0.1)	0.5 (0.1)	<0.0001

mean (SD), Assessment 2 & 3 were statistically significant as compared to assessment 1 in Tukey HSD Post-hoc Test

*- statistically significant as compared to assessment 1 in Tukey HSD Post-hoc Test

Effectiveness Endpoints

Clinical Cure Rate

A progressive and statistically significant increase in the clinical cure rate was observed over the study period. By Assessment 2, 77.4% (n=5,239) of patients achieved complete resolution of clinical signs and symptoms, as shown in Figure 2. By Assessment 3, all patients (100%) had fully recovered, with no residual symptoms (P < 0.0001), demonstrating the high therapeutic effectiveness of cefixime.

Microbiological Cure Rate

Microbiological clearance followed a similarly favourable trajectory. All patients were culture-positive at baseline; microbiological eradication reached 83.9% by EOT and 100% at follow-up (Figure 2). Initially, all patients had positive cultures for bacterial pathogens. *Salmonella typhi* was the most prevalent organism (59.4%), followed by *E. coli* and *Shigella* (16.9%), *Klebsiella* and *Streptococcus species* (11.7%), *Haemophilus influenzae* and *Streptococcus pneumoniae* (5.9%), *Staphylococcus aureus* and *Pseudomonas aeruginosa* (3.5%), and *E. coli/Klebsiella*-associated urinary tract infections (2.6%). The observed reduction in bacterial load was statistically significant (P < 0.0001), highlighting the robust bacteriological effectiveness of cefixime (Table 5).

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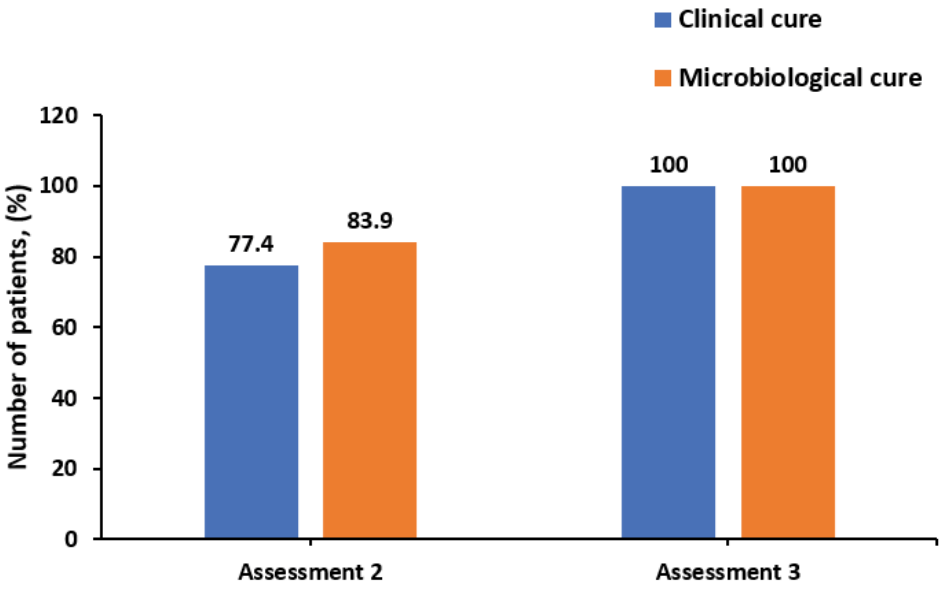

Figure 2: Clinical and microbiological cure rate

Table 5: Organisms reported in culture tests

Microbiological Parameter	Assessment 1	Assessment 2	Assessment 3
Bacterial Species Isolated (n, %)	6768 (100%)	1083 (16.0%)	0 (0%)
Salmonella typhi/paratyphi (Typhoid)	4020 (59.4%)	643 (9.5%)	0 (0%)
E. coli / Shigella (Gastroenteritis)	1145 (16.9%)	224 (3.3%)	0 (0%)
Klebsiella / Streptococcus (Bronchitis)	789 (11.7%)	103 (1.5%)	0 (0%)
H. influenzae / S. pneumoniae (LRTI)	402 (5.9%)	67 (1.0%)	0 (0%)
S. aureus / P. aeruginosa (Otitis Media)	234 (3.5%)	33 (0.5%)	0 (0%)
E. coli / Klebsiella (UTI)	178 (2.6%)	13 (0.2%)	0 (0%)

Duration of Treatment and Hospital Stay

The mean duration of cefixime therapy required to achieve both clinical and microbiological cure was 7.7 days, aligning with standard treatment recommendations for pediatric bacterial infections. Among hospitalized patients, the average length of stay was 1.32 days, reflecting the rapid clinical improvement and early discharge observed with cefixime treatment (Table 6).

Table 6: Duration of hospital stay

Endpoints	Assessment 2 Mean (SD)
Duration of treatment (Days)	7.7 ± 3.6
Duration of Hospital Stay	1.32 ± 2.27

Safety Outcomes

Cefixime demonstrated an excellent safety profile in the pediatric population studied. Only four patients (0.05%) reported mild, non-serious adverse events by Assessment 2, none of which required discontinuation of therapy or additional medical intervention. By Assessment 3, no adverse events were reported. Notably, no serious adverse events occurred at any point during the study, reaffirming the favourable tolerability of cefixime in children (Table 7).

Table 7: Safety Endpoints

Event	Assessment 2	Assessment 3
Adverse Events (AE)	4 (0.05%)	0 (0%)
Serious Adverse Events (SAE)	0 (0%)	0 (0%)

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Discussion

In this large-scale, retrospective study, cefixime demonstrated high clinical and microbiological effectiveness in the management of pediatric bacterial infections. By the final assessment, 100% of patients achieved complete clinical and microbiological cure, with statistically significant improvements observed in vital signs, inflammatory markers, and organ function parameters ($P < 0.0001$). The mean treatment duration was 7.7 days, with rapid symptomatic relief contributing to shorter hospital stays. Notably, cefixime exhibited an excellent safety profile, with only a minimal incidence of mild, self-limiting adverse events and no serious drug-related complications. Clinical trials in children report strong effectiveness (~97%) for common infections. A study by Nakayama et al. found that cefixime given at 4.4–11.6 mg/kg/day for 4–15 days achieved a 97% clinical effectiveness rate, with excellent tolerability and no lab abnormalities observed [18]. Another study by Nakazawa et al. demonstrated that doses ranged from 3 to 13.5 mg/kg/day, peak serum 1.75–3.36 µg/mL, and effectiveness in 97.1% of cases (respiratory & urinary infections) [16]. Microbiological cure at the end of therapy is a key endpoint in antimicrobial trials and is closely linked to improved long-term survival [19]. Clinical cure rate, defined as the proportion of patients with complete resolution of symptoms after treatment, is a key indicator of therapeutic effectiveness and its impact on patient outcomes [20, 21]. In this study, clinical cure improved significantly over time ($P < 0.0001$), with 77.4% cured by the second assessment and 100% by the final assessment. These findings are consistent with a large-scale study by Wu et al., in which 25,863 evaluable children with acute otitis media were treated with cefixime (8 mg/kg once daily for at least 10 days). At the end of therapy, 86% of patients were classified as either cured or improved [22]. In a study by Quintiliani et al., clinical success (defined as cure or improvement) was observed in 94% of cefixime-treated patients, compared to 79% in the amoxicillin–clavulanate group [23]. Further supporting these outcomes, an open, prospective study by Dreshaj et al. reported successful treatment outcomes in 100% (30/30) of patients with acute otitis media (AOM), 83.3% (10/12) with acute sinusitis, 100% (12/12) with pneumonia, and 88.6% (31/35) with uncomplicated urinary tract infections (UTI) [24].

Cefixime in oral form has been shown to improve compliance in pediatric patients. To further enhance acceptability, a study by Philip et al. developed fast-dispersing, taste-masked cefixime tablets that dissolve in minimal water, effectively addressing swallowing difficulties and improving adherence in children [25]. In addition to this, one more factor contributing to enhanced compliance among pediatric patients is the fewer doses aspect. Cefixime offers the advantage of maintaining therapeutic serum levels for up to 24 hours when administered once daily or in equally divided doses, thereby eliminating the need for three- or four-times-daily dosing required with older antibiotics [14]. Pediatric studies consistently demonstrate that adherence decreases as the number of daily doses increases. For instance, a Spanish multicentre study involving 2,244 children reported significantly better adherence with regimens requiring fewer than three daily doses [23]. Similarly, a population-based study further confirmed that adherence declines as the frequency of antibiotic dosing increases. These findings highlight cefixime as a preferable option for improving overall compliance and adherence in pediatric patients [24]. The overall average treatment course was 7.7 days, which is in line with the length advised by earlier literature as a standard for pediatric bacterial infections. Reduced hospital stays of just 1.32 days on average demonstrate the quick clinical response after the cefixime start and imply that cefixime can be a factor in lowered healthcare resource consumption [1]. The safety profile in this study was favourable, with only 0.05% of patients experiencing mild, self-limiting adverse events. This aligns with established data showing cefixime is well-tolerated, with transient gastrointestinal disturbances as the most common side effect. Prior studies, including Sudharsan et al., have also reported low toxicity and high tolerability in children [22]. Future research should address these limitations through prospective, controlled studies that include comparator antibiotic arms and longer follow-up durations. Pharmacokinetic and pharmacodynamic (PK/PD) evaluations in the pediatric Indian population would further help optimize dosing strategies for varying infection severities. Additionally, quality-of-life measures and patient-reported outcomes could be integrated into future studies to capture the broader impact of treatment on pediatric health and well-being.

As a retrospective observational study, the analysis was inherently subject to selection bias, missing data, and confounding factors that could not be fully controlled. The reliance on existing medical records meant that some key variables, such as adherence to therapy, severity grading of infections, and detailed microbiological resistance patterns, were not consistently captured across all sites. The study also lacked a comparative control arm with other standard antibiotics, which limits the ability to compare the relative effectiveness and safety profiles directly. Long-term outcomes beyond the 7–14-day post-treatment follow-up period were not assessed, restricting insights into late relapse or reinfection rates.

Conclusion

This multicentre, large-scale, real-world evidence study demonstrates cefixime to be an effective and well-tolerated treatment for paediatric bacterial infections in areas with high

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typhoid fever prevalence and emerging antibiotic resistance. The notable clinical and microbiological cure rates, substantial reductions in vital signs and inflammatory markers, combined with a very low rate of adverse events, reassert cefixime's position as a potential therapy. Its good safety profile, oral availability, and wide-spectrum activity make it an efficient option for both outpatient and inpatient use. Additional controlled trials are needed to solidify comparative effectiveness, but current evidence supports its ongoing use in evidence-based paediatric practice.

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