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Real-World Evidence on the Clinical Effectiveness and Safety of Faropenem in the Management of Paediatric Upper Respiratory Tract Infections: A Multicentre Retrospective Study

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ABSTRACT

Objectives: To evaluate real-world evidence on the clinical effectiveness and safety of faropenem in the management of upper respiratory tract infections (URTIs) in Indian paediatric patients.
Methods: This multicentre, retrospective study analyzed medical records of paediatric patients (≤12 years) treated with faropenem oral suspension for URTIs. Records with complete and evaluable clinical data were included. Data collected comprised type of URTI, prescribed and actual duration of therapy, dosage and dosing frequency, laboratory parameters such as white blood cell (WBC) count and C-reactive protein (CRP) levels (where available), clinical outcomes, and adverse events. Assessments were conducted at baseline and follow-up, and results were analyzed using descriptive statistics.
Results: A total of 965 records (673 males; 292 females) were evaluated, with a mean age of 7.65 ± 2.87 years. Diagnoses included undifferentiated URTI (n=648), acute otitis media (n=142), tonsillitis (n=81), pharyngitis (n=79), and acute sinusitis (n=15). The mean prescribed and actual treatment durations were 5.96 ± 1.83 and 5.87 ± 1.81 days, respectively. Faropenem was administered twice daily in 309 patients and thrice daily in 656 patients. Clinical cure was achieved in 505 patients (52.33%), while 460 (47.67%) showed improvement. Among patients with available laboratory data, elevated baseline CRP and WBC values normalized in the majority at follow-up (CRP: 88%; WBC: 84%). No major adverse events were reported.
Conclusion: Faropenem demonstrated excellent real-world effectiveness and safety in paediatric URTIs. Consistent clinical improvement and normalization of inflammatory markers support its role as a well-tolerated therapeutic option in this population.

Keywords: Oral carbapenem, Real-world data, Clinical outcomes, Inflammatory biomarkers

INTRODUCTION

URTIs, encompassing conditions such as AOM, pharyngitis, tonsillitis, and sinusitis, represent one of the most common reasons for paediatric medical consultations worldwide (1). These infections are a significant driver of antimicrobial prescribing in the community. While a large proportion of URTIs are viral and self-limiting, the difficulty in clinically distinguishing viral from bacterial etiologies, coupled with diagnostic uncertainty, often leads to the empirical prescription of antibiotics (2). This practice is a primary contributor to the escalating crisis of antimicrobial resistance (AMR). The global burden of bacterial AMR is substantial, and it has been estimated to be associated with millions of deaths annually, with the highest burden often found in low- and middle-income countries (3).

Pathogens commonly responsible for bacterial URTIs, such as *Streptococcus pneumoniae* and *Haemophilus influenzae*, have demonstrated increasing resistance to first-line agents like amoxicillin and macrolides. This trend threatens the effectiveness of standard empirical therapies, making it necessary for a careful evaluation of alternative treatment options. Faropenem, an oral carbapenem, is a beta-lactam antibiotic with a broad spectrum of in-vitro activity. It is structurally distinct from other penems and demonstrates stability against many beta-lactamases, including extended-spectrum beta-lactamases (4). Its activity covers common respiratory pathogens, including penicillin-resistant S. pneumoniae, making it a potentially valuable option in regions with high rates of resistance or for infections that have not responded to first-line agents (5).

Despite its availability and theoretical advantages, there is a distinct gap between the data from controlled clinical trials and its actual utility in routine clinical practice. Real-world evidence (RWE) is essential for understanding the effectiveness and safety of an antibiotic in a heterogeneous patient population, reflecting diverse clinical diagnoses, prescribing patterns, and adherence. This need is particularly acute in India, which faces a unique and severe AMR landscape (6). To date, there is a scarcity of large-scale, multicentre RWE studies evaluating faropenem's use for paediatric URTIs specifically within the Indian context. Therefore, the present study was conducted to evaluate the real-world clinical effectiveness and safety of faropenem in the management of URTIs in a large, multicentre group of Indian paediatric patients.

MATERIALS & METHODS

This was a multicentre, retrospective, RWE study conducted in India. The study involved the evaluation of medical records of paediatric patients (aged ≤12 years) who were prescribed faropenem oral suspension for the management of URTI.

Medical records were sourced from multiple centers. To be included in the analysis, records were required to have complete and evaluable clinical information regarding the patient's diagnosis, treatment and follow-up.

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, acute sinusitis, or undifferentiated URTI), treatment details including prescribed faropenem dosage, dosing frequency (twice or thrice daily), prescribed and actual duration of therapy, laboratory parameters such as WBC count and CRP levels at baseline and follow-up where available, clinical outcomes assessed at the follow-up visit, and any adverse events reported during or after the treatment period.

Endpoints

The primary endpoints were the clinical outcomes at the follow-up evaluation, which were categorized as 'cure' (complete resolution of signs and symptoms) or

'improvement' (partial resolution of signs and symptoms).

Secondary endpoints included the change in inflammatory markers (WBC count and CRP levels) from baseline to follow-up and the overall safety and tolerability of faropenem, as determined by the incidence and nature of 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 URTI, dosing frequency, and clinical outcomes (cure/improvement), were presented as frequencies and percentages (n, %). The normalization of laboratory parameters (WBC and CRP) at follow-up was also calculated as a percentage for whom baseline and follow-up data were available.

RESULT

Study Population and Baseline Characteristics

A total of 965 patient medical records were evaluated and included in the final analysis, comprising 673 males (69.74%) and 292 females (30.26%). The mean age of the participants was 7.65 ± 2.87 years. The mean weight was 26.84 ± 13.40 kg, while the mean height was 119.88 ± 14.48 cm, reflecting the overall anthropometric profile of the group (Table 1).

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

Table 1: Demographic characteristics

Parameter		Number	Percentage
Gender	Male	673	69.74%
	Female	292	30.26%
		Mean	**Standard deviation**
Age (in years)		7.65	2.87
Weight (in kg)		26.84	13.40
Height (in cm)		119.88	14.48

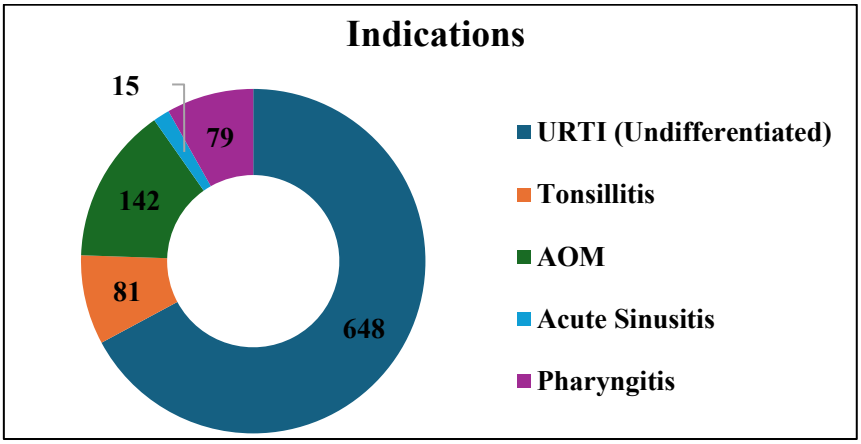

Figure 1: Indications of Faropenem

Treatment Details

The prescribed duration of faropenem therapy showed a narrow range and close alignment with the actual duration of treatment, suggesting high patient adherence. The mean prescribed duration was 5.96 ± 1.83 days, while the mean actual duration of therapy was 5.87 ± 1.81 days. Regarding dosing frequency, n=309 patients received faropenem twice daily (BD), and n=656 patients received it thrice daily (TID) as shown in Fig. 2.

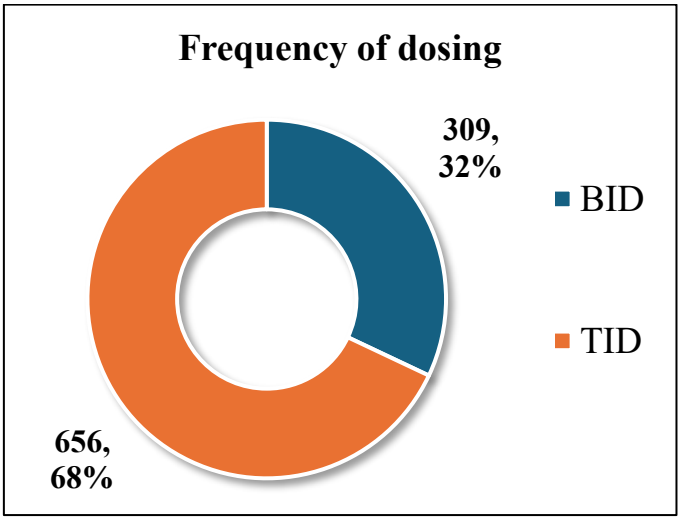

Figure 2: Frequency of oral Faropenem dosing

Clinical Effectiveness (Primary Endpoint)
Faropenem demonstrated high effectiveness in the real-world setting, achieving either complete cure or significant improvement in all patients (100%). Specifically, the clinical outcomes at the follow-up evaluation were as the following (Fig. 3):

- Cure (complete resolution of signs and symptoms): n=505 (52.33%)
- Improvement (partial resolution of signs and symptoms): n=460 (47.67%)

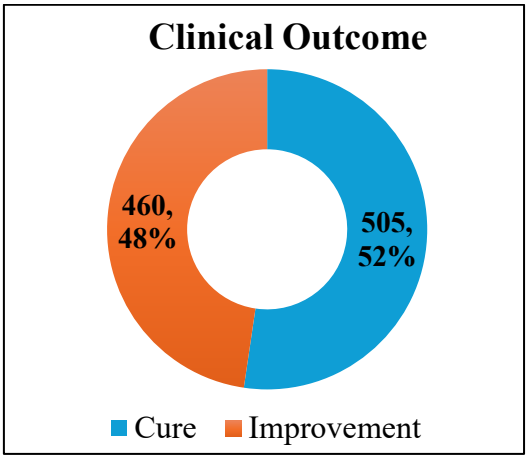

Figure 3: Clinical effectiveness in terms of outcomes

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:** Baseline CRP levels were available for 120 patients, of which 106 (88.3%) had elevated values and 14 were within the normal range. At follow-up, CRP data were available for 101 patients; 89 (88.1%) were within the normal range, while 12 remained elevated, with the mean CRP level reducing significantly to 5.53mg/L.
- **White Blood Cell Count:** Baseline WBC counts were available for 171 patients, with 154 (90.1%) showing elevated counts and 17 within the normal range. At follow-up, WBC data were available for 94 patients; 79 (84%) had normalized counts, and 15 remained elevated.

Table 2: Inflammatory Marker Changes

	Baseline			Follow-up		
Parameter	**(n)**	**Raised Count**	**Normal Range**	**(n)**	**Raised Count**	**Normal Range**
CRP (mg/L)	120	106	14	101	12	89
WBC Count	171	154	17	94	15	79

Safety and Tolerability (Secondary Endpoint)

- Faropenem was well-tolerated across the study population. The medical records indicated that no major adverse events were reported during or after the treatment period in any of the 965 patients.

DISCUSSION

The present multi-centre, retrospective real-world evidence (RWE) study demonstrates that faropenem is highly effective and well-tolerated in the management of paediatric URTIs, including AOM, tonsillitis, pharyngitis, and sinusitis. The observed clinical cure rate of 52.3% and improvement in 47.7% of patients aligns with previously reported efficacy rates of oral faropenem in paediatric respiratory infections, which range from 90–94% in controlled clinical settings (7,8). These findings reinforce faropenem's role as a potent oral β-lactam antibiotic within the penem class, offering broad-spectrum coverage against Gram-positive and Gram-negative pathogens, including β-lactamase–producing strains (9).

Faropenem's unique pharmacological profile—high oral bioavailability and stability against β-lactamases—addresses a critical gap in paediatric antimicrobial therapy, particularly in regions with rising resistance to conventional agents such as amoxicillin-clavulanate and macrolides (10). In vitro studies have consistently demonstrated faropenem's activity against penicillin-resistant *Streptococcus pneumoniae* and *Haemophilus influenzae*, common URTI pathogens (9,11). Clinical trials in Japan and India have reported cure rates exceeding 90% for URTIs and otitis media, with minimal adverse events (12,13). Our findings corroborate these results in a real-world Indian setting, suggesting that faropenem maintains efficacy outside controlled trial environments.

The normalization of CRP and WBC counts in 84–88% of patients further substantiate the clinical effectiveness of faropenem. CRP is a well-established biomarker for monitoring infection resolution, and its rapid decline post-therapy is associated with favourable outcomes (14,15). In our study, mean CRP levels decreased from 50.67 mg/L at baseline to 5.53 mg/L at follow-up, indicating robust anti-infective activity. This trend mirrors previous observations where CRP-guided antibiotic therapy correlated with improved clinical outcomes and reduced treatment duration (16).

No major adverse events were reported, consistent with earlier studies where faropenem exhibited an excellent safety profile, with only mild gastrointestinal disturbances such as diarrhoea occurring in <10% of cases (12,9). This tolerability is particularly relevant in paediatric populations, where adherence and palatability significantly influence therapeutic success.

The findings have important implications for antimicrobial stewardship in India. Current Indian Academy of Pediatrics (IAP) guidelines recommend judicious antibiotic use for URTIs, reserving broad-spectrum agents for confirmed bacterial infections (17). Faropenem's efficacy against resistant pathogens and favourable safety profile position it as a viable alternative when first-line therapies fail or resistance is suspected. However, its use should be guided by local resistance patterns and clinical judgment to mitigate the risk of resistance development, particularly cross-resistance to carbapenems (4).

A key strength of this study is its large sample size (n=965) and inclusion of diverse URTI subtypes, enhancing generalizability. However, limitations include its

retrospective design, lack of microbiological confirmation, and incomplete laboratory data for all patients. Prospective, randomized controlled trials comparing faropenem with standard first-line agents are warranted to validate these findings and assess cost-effectiveness.

Future research should focus on evaluating faropenem's role in antimicrobial stewardship programs, monitoring resistance trends and potential cross-resistance to carbapenems, and exploring CRP-guided therapy protocols to optimize treatment duration and reduce unnecessary antibiotic exposure.

CONCLUSION

In summary, this study demonstrates that faropenem is highly effective and safe for the management of paediatric URTIs in the real-world Indian clinical setting, providing a critical therapeutic option in the face of escalating AMR.

Declaration by Authors

Ethical Approval: Approved

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Conflict of Interest: Author no. 4, 5, 6, & 7 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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