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EVALUATING THE SAFETY AND EFFECTIVENESS OF CEFUROXIME IN INDIAN PATIENTS: A REAL WORLD MULTICENTER RETROSPECTIVE STUDY

Medical Science

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ABSTRACT

Objective: To evaluate the use of cefuroxime in the management of various bacterial infections and provide insights into the overall use of the drug across different anatomical sites and pathogens. **Methods:** The observational, multi-center, retrospective study collected data from 5,313 patients across 267 centers presenting with bacterial infections including upper respiratory tract infections, lower respiratory tract infections, skin and soft tissue infections, urinary tract infections, intra-abdominal infections, or bone infections managed with cefuroxime. **Results:** Upper respiratory tract infections were the most frequently reported infections (32.71%), followed by lower respiratory tract infections (17.9%) and skin and soft tissue infections (17%). Pain was present in 27.20% of cases, followed by fever (20.63%) and cough in 13.42% of the patients. The average duration of treatment was 7.39 days. Out of the total cohort, 71.85% of patients (n = 3,817) experienced the resolution of their symptoms, and 93.92% of the study population did not experience any adverse events. The average time to symptom improvement was 4.92 days. Gram-positive bacteria were the most prevalent cause of infection, detected in 36.97% of the cases. **Conclusion:** Cefuroxime is a well-established, safe, and effective treatment for a wide range of infections. It demonstrates a rapid and high rate of symptom resolution.

KEYWORDS

cephalosporins, infection, respiratory tract infections, urinary tract infection

INTRODUCTION

Bacterial infections, which continue to be a significant cause of mortality, present a substantial global health burden.[1] Although the threats posed by infectious diseases have been recognized for centuries, their impact has become increasingly prominent in recent decades, as they are now identified as a leading contributor to health loss worldwide. The recent Global Burden of Diseases report published in 2022 reported approximately 13.7 million mortalities due to infections in 2019.[2] Among these, 7.7 million deaths were attributed to 33 common bacteria. Over 2 million deaths occurred due to lower respiratory tract infections (LRTI) and blood infections, while 1 million died due to intra-abdominal infections (IAI) and peritoneal infectious syndromes. [2] Therefore, lowering the incidences of mortality due to contracting infections is fundamental to achieving health equity, particularly due to the disproportionate burden of infections in low- and middle-income countries (LMICs) compared to their developed counterparts.[3,4]

Infections acquired due to bacterial pathogens are generally easy to treat as compared to viral and parasitic infections. However, treating bacterial infections is becoming challenging due to extensive bacterial resistance to existing treatments.[5]Treatments with antibiotics remain the mainstay of infection management. The emergence of antibiotic-resistant microorganisms complicates patient treatment and necessitates ongoing evaluation of antibiotic efficacy.[6]

To combat this challenge, antibiotics that are effective against both gram-positive and negative bacteria play a crucial role in infection control. One such antibiotic is cefuroxime, a second-generation cephalosporin with a broad spectrum activity against gram-positive and negative bacteria.[7] The mechanism of action of cefuroxime includes the inhibition of bacterial cell wall synthesis, preventing bacterial proliferation. [7] After regulatory approval of cefuroxime in 1988, the drug was widely adopted by physicians in managing infections arising in various anatomical locations, such as the lungs, respiratory tract, digestive tract, urinary tract, muscles, bones, dermal cells, and soft tissues.[8,9] Cefuroxime is effective in preventing post-surgical sepsis across a range of procedures, including cardiac, gynecologic, orthopedic, dental, vascular, and general surgeries.[6,10] Cefuroxime remains a valuable drug in both preventive and therapeutic medicine.

Additionally, cefuroxime use carries a minimal risk of severe anaphylactic reactions, altered blood parameters, elevated liver enzymes, and the potential for antibiotic resistance.[11,12,13]

There are limited studies assessing the real-world safety & effectiveness of cefuroxime in Indian Patients, despite its widespread use in India. Therefore, the aim of the present real-world study is to evaluate the use of cefuroxime in the management of various bacterial infections and provide insights into the overall use of the drug across different anatomical sites and its effectiveness against different microorganisms.

Methods

Study design and population:

The present study employed an observational, multi-center, retrospective study design to collect patient data across diverse geographical locations in India. Retrospective collection of electronic medical records of patients was performed for those fulfilling the inclusion criteria. The inclusion criteria were: 1) Patients of all ages diagnosed with upper respiratory tract Infections (URTI), lower respiratory tract infections (LRTI), skin and soft tissue infections (SSTI), urinary tract infections (UTI), intra-abdominal infections (IAI), or bone infections, 2) Patients who received cefuroxime as monotherapy or as part of combination therapy, and 3) patients whose medical records were available for review. The exclusion criteria were: 1) Patients with incomplete medical records, 2) Patients with known allergies to cefuroxime or other cephalosporins.

Data Collection

Patient data was collected from patient health records present across 267 healthcare institutes from March 2024 to Dec. The data was extracted from the medical records by physicians. Collected data included patient demographics like age, gender, and existing comorbidities. Clinical data of the patient included primary diagnosis at admission, type of infection, severity and manifestation of the infection upon hospital admission, microbiology results for patients undergoing microbiological assessment of samples, treatment regimen encompassing dosage and duration, clinical response to the therapy, and reported adverse events associated with cefuroxime.

Data Analysis

Descriptive statistics were used to summarize demographic and clinical characteristics, providing a comprehensive overview of the patient population. Continuous variables, such as age and treatment duration, were analyzed using means and standard deviations, while categorical variables, including gender and diagnoses, were summarized using frequencies and percentages. All statistical analyses were performed with a 95% confidence interval, and p-values less than 0.05 were considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the life Point Research Ethics Committee, Pune (ECR/751/MH/2015/RR-21). Patient confidentiality was maintained throughout the study, and informed consent was waived due to the retrospective nature of the research.

RESULTS

Patient demographics

The cohort consisted of 5,313 patients with a significant male predominance, as 70.39% (n = 3,740) were male and 29.61% (n = 1,573) were female. The mean age of the patients was 47.3 years.

Several patients presented with comorbid conditions. The most prevalent comorbidity was diabetes, affecting 13.33% (n = 708) of the cohort. Hypertension was observed in 9.30% (n = 494) of patients. Other conditions included asthma (0.51%, n = 27), coronary artery disease (CAD) (0.40%, n = 21), hypothyroidism (0.21%, n = 11), dyslipidemia (0.15%, n = 8), cardiovascular disease (CVD) (0.11%, n = 6), gastroesophageal reflux disease (GERD) (0.11%, n = 6), cancer (0.04%, n = 2), and chronic kidney disease (CKD) (0.04%, n = 2).

Clinical presentation at admission

The primary diagnoses at admission included various infections (Table 1). URTIs were the most common, accounting for 32.71% (n = 1,738) of all admissions. LRTIs were the second most frequent diagnosis in 17.90% (n = 951) of the study population. SSTIs were diagnosed in 17.03% (n = 905) of patients, followed by UTIs in 15.47% (n = 822), and bone infections in 12.23% (n = 650). Intra-abdominal infections (IAI) were less common and diagnosed in 4.65% (n = 247) of the cases.

Patients presented with a range of symptoms upon admission (Table 1). Pain was the most commonly reported symptom, present in 27.20% (n = 1,445) of cases. Fever was also a frequent symptom, occurring in 20.63% (n = 1,096) of patients, followed by cough in 13.42% (n = 713). Other symptoms were less common, with a sore throat, cold, and headache reported in smaller numbers. Dyspnea and vomiting were rare symptoms, affecting only 0.19% and 0.04% of the cohort, respectively.

Table 1: Clinical presentation at admission

Diagnoses at admission	**n**	**%**
URTI	1738	32.71%
LRTI	951	17.90%
SSTI	905	17.03%
UTI	822	15.47%
Bone Infection	650	12.23%
IAI	247	4.65%
Symptoms at admission	**n**	**%**
Pain	1445	27.20%
Fever	1096	20.63%
Cough	713	13.42%
Sore throat	149	2.80%
Cold	96	1.81%
Headache	53	1.00%
Dyspnoea	10	0.19%
Vomiting	2	0.04%
	Mean	**SD**
Duration of treatment (in days)	7.39	4.33

Severity of symptoms and duration of treatment

The severity of symptoms was categorized as mild, moderate, or severe. A majority of the patients, 44.10% (n = 2,343), presented with moderate symptoms. Mild symptoms were seen in 40.02% (n = 2,126) of the patients, while 15.89% (n = 844) had severe symptoms. This distribution highlights that the majority of the patients experienced either mild or moderate symptoms, with a smaller subset dealing with severe manifestations of their illness.

The average duration of treatment was 7.39 days (SD = 4.33), indicating a moderate length of care required for most patients. The range of treatment durations suggests variability in patient recovery times depending on the nature and severity of the infection.

Symptom resolution

Out of the total cohort, 71.85% of patients (n = 3,817) experienced resolution of their symptoms.

The average time to symptom resolution after administration of cefuroxime was 4.92 days (SD = 2.78). The most common periods of cefuroxime intake leading to symptom improvement were 5 days (29.53%, n = 1,569) and 7 days (22.38%, n = 1,189) (Table 2). Approximately 20.89% (n = 1,110) of patients observed an improvement by the 3rd day. This reflects a relatively quick response to treatment for a substantial portion of the cohort.

Table 2: Time to symptom resolution post-initiation of cefuroxime

	Mean	**SD**
Time to symptom improvement (days)	4.92	2.78
	n	**%**
1	172	3.24%
2	654	12.31%
3	1110	20.89%
4	268	5.04%
5	1569	29.53%
7	1189	22.38%
10	216	4.07%

Adverse events:

Adverse events (AEs) were reported in 6.08% (n = 323) of the cohort, while 93.92% (n = 4,990) did not experience any adverse events. Most common adverse events were Gastrointestinal disturbances including nausea/vomiting (n=79), diarrhea (n=7), stomach ache (n=8), headache (n=7) and fewer injection site reactions (n=13) like rash, pruritus.

Microbial testing results:

Microbial testing were done for 248 samples identified various pathogens (Table 3). Gram-positive bacteria being the most prevalent, detected in 71.77% (n =178) of cases. The most commonly isolated pathogen was Staphylococcus aureus (38.30%, n = 95), Streptococcus pneumoniae (28.63%, n=71) and Escherichia coli (14%, n=35). Other less frequently detected pathogens included Haemophilus influenzae in 15 patients (6%), and pseudomonas in 15 patients (6%).

Table 3: Microbial testing result identifying the causative pathogen (n= 248)

Microbiological results	**n**	**%**
Gram-positive bacteria	**178**	71.77%
Staphylococcus aureus	95	38.30%
Streptococcus pneumoniae	71	28.63%
Klebsiella pneumonia	12	4.83%
Gram-negative bacteria	**70**	28.22%
Escherichia coli	35	14.11%
Haemophilus influenzae	15	6%
Pseudomonas	15	6%
Salmonella	5	2 %

DISCUSSION

The present study was a retrospective study assessing the safety and efficacy of cefuroxime against bacterial infections among Indian patients presenting with infections at different anatomical locations. Upper respiratory tract infections and lower respiratory tract infections accounted for the majority of the admissions, with clinical manifestations of pain and fever in the patients. Microbial testing revealed that Gram-positive bacteria, particularly Staphylococcus aureus was the causative agent for the infections. A significant proportion of the population reported mild or moderate severity of symptoms. Furthermore, most of the patients experienced resolution of their symptoms by the between 3rd and 7th day following the administration of cefuroxime. Only a few patients encountered cefuroxime-related adverse events, indicating well-tolerability in most of the patients. The short average duration of treatment and rapid symptom resolution with cefuroxime reflects the drug's prompt efficacy in patients.

The most common types of infection were identified as LRTI, URTI, and UTI in the present study population. The guidelines of the American Thoracic Society (ATS) recommend cefuroxime as an appropriate therapeutic option for managing acquired pneumonia in adults.[14] A study compared the efficacy of levofloxacin and cefuroxime in acute exacerbation of chronic obstructive pulmonary arising due to respiratory pathogens in South Korean patients. Within the cefuroxime-treated cohort, 90.6% of the patients were successfully treated, with a similar rate of infection resolution in the levofloxacin-treated group (90.4%).[15] An American real-world retrospective study assessed the clinical efficacy and safety of cefuroxime in UTI patients. The study reported that 98% of the patients achieved complete clinical resolution, with a rate of UTI recurrence of 16%. The adverse event incidences were also limited with a few patients encountering antibiotic-resistant pathogens.[16]

Cefuroxime is particularly beneficial in the treatment of UTIs arising

due to Escherichia coli and Klebsiella pneumonia which are susceptible to the drug.[17] According to Omele et al. (2024), cefuroxime is indicated for the treatment of LRTI frequently caused by pathogens such as Staphylococcus aureus, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, and Klebsiella species.[18] However, a recent study conducted by Mao et al. (2022) reported antibiotic resistance of various LRTI-causing bacteria against cefuroxime.[19] The retrospective study observed low susceptibility of Escherichia coli, Serratia species, and Citrobacter species towards cefuroxime, indicating a high risk of cefuroxime resistance.[19] Therefore, the administration of cefuroxime after determining the causative agent for LRTIs is recommended, ensuring bacterial susceptibility and reducing the risk of treatment failure.

While Intra Abdominal Infections (IAI) was the least frequently reported type of infection in the present study, existing literature provides strong evidence for the use of cefuroxime in IAI.[20,21] Furthermore, the Surgical Infection Society (SIS) guidelines concluded that while this cefuroxime remains appropriate for managing low-risk patients with community-acquired IAI, other treatment options supported by more recent evidence should be preferred.[24] This highlights the lack of clinical translation of cefuroxime in IAI due to limited evidence.

The mean duration of treatment was 7.39 days with mean symptom resolution time observed as 4.92 days. Other studies have reported a higher duration of cefuroxime treatment. Furthermore, studies have reported similar clinical outcomes of cefuroxime 5-day therapy compared to a 10-day regimen.[25] Therefore, cefuroxime demonstrates fast symptom resolution potentially reducing hospitalization days. The study findings suggest good safety profile safety of cefuroxime, with adverse events occurring in only 6% of the patients.

The study retrospectively analyzed data from 5313 patients across multiple Indian institutions, providing real-world clinical insights. Given the limited efficacy and safety data on cefuroxime in India, this large cohort and diverse infection types enhance the study's relevance and generalizability. However, several limitations must be noted. The absence of a comparator arm, especially against newer third-generation cephalosporins, restricts comparative efficacy analysis. Additionally, factors like patient adherence, prior antibiotic use, and specific cefuroxime doses were not accounted for, limiting the depth of insights. Furthermore, studies must focus on susceptibility of various bacteria against cefuroxime to identify optimal targets.

CONCLUSION

Cefuroxime is a safe and effective treatment for various respiratory, skin and soft tissue, urinary tract and bone infections, demonstrating a high symptom resolution rate. Its short treatment duration facilitates rapid recovery, potentially reducing hospitalization duration stay in Indian patients.

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