Indian Journal of Health Care, Medical & Pharmacy Practice (Vol 7, Issue 2, July-December 2026)
Home page of the journal: https://ijhmp.com/Home

Research Article

ASSESSMENT OF CEFTRIAXONE-SULBACTAM THERAPY IN HOSPITALIZED PATIENTS; TREATMENT OUTCOMES AND ADVERSE DRUG EVENT IN TERTIARY CARE HOSPITAL BATHINDA

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DOI: https://doi.org/10.59551/IJHMP/25832069/2026.7.2.158

How to cite this article: Rai KmA, Dar MM, Singh A et al. Assessment of Ceftriaxone-Sulbactam Therapy in Hospitalized Patients; Treatment Outcomes and Adverse Drug Event in Tertiary Care Hospital Bathinda. *Indian J. Health Care, Med. Pharm. Pract.* 2026;7(2):385-392.

Received: 03 Aug, 2026, Decision for Acceptance: 19 Sept, 2026

ABSTRACT

Background: Antimicrobial resistance (AMR) is an increasing global problem that makes the treatment of infections with traditional antimicrobials less effective. The clinical efficacy and safety of ceftriaxone–sulbactam treatment was evaluated in hospitalized patients.

Methods: A prospective observational hospital based study was done at Adesh Hospital, Bathinda with 113 adult inpatients on ceftriaxone–sulbactam therapy for a period of 3 months. Demographic, clinical, treatment, response, and adverse drug events (ADEs) were recorded. The data were analyzed by descriptive statistics and chi square test.

Results: The majority of patients (68.1%) were treated for 3-7 days. The overall success rate for ceftriaxone–sulbactam therapy was 76.1% (highly effective), 20.4% (effective), and 3.5% (partial success). There was a significant association between the duration in treatment and effectiveness ($p < 0.05$). Of patients, 33.6% improved within 48–72 hours and 43.4% improved after 72 hours. During treatment, no patient needed further antibiotic treatment. The most common clinical indication was cholelithiasis (34.5%).

Conclusion: In the hospitalized population, ceftriaxone–sulbactam was shown to be clinically effective and well tolerated, and experienced a low rate of mild ADEs. Further studies of larger size with microbiological and antimicrobial susceptibility data are warranted to confirm the findings and to provide a rational approach to antimicrobial use.

KEYWORDS: Ceftriaxone, Sulbactam, Combination Therapy, Antimicrobial Resistance, β-lactamase Inhibitor, Clinical Efficacy, Hospital-acquired Infections, Multi-drug Resistant Organisms.

Introduction

Ceftriaxone is a third-generation cephalosporin antibiotic of the β-group of antibiotics known as β-lactam antibiotics which are used in the treatment of different bacterial infections because of its broad spectrum and good pharmacokinetics characteristics[1]. It has a bactericidal effect by covalently attaching to penicillin-binding proteins (PBPs), which are enzymes that link the peptidoglycan chains required to construct bacterial cell-walls. The blocking of PBPs prevents

the formation of cell-walls, resulting in cell lysis and the death of bacteria[2].Sulbactam is a β-lactamase inhibitor which augments the impact of Beta-lactam antibiotics by suppressing the manifestation of the Beta-lactamase enzymes (disintegrating Beta-lactam antibiotics)[3]. This suicide inhibition is useful in protecting partner Beta-lactam drugs such as ceftriaxone against enzyme degradation. Sulbactam is intrinsically weak against some bacteria[4]. Ceftriaxone has a good tissue penetration and is highly bound to proteins and is excreted through both urine and bile with a long half-life that allows single-dose therapy in most of its indications[5]. Combination products that contain Sulbactam have much higher Ceftriaxone peaks than Sulbactam peaks and Ceftriaxone plasma half-life is longer than sulbactam plasma half-life[6].

Ceftriaxone combined with sulbactam has been suggested as a plan to surpass extended-spectrum β-lactamase (ESBL) mediated resistance and enhance clinical efficacy among hospitalized patients[1].It has a wide-spectrum gram-negative effect, *including Escherichia coli and Klebsiella pneumonia,* as well as a gram-positive activity against a number of gram-positives including *Streptococcus pneumonia and methicillin-susceptible Staphylococcus aureus*[3].Ceftriaxone has a great clinical usefulness in the treatment of community-acquired pneumonia, Urinary Tract Infections, Tract Infections, intra-abdominal infections because of its high activity against *Enterobacteriaceae* and respiratory pathogens[4].Integration of Sulbactam and Ceftriaxone has been suggested as a solution to overcome extended-spectrum β-lactamase (ESBL) mediate resistance and enhance clinical outcome amongst hospitalized patients[1].

It is also important to understand the adverse drug events related to the use of antibiotic therapy as antibiotics like Ceftriaxone have established hematologic and hepatic side effects when administered at higher dosages[7].With the growing risk of antimicrobial resistance and an increase in the use of β-lactam/ β-lactamase inhibitor combinations in tertiary care hospitals, the need to determine actual effectiveness and safety outcomes in hospitalized patients is urgent[3,8].Ceftriaxone/sulbactam, which had been reported as in a multicentre clinical study clinical cure rates (~39.5) and bacterial eradication rates (~83.6) were similar to those of cefoperazone/sulbactam in respiratory and urinary infections[9].

This had been mentioned within a review carried out by[10], which had indicated that β-lactam/ β-lactamase inhibitor combinations, including sulbactam-containing regimens, might pose a risk to mild injection-site reactions and reversible liver enzyme increase but tend to have a favorable safety profile[10]. A different review had also noted that Ceftriaxone can lead to the presence of biliary sludge (pseudolithiasis), especially when used in high doses or over a long duration of treatment, although the complication is generally reversible with the Ceftriaxone being used[11]. Retrospective clinical trials had also been carried out to determine the effectiveness and safety of Ceftriaxone-Sulbactam combinations, yet data regarding the results of the treatment and drug safety events has not been examined extensively and thus need to be studied further[12]. With the above in mind, the current study was done to determine the effectiveness of Ceftriaxone-sulbactam therapy in hospitalized patients, treatment outcomes, and adverse drug events in a tertiary care hospital.

Material and Methods

This hospital-based prospective observational study was conducted at Adesh Hospital Bathinda after the approvals from College Research Committee (CRC) and Ethical Research Committee of Biomedical and Health Research, Adesh University.

Data was collected from inpatient Department (IPD) of General Medicine, General Surgery and Orthopedics patients being treated with Ceftriaxone-Sulbactam. Data was collected from the patients using data collection form and a self-prepared questionnaire afterproper written consent

Inclusion and Exclusion Criteria

Patients above 18 years of age who were treated with Ceftriaxone-Sulbactam for infections were included in the study where as patient already taking any other antibiotics were excluded from the study.

Sample Size (n): The sample size was determined using Slovin's formula, yielding a final sample size of 113based on the estimated population and selected margin of error. Consequently, 113 eligible patients were included in the study to ensure robustness, representativeness, and reliability of the findings.

$$\text{Sample size } \mathbf{(n)} = \frac{N}{1+N(\alpha)^2}$$

- Imposing of Slovin's formula is due to awareness of population size.

Distribution of Taken Sample Size

In the present study a total of 113 subjects were included for the assessment of Ceftriaxone-sulbactam therapy outcome. Out of total 113 participants 65 (57.5%) were male, and 48 (42.5%) were female. The highest number of patients 43 (38.1%) was from 57-69 years of age group followed by the age group of 44-56 years 34 patients (30.1%), 31-43 years 28 patients (24.8%) and 8 (7.1%) patients from 18-30 years of age group respectively.

Out of the total population, 4 (3.5%) patients had a previous medical history, whereas 109 (96.5%) patients had no previous medical history. Out of the total population, 4 (3.5%) patients had a previous history of sepsis, whereas 109 (96.5%) patients had no history of sepsis.Out of the total population, in this study, none of the participating patients had having history of known Drug Allergy as

shown in Table 1.

Distribution of Dose Prescribed and Duration of Treatment

Out of total 113 participants;6 (5.3%) patients were given dose of 1-2g/day and 107 (94.7%) participants were given dose>2g/day. Out of total 113 participants12 (10.6%) patients were admitted for <3 days, 77 (68.1%) patients were admitted for 3-7 days, , 21 (18.6%) patients were admitted for 7-14 days, and 3 (2.7%) patients were admitted for >14 days as shown in Table 2.

Distribution of Severity of Reported ADE

The severity of the ADE resulted due to the ongoing Ceftriaxone-Sulbactam Therapy was noted Out of 113 participants, 4 (3.5%) patients were detected with very mild ADE (Diarrhea, Rashes on forearm, Nausea, Fever), whereas no ADE was reported in 109(96.5%).

Distribution of Time Taken to Observe Clinical Improvement

As a whole, 113 subjects were included in this study for the assessment of Ceftriaxone-sulbactam therapy outcome. Participants were divided into 4 groups, Based on the Time taken to observe clinical improvement with the ongoing ceftriaxone-sulbactam therapy participants were divided into 4 groups (<24 hours, 24-48 hours, 48-72 hours, >72 hours). 4 patients, showed improvement in less than 24 hours, 22 patients, showed improvement in between 24-48 hours, in 38 patients, the improvement was seen between 48-72 hours, and in 49 patients, the improvement was seen after 72 hours a shown in Table 2.

Distribution of Effectiveness in Treatment

Table 1: Clinical History of Participants (n = 113)

	Absent/No	Present/Yes
Previous Medical History	4 (3.5%)	109 (96.5)
History of Drug Allergy	113 (100%)	00 (0%)
Previous Use of Other Antibiotics	4 (3.5%)	109 (96.5)

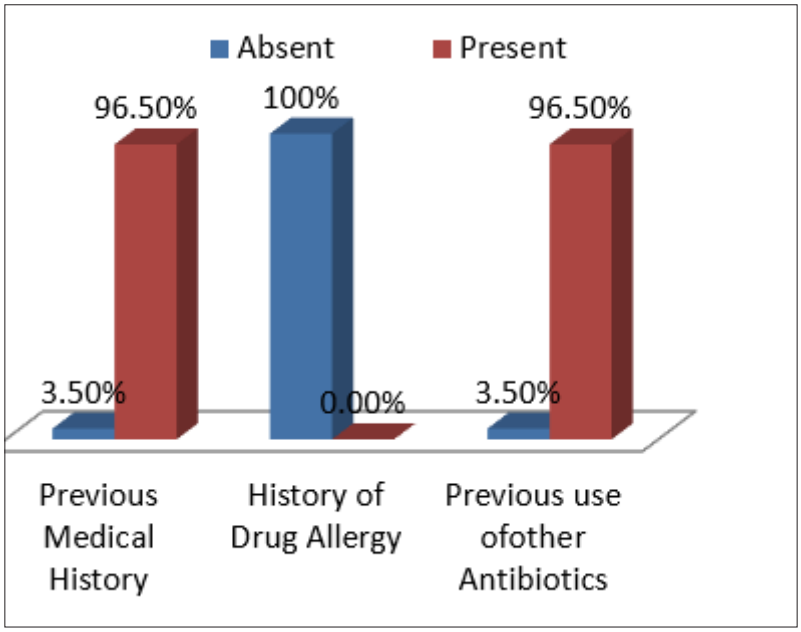

Figure 1.Clinical History of Participants

Table 2: Distribution of Time Taken to Observe Clinical Improvement

Duration for clinical improvement	Frequency	Percent
<24 hours	**4**	**3.5**
24-48 hours	**22**	**19.5**
48-72 hours	**38**	**33.6**
>72hours	**49**	**43.4**
Total	**113**	**100**

ISSN 2583-2069

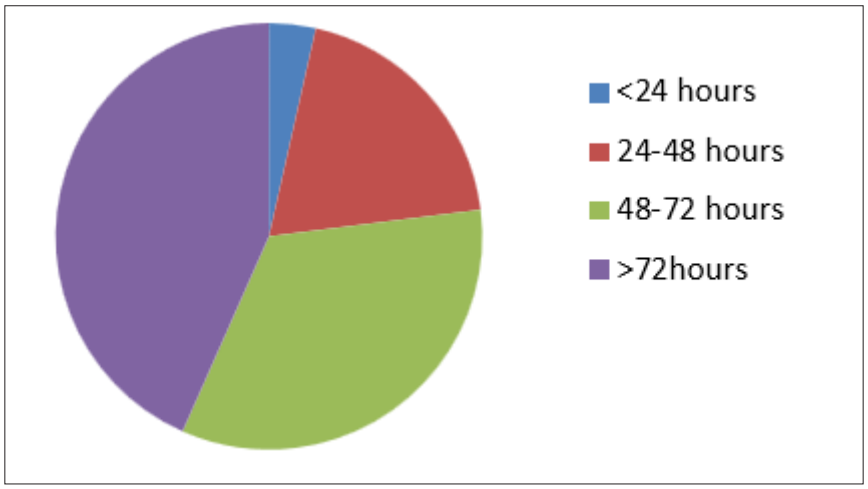

Figure 2: Distribution of Time Taken to Observe Clinical Improvement

Table 3: Distribution of Effectiveness in Treatment

Effectiveness	Frequency	Percent
Highly Effective	86	76.1
Effective	23	20.4
Partially Effective	4	3.5
Total	113	100

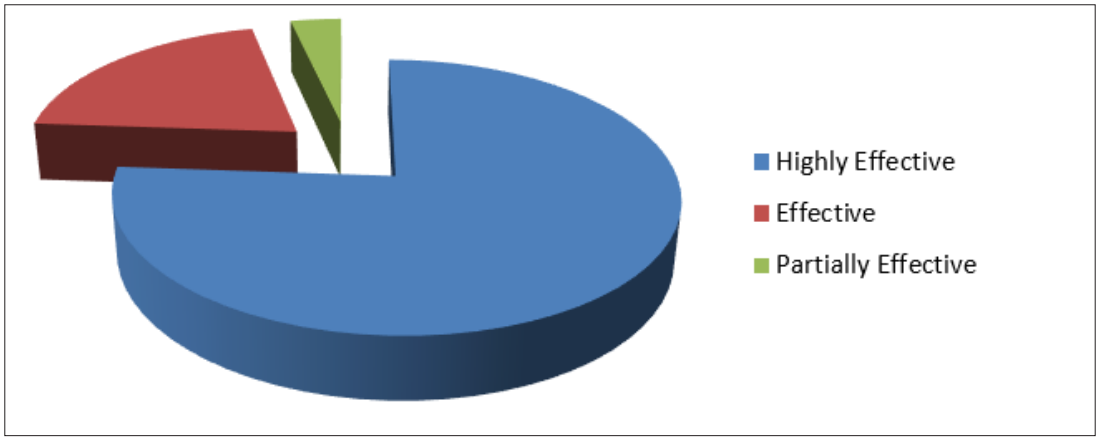

Figure 3.Distribution of Effectiveness in Treatment

Out of 113 subjects among 86 patients, Ceftriaxone-sulbactam Therapy was seen as Highly Effective followed by Effective in 23 patients, and Partially Effective in 4 patients for treating the infection as shown in Table 3. None of the patients were in need of any additional antibiotics during the treatment

Association Between Treatment Duration and Clinical Effectiveness

The association between treatment duration and clinical effectiveness was initially evaluated using a contingency table. However, after examining the expected cell frequencies, several cells had expected counts below 5, including one cell with an expected count below 1. Since this violates the assumptions of Pearson's chi-square test, the chi-square statistic was not considered appropriate for inferential analysis in the present study. Therefore, the relationship between treatment duration and clinical effectiveness is presented descriptively, and no statistically significant association is claimed.

These findings indicate that treatment duration plays an important role in determining the effectiveness of therapy in managing the primary infection.

Distribution of the Disease in the Patients

Table 4: Duration of Treatment with Effectiveness

Duration of treatment	Highly Effective	Effective	Partially Effective	Total
<3 days	12	0	0	12
3-7days	65	12	0	77
7-14days	9	11	1	21
>14days	0	0	3	3
Total	86	23	4	113

Data are presented as frequencies (n). Pearson's chi-square test was not interpreted because several expected cell frequencies were below the recommended threshold for valid chi-square analysis.

Table 5: Distribution of Disease among participants (n=113)

Disease/ Clinical Condition	Frequency (n = 113)	Percentage (%)
Cholelithiasis	39	34.5
Appendicitis ,	12	10.6
Infection	12	10.6
Hernia	8	7.1
Pancreatitis	7	6.2
Abscess	5	4.4
Gastritis	4	3.5
Hepatomegaly,	3	2.7
Pyelonephritis	3	2.7
Gastrointestinal (GI) Obstruction	2	1.8
Mirizzi's Syndrome	2	1.8
Other conditions*	16	15.0

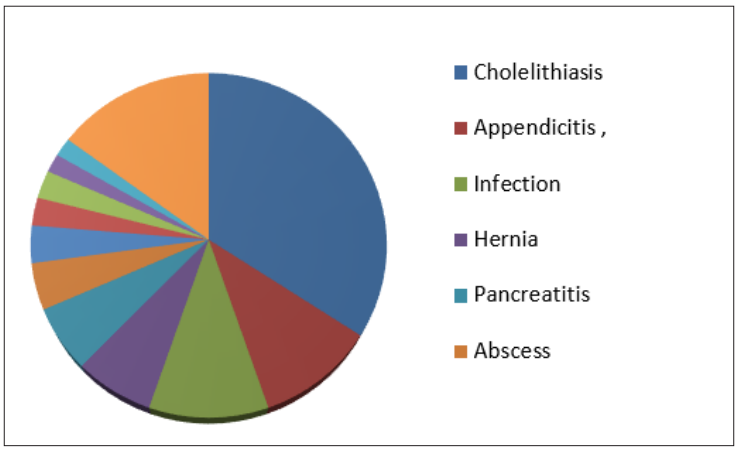

Figure 3.Distribution of Disease among participants

Out of 113 patients included in the study, the most common clinical condition was cholelithiasis, observed in 39 patients (34.5%), and followedby Appendicitis reported in 12 patients (10.6%), while other infections were also noted in 12 patients (10.6%). Pancreatitis was recorded in 7 patients (6.2%), and hernia in 8 patients (7.1%). Less frequently reported conditions included gastritis in 4 patients (3.5%) and hepatomegaly in 3 patients (2.7%). Gastrointestinal (GI) obstruction and Mirizzi syndrome were each observed in 2 patients (1.8%), abscess in 5 patients (4.4%), diabetic foot ulcer in 1 patient (0.9%), and flail chest in 1 patient (0.9%, as shown in Table 4.

*Other conditions Prostatic Hyperplasia, , Diabetic Foot Ulcer, Flail Chest, Fournier's Gangrene, Hepatitis, Hypochondrial Swelling, Hypoglycemic Episode, Lipoma Excision, Perforated Duodenal Ulcer, Rectal Bleeding,

ISSN 2583-2069

Rectal Prolapse, Segmented Distal and Terminal Ileal Resection, Spondylitis, Liver Space-Occupying Lesion, Subcoronal Hypospadias, Varicose Vein, Viral hepatitis were Reported 1(0.9%) in each participant respectively.

Discussion

The effectiveness and safety of Ceftriaxone-sulbactam therapy were evaluated on patients in the hospital who were being treated on bacterial infections. The results illustrated that overall most of the patients had positive therapeutic effects and limited adverse drug events when using β-lactam and β-lactamase inhibitor combinations in the hospital[13,3]The synergistic effect of Ceftriaxone and sulbactam boosts antibacterial effect by inhibiting enzymes (β-lactamase) that are produced by resistant bacteria, thus reverting Ceftriaxone activity on the activity of β-lactamase-producing organisms[1].

The participants in the current study were mostly males (57.5%) and the greatest percentage of patients was those who were in the 57-69 years of age group. This finding can be explained by the fact that older adults are more prone to infectious diseases because of immunological loss and the prevalence of comorbid conditions necessitating hospitalization and antimicrobial treatment[14].There are also previous clinical studies that elderly populations do constitute a high ratio of hospitalized patients placed under broad-spectrum antibiotics[15].

The majority of patients in the current study had a history of a past medical condition (62.8%), which meant that underlying conditions can cause the predisposition to infection and antibiotic treatment. Bacterial infections have been identified to pre-dispose people with chronic diseases like diabetes, hepatobiliary diseases, and gastrointestinal disorders to the use of broad-spectrum antimicrobials[5]. The utilization of Ceftriaxone in such a clinical case is heavily motivated by the fact that the latter has a broad spectrum of activity against Gram-positive and Gram-negative bacteria[1].

The period of treatment showed that most of the patients were treated with more than 2 g/day Ceftriaxone-sulbactam and spent 3-7 days in the hospital. This is in line with common clinical guidelines where Ceftriaxone-based therapy is widely used to treat moderate to severe infections which suggest short-term inpatient treatment[16].

Clinical improvement assessment in the current study indicated that majority of the patients improved after 72 hours of treatment. This is in line with the pharmacodynamic property of Beta-lactam antibiotics that inhibit cell wall synthesis in bacteria and need sufficient time of exposure to exert bactericidal effects[1]. There has also been clinical improvement with a significant duration following the treatment initiation with the use of ceftriaxone-sulbactam therapy as reported in previous clinical trials[9].

A high success rate of therapy was also proven in the current study as 76.1 percent of the patients were classified as highly successful in their treatment. Similar results are documented in the multicenter clinical trials assessing the efficacy of Ceftriaxone-sulbactam, in which the overall rates of clinical effectiveness are above 80 per cent supporting the perspective of high antibacterial efficacy of Ceftriaxone-sulbactam in treating common pathogens, causing respiratory and urinary tract infections[9]. Because culture and antimicrobial susceptibility data were not systematically available in the present study, microbiological eradication, pathogen-specific response, and antimicrobial susceptibility could not be assessed[3].

The distribution of clinical effectiveness varied across different treatment-duration categories. Patients receiving ceftriaxone-sulbactam for 3–7 days showed the highest frequency of clinical improvement. However, because the contingency table contained sparse cells with low expected frequencies, inferential statistical testing using Pearson's chi-square test was not appropriate. Therefore, these findings should be interpreted as descriptive observations rather than evidence of a statistically significant association[17]. With regards to the safety outcomes, a limited percentage of patients (3.5 percent) had the mild adverse drug events, diarrhea, rash on forearms, nausea, and fever, and majority of the patients did not record any adverse events. Past research has also indicated that ceftriaxone based treatment is usually well tolerated and has a low prevalence of adverse drug reactions in hospitalized patients[16]. These findings suggest that ceftriaxone-sulbactam was generally well tolerated in the present study population. However, the small number of observed adverse drug events limits the strength of conclusions regarding its overall safety.

The morbidity of the diseases in the study subjects revealed that cholelithiasis and appendicitis were some of the diseases that had the highest prevalence that needed antibiotic treatment. The regimens of ceftriaxone are commonly applied in surgical and gastrointestinal infections since the medicine has a wide antimicrobial spectrum and is effective against pathogens commonly selected during intra-abdominal infections[5]. Also, β-lactam/β-lactamase inhibitor combinations have been exhibited to have a better activity against the resistant Gram-negative organisms, and therefore they are effective therapeutic choices in hospitals[3].

Conclusion

To sum up, the given study has done a top-notch performance of accomplishing its goal of evaluating the efficacy and safety of Ceftriaxone-Sulbactam therapy at a real-world tertiary care hospital. Based on the analysis, this combination of antibiotics is highly potent, with a success rate above 96% and a partial response rate of only 3.5%. The almost zero outbreaks of mild negative drug reactions, as well as the non-occurrence of severe adverse drug reactions despite the large number of patients with already existing medical

complications, testify that Ceftriaxone-Sulbactam is an easily tolerated and safe drug that could be widely applied in hospital practice.

The fact that underlying diseases have a strong relational bond with the success of treatment efficacy is vital to the point that treatment plans shall be built accordingly, and a precise diagnosis shall be made to enhance results. Moreover, the overall pattern between the right use of treatment and reduced complications strengthens the current trends in antibiotic stewardships that recommend the administration of the right drug at the right dose and at the right amount in order to reduce resistance and facilitate full recovery of a patient. The present study provides descriptive evidence regarding treatment duration and clinical effectiveness; however, statistical association could not be confirmed because the assumptions required for Pearson's chi-square analysis were not met.

In general, the results are highly supportive of Ceftriaxone-Sulbactam as a viable, reliable choice to be used as empirical and focused therapy, and in particular in cases of intra-abdominal and surgical infection, as is typical in cases of tertiary care. In order to venture further on this work, it is worth conducting a study with larger populations, microbial culture-sensitivity correlation, and follow-ups in order to gain further insights to this development and possibly help in the justification of rational use policies of this common antibiotic combination.

Acknowledgments

NA

Funding

NA

Ethics Statement

Institutional Review Board approval is required.

Conflict of interest

None

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