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Study on the Efficacy of Cefoperazone-Sulbactam and Piperacillin-Tazobactam in Managing Severe Community-Acquired Pneumonia

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ABSTRACT

Background: Severe community-acquired pneumonia is associated with high illness and mortality. Cefoperazone–sulbactam has broad-spectrum activity and may serve as an alternative to piperacillin–tazobactam, but comparative evidence in severe community-acquired pneumonia (CAP) is limited.

Methods: This observational, prospective cohort study aimed to compare the efficacy, safety, and outcomes of cefoperazone-sulbactam and piperacillin-tazobactam in treating severe CAP. Adult patients diagnosed with severe SEVERE CAP were assigned to treatment groups based on physician discretion, and the study assessed clinical cure rates, microbiological eradication, adverse drug reactions, and 30-day mortality. Sputum and blood cultures were analysed for pathogen resistance. The study continued until the required sample size was met, with a focus on treatment efficacy and safety.

Results: The study found that the CEFOPERAZONE-SULBACTAM and PIPERACILLIN-TAZOBACTAM groups had similar demographic characteristics, with no significant differences in age, BMI, or sex distribution. Blood tests showed no significant differences in WBC, RBC, or haemoglobin levels. However, the CEFOPERAZONE-SULBACTAM group had higher neutrophils (64.1 vs. 50.5) and lower eosinophils (1.74 vs. 3.1), while the PIPERACILLIN-TAZOBACTAM group had higher lymphocytes (39.84 vs. 29.94). The PIPERACILLIN-TAZOBACTAM group achieved sputum negativity faster (10.43 vs. 12.93 days). Adverse reactions like nausea and vomiting were more frequent in the PIPERACILLIN-TAZOBACTAM group, whereas urticaria and anaemia were more common in the CEFOPERAZONE-SULBACTAM group.

Conclusion: The study has concluded that both cefoperazone-sulbactam and piperacillin-tazobactam demonstrated similar efficacy in treating patients, with piperacillin-tazobactam achieving sputum negativity more quickly.

Key-words: Severe Community-Acquired Pneumonia, Cefoperazone–Sulbactam, Piperacillin–Tazobactam, Non-Inferiority Trial, Antimicrobial Therapy

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INTRODUCTION

Severe community-acquired pneumonia remains a major cause of intensive-care admission and mortality worldwide, necessitating empiric antibiotic regimens that rapidly cover the likely pathogens (*Streptococcus pneumoniae, Staphylococcus aureus,* and Gram-negative bacilli, including *Pseudomonas*) while balancing toxicity and risk of resistance. Current

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emphasise the use of a beta-lactam with appropriate anti-pneumococcal activity and additional agents for atypical organisms or risk factors for multidrug-resistant pathogens; for patients at risk of *Pseudomonas* or with severe disease, antipseudomonal β-lactams such as piperacillin–tazobactam are commonly recommended as core therapy. Guideline recommendations also stress tailoring empiric choices to local epidemiology and individual risk factors [1,2].

Cefoperazone combined with sulbactam (typically supplied as 1:1 or 2:1 formulations) is a broad-spectrum third-generation cephalosporin paired with a β-lactamase inhibitor that extends activity against many Gram-negative organisms and offers intrinsic activity against certain organisms (particularly Acinetobacter when sulbactam reaches adequate concentrations). Piperacillin–tazobactam, an extended-spectrum ureidopenicillin with tazobactam, provides extensive Gram-negative, including antipseudomonal coverage and is widely used in severe lower-respiratory infections. Pharmacologic differences, spectrum, protein binding, renal versus biliary excretion, and differing PK/PD indices underpin clinical choice in different settings [3].

Direct comparative data specifically in severe CAP are limited, but emerging observational and comparative cohort studies suggest broadly comparable clinical effectiveness between CFP–SUL and PIP–TAZ when used as empirical or targeted therapy for severe pulmonary infections. Recent retrospective analyses and cohort studies have reported similar clinical cure rates and mortality between CFP–SUL and PIP–TAZ in hospitalised adults with severe pneumonia after adjustment for disease severity, although subgroup differences (elderly patients, organisms with higher minimum inhibitory concentrations) have been reported in some series. These data indicate CFP–SUL can be an effective alternative in contexts where PIP–TAZ use is constrained by supply, allergy patterns/ local susceptibility profiles [4].

Randomised controlled trial evidence directly comparing CFP–SUL and PIP–TAZ in severe CAP is scarce; existing RCTs have more often compared CFP–SUL with other cephalosporins (e.g., cefepime) or evaluated PIP–TAZ against other comparators in nosocomial settings. Non-inferiority trials and well-conducted observational studies provide supportive—but not definitive evidence that CFP–SUL is not uniformly inferior to broad antipseudomonal regimens in severe lower-respiratory infections. At the same time, pharmacokinetic/ pharmacodynamic analyses stress the importance of dosing and infusion strategies to optimise %T>MIC for each agent [5].

Specified limited head-to-head randomised data in SCAP, treatment decisions should integrate guideline recommendations, local antibiograms, patient-level risk factors for resistant pathogens, organ function (renal/biliary), and drug-specific toxicity profiles. Well-designed prospective randomised trials or multicentre pragmatic effectiveness studies comparing CFP–SUL and PIP–TAZ in SCAP, stratified by pathogen, MIC distribution, and severity, would help define optimal empirical and targeted strategies and minimise unnecessary use of broader antipseudomonal agents.

MATERIALS AND METHODS

Research Design- This observational, prospective cohort study aims to compare the clinical efficacy, safety, and outcomes of cefoperazone-sulbactam (CFP-SUL) and piperacillin-tazobactam (PIP-TAZ) in treating Severe Community-Acquired Pneumonia (SCAP) at Santosh Medical College & Hospital**.** Conducted within the Department of Pharmacology and the Department of Respiratory Medicine**,** the study will include adult patients (≥18 years) diagnosed with SCAP, as per the Infectious Diseases Society of America and American Thoracic Society guidelines. Patients will be assigned to either treatment arm based on the physician's discretion, considering factors like comorbidities and antibiotic availability, with no randomisation. The primary outcome will be clinical cure rates, while secondary outcomes include microbiological eradication, ICU admissions, length of stay, adverse drug reactions, and 30-day mortality. Microbiological assessments, including blood and sputum cultures, will be conducted to evaluate pathogen resistance profiles. The study aims to make clinical decision-making for severe CAP management, particularly in high-acuity settings. Standard supportive care and appropriate adjunctive therapies will be provided, and all data will be collected using structured case report forms for subsequent analysis. The study will continue until the required sample size is achieved.

Participant Selection- Participants were randomised 1:1 to receive either CFP–SUL or PIP–TAZ using a centralised, computer-generated permuted block schedule with

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variable sizes. Randomisation was stratified by site and need for invasive ventilation at enrolment. Allocation concealment was maintained via a secure web-based system. The trial was open-label due to drug preparation differences, but outcome assessors for the primary endpoint were blinded.

Patients in the CFP–SUL arm received cefoperazone–sulbactam 2 g/2 g IV every 8–12 h (or 3 g/3 g q12h per local formulary), infused over 3 h. Dose adjustments were made for hepatic dysfunction or combined renal-hepatic impairment. Patients in the PIP–TAZ arm received piperacillin–tazobactam 4.5 g IV every 6–8 h, infused over 3–4 h, with renal adjustment as required. All patients also received empiric atypical coverage with azithromycin (500 mg IV/PO daily) or levofloxacin (750 mg daily) for 48–72 h unless non-atypical bacteria were identified. Antibiotic escalation/de-escalation followed predefined rules based on culture and clinical response. Total antibiotic duration was 7–10 days, extended up to 14 days for *P. aeruginosa, S. aureus* bacteraemia, or delayed recovery.

Concomitant care followed institutional standards: fluid resuscitation, vasopressors, oxygen or ventilation, venous thromboembolism and stress-ulcer prophylaxis, and glycaemic control. Corticosteroids were allowed for septic shock or COPD/asthma exacerbations per guidelines, with all use documented.

Before the first study dose, patients underwent standardised microbiological evaluation: two sets of blood cultures, sputum for Gram stain and culture, and nasopharyngeal multiplex PCR for respiratory viruses when available. Pathogen identification and susceptibility testing were performed at accredited labs using CLSI or EUCAST methods. Minimum inhibitory concentrations were recorded when available for pharmacodynamic analysis.

Inclusion criteria

- Age ≥18 years.
- Community-onset pneumonia is defined by: (a) new infiltrate(s) on chest radiograph/CT within 48 h of presentation, and (b) ≥1 compatible clinical feature (fever ≥38°C or hypothermia ≤36°C, leucocytosis/leukopenia, purulent sputum, cough, pleuritic chest pain, dyspnoea, or hypoxemia).
- Severe CAP per ATS/IDSA major/minor criteria at presentation or within 24 h (≥1 major criterion, need for invasive mechanical ventilation or septic shock requiring vasopressors, or ≥3 minor criteria such as RR ≥30/min, PaO2/FiO2 ≤250, multipolar infiltrates, confusion, BUN ≥20 mg/dL, leukopenia, thrombocytopenia, hypothermia, hypotension requiring aggressive fluid resuscitation).
- Enrolment within 24 h of the first dose of the study antibiotic.

Exclusion criteria

- Hospital-acquired or ventilator-associated pneumonia; healthcare-associated pneumonia with hospitalization ≥48 h in the prior 90 days.
- Known or suspected viral pneumonia as the sole aetiology without bacterial coinfection.
- Prior systemic antibacterial therapy >24 h for the current episode.
- Immediate β-lactam anaphylaxis or severe cutaneous adverse reaction history.
- Concomitant infection requiring non-protocol systemic antibiotics with activity against likely severe CAP pathogens.
- Known pregnancy or lactation.
- End-stage renal disease on dialysis or Child-Pugh C cirrhosis if dosing/PK targets could not be met.
- Anticipated survival <72 h due to comorbid illness, or enrolment in another interventional trial.

Outcome Assessment- The primary endpoint of the study was sputum negative and CURB-65 at Day 10. Clinical cure was defined as complete resolution or significant improvement of pneumonia-related symptoms and signs, absence of requirement for additional systemic antibiotics active against community-acquired pathogens, and radiographic stability or improvement without the development of new foci of infection.

Statistical Analysis- The statistical analysis was conducted using SPSS-27, and comparisons between the two groups were made using independent t-tests for continuous variables and chi-square tests for categorical variables. A significance level of $p<0.05$ was considered, and the results indicated whether differences were statistically significant or not based on the respective p-values.

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RESULTS

In Table 1, the demographic characteristics of patients in the two groups were compared, focusing on age, BMI, and sex distribution. The mean age in the CEFOPERAZONE-SULBACTAM group was 50±17.58 years, while the PIPERACILLIN-TAZOBACTAM group had a mean age of 50.83±16.69 years. The statistical analysis yielded an F-value of 0.01 and a p-value of 0.85, suggesting that there was no significant difference in age between the two groups. Similarly, the mean BMI for the CEFOPERAZONE-SULBACTAM group was 21.55±1.05, and for the PIPERACILLIN-TAZOBACTAM group, it was 21.73±1.04. With an F-value of 0.023 and a p-value of 0.497, there was no significant difference in BMI between the groups. In terms of sex distribution, the CEFOPERAZONE-SULBACTAM group consisted of 14 males (46.67%) and 16 females (53.33%), while the PIPERACILLIN-TAZOBACTAM group had 13 males (43.33%) and 17 females (56.67%). This indicates no meaningful difference in sex distribution between the two groups.

Table 1: Demographic characteristics of the patients in each group

Group	CEFOPERAZONE-SULBACTAM	PIPERACILLIN-TAZOBACTAM	F-value	p-value
Age (Mean±SD)	50±17.58	50.83±16.69	0.01	0.85
BMI (Mean±SD)	21.55±1.05	21.73±1.04	0.02	0.49
Sex (Frequency % out of 30)				
Male	14 (46.67%)	13 (43.33%)	0.02	0.08
Female	16 (53.33%)	17 (56.67%)		

When examining Platelet Count, the CEFOPERAZONE-SULBACTAM group had a mean count of 288202.27±89381.43, while the PIPERACILLIN-TAZOBACTAM group had 280016.37±84834.24. With a p-value of 0.71 (t=0.36), there was no significant difference between the two groups. The Neutrophil count was significantly higher in the CEFOPERAZONE-SULBACTAM group (64.1±5.29) compared to the PIPERACILLIN-TAZOBACTAM group (50.5±7.71), with a p-value less than 0.01 (t=7.9), indicating a strong statistically significant difference. On the other hand, Lymphocytes were significantly higher in the PIPERACILLIN-TAZOBACTAM group (39.84±4.18) than in the CEFOPERAZONE-SULBACTAM group (29.94±2.87), with a p-value of 0, which also indicates a strong statistical significance (t=-10.70). Regarding other parameters like Monocytes, Eosinophils, and Basophils, there were no significant differences between the two groups, as indicated by p-values of 0.8 (t=0.25), less than 0.01 (t=-3.90), and 1 (t=<0.01), respectively. The liver function tests showed no significant differences between the two groups. AST had a mean of 23.6±12.01 in the CEFOPERAZONE-SULBACTAM group and 28.4±7.07 in the PIPERACILLIN-TAZOBACTAM group, with a p-value of 0.06 (t-value=-1.88). ALT values were also similar, with a mean of 32.07±16.38 in the CEFOPERAZONE-SULBACTAM group and 31.2±12.89 in the PIPERACILLIN-TAZOBACTAM group (p=0.82, t=0.22). There were no significant differences in ALP, Bilirubin Total, Albumin, or Total Protein levels either, with all respective p-values being greater than 0.05 (Table 2).

Table 2: Blood Tests of the patients at Day 10 (Follow-up) in each group

Parameters	Group	Mean±SD	p-value	t-value
WBC	CEFOPERAZONE-SULBACTAM	8866.07±4711.96	0.29	1.06
	PIPERACILLIN-TAZOBACTAM	7865.44±2049.02		
RBC	CEFOPERAZONE-SULBACTAM	5.47±0.43	0.75	-0.30
	PIPERACILLIN-TAZOBACTAM	5.5±0.33		
Hemoglobin	CEFOPERAZONE-SULBACTAM	15.79±1.06	0.50	0.67
	PIPERACILLIN-TAZOBACTAM	15.62±0.96		

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Platelet Count	CEFOPERAZONE-SULBACTAM	288202.27±89381.43	0.71	0.36
	PIPERACILLIN-TAZOBACTAM	280016.37±84834.24		
Neutrophils	CEFOPERAZONE-SULBACTAM	64.1±5.29	<0.01	7.97
	PIPERACILLIN-TAZOBACTAM	50.5±7.71		
Lymphocytes	CEFOPERAZONE-SULBACTAM	29.94±2.87	0	-10.70
	PIPERACILLIN-TAZOBACTAM	39.84±4.18		
Monocytes	CEFOPERAZONE-SULBACTAM	4.67±2.69	0.8	0.25
	PIPERACILLIN-TAZOBACTAM	4.5±2.39		
Eosinophils	CEFOPERAZONE-SULBACTAM	1.74±1.29	<0.01	-3.90
	PIPERACILLIN-TAZOBACTAM	3.1±1.43		
Basophils	CEFOPERAZONE-SULBACTAM	0.34±0.48	1	<0.01
	PIPERACILLIN-TAZOBACTAM	0.34±0.48		
AST	CEFOPERAZONE-SULBACTAM	23.6±12.01	0.06	-1.88
	PIPERACILLIN-TAZOBACTAM	28.4±7.07		
ALT	CEFOPERAZONE-SULBACTAM	32.07±16.38	0.82	0.22
	PIPERACILLIN-TAZOBACTAM	31.2±12.89		
ALP	CEFOPERAZONE-SULBACTAM	94.1±40.23	0.66	0.43
	PIPERACILLIN-TAZOBACTAM	90.3±26.05		
Bilirubin Total	CEFOPERAZONE-SULBACTAM	0.8±0.5	0.41	0.82
	PIPERACILLIN-TAZOBACTAM	0.71±0.31		
Albumin	CEFOPERAZONE-SULBACTAM	4.23±0.57	0.89	0.13
	PIPERACILLIN-TAZOBACTAM	4.21±0.44		
Total Protein	CEFOPERAZONE-SULBACTAM	7.09±0.71	0.79	-0.26
	PIPERACILLIN-TAZOBACTAM	7.14±0.69		

In Fig. 1, the comparison of adverse drug reactions between the two groups showed similar rates of diarrhoea, nausea, vomiting, and abdominal pain. However, the PIPERACILLIN-TAZOBACTAM group experienced more cases of nausea (7 vs. 4) and vomiting (8 vs. 3), while the CEFOPERAZONE-SULBACTAM group had more cases of urticaria (4 vs. 1). Anaemia was more common in the CEFOPERAZONE-SULBACTAM group (5 vs. 1).

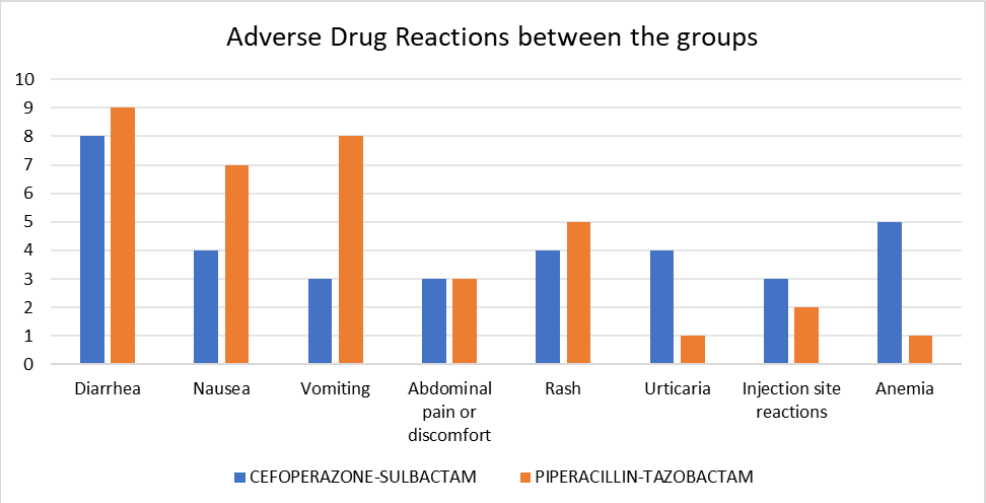

Fig. 1: Comparison between the groups showing Adverse Drug Reactions between them

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In Fig. 2, the average number of days to obtain sputum negativity was 12.93 days for the CEFOPERAZONE-SULBACTAM group and 10.43 days for the PIPERACILLIN-TAZOBACTAM group, suggesting that patients in the PIPERACILLIN-TAZOBACTAM group took fewer days to achieve sputum negativity.

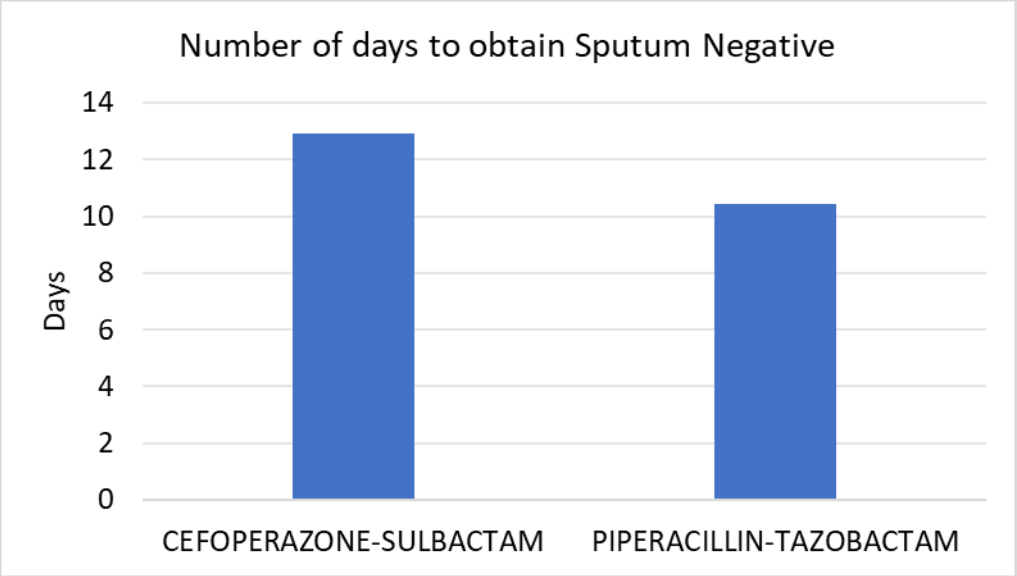

Fig. 2: Number of days to obtain sputum negative

DISCUSSION

The available comparative literature, largely retrospective cohorts and observational series, suggests that CFP–SUL and PIP–TAZ achieve broadly similar clinical outcomes when used to treat severe lower-respiratory infections, but signal differences appear in specific subgroups and safety endpoints. A multi-centre retrospective analysis of patients with severe CAP reported comparable crude clinical cure and mortality rates between CFP–SUL and PIP–TAZ, and after propensity adjustment CFP SUL showed non-inferior and, in some analyses, superior adjusted clinical outcomes. This finding supports CFP–SUL as a reasonable empirical option in settings where local susceptibility favours its use [6].

Studies in nosocomial pneumonia similarly report comparable effectiveness between the two agents. A large Taiwanese multicentre retrospective study found similar treatment success for CFP–SUL and PIP–TAZ in hospitalised pneumonias, including ventilator-associated cases, reinforcing the notion that both regimens can be effective against a spectrum of Gram-negative and mixed infections encountered in severe pulmonary disease. However, these data derive from observational databases and are subject to confounding by indication and selection bias [7].

In contrast, several reports focused on elderly or specific populations have suggested advantages for one agent over the other. Some studies in elderly inpatients with respiratory infections reported higher overall response rates with PIP–TAZ compared with CFP–SUL, whereas certain adjusted analyses in severe CAP observed higher adjusted cure rates for CFP–SUL. The apparent discordance likely reflects heterogeneity in pathogen distribution (e.g., differing rates of Pseudomonas, Acinetobacter, or ESBL producers), MIC distributions, dosing strategies, and co-morbid conditions across study populations. Clinicians must therefore interpret comparative effectiveness through the lens of local epidemiology and individual patient risk [8].

Mechanistic and pharmacologic differences offer plausible explanations for subgroup findings. Sulbactam confers intrinsic activity against Acinetobacter spp. and, when paired with cefoperazone, can yield favourable pharmacodynamic target attainment against some difficult Gram-negatives; conversely, piperacillin–tazobactam has robust antipseudomonal activity and an established role in empiric antipseudomonal coverage. Pharmacokinetic behaviour, protein binding, and %T>MIC requirements mean that dosing and infusion method materially affect clinical performance and could explain interstudy variability [9].

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Safety profiles differ modestly and are clinically relevant. Several series reported similar overall adverse-event rates but noted a higher incidence of coagulation abnormalities with cefoperazone formulations, a known class effect linked to cephalosporins with N-methylthiotetrazole side chains, whereas PIP–TAZ has been variably associated with hematologic or renal effects depending on exposure. Awareness of these safety signals should guide drug selection, particularly in patients with baseline coagulopathy or on anticoagulation [10].

Limitations of the current evidence base are substantial. Randomised controlled trials are scarce directly comparing CFP–SUL and PIP–TAZ in severe CAP; most data are retrospective, heterogeneous in case-mix, and influenced by local prescribing practices and resistance patterns. Many studies group community-acquired and nosocomial infections or include mixed indications, complicating extrapolation to strictly defined severe CAP populations. Guideline frameworks, therefore, continue to recommend empiric antipseudomonal beta-lactams for critically ill patients at risk of resistant Gram-negatives, while also underscoring the need to tailor therapy to local antibiograms [11].

Implications and future directions: until high-quality randomised evidence is available, pragmatic selection between CFP–SUL and PIP–TAZ should be individualised, based on local susceptibility data, suspected pathogens. A well-designed randomised or pragmatic trial stratified by pathogen/MIC, severity score, and renal/hepatic function would address remaining uncertainty and help refine empiric stewardship strategies in severe CAP [12,13].

CONCLUSIONS

The study has concluded that both cefoperazone-sulbactam and piperacillin-tazobactam demonstrated similar efficacy in treating patients, with piperacillin-tazobactam achieving sputum negativity more quickly. This study assessed the efficacy and adverse drug reactions of both cefoperazone-sulbactam and piperacillin-tazobactam. Regarding efficacy, piperacillin-tazobactam showed a slightly faster time to achieve sputum negativity, indicating a potential advantage in terms of treatment efficacy. However, the differences in blood parameters, including neutrophil and lymphocyte counts, were more nuanced and did not suggest a clear superiority of either antibiotic in terms of overall effectiveness. When considering adverse drug reactions, both groups experienced similar rates of gastrointestinal issues such as diarrhoea, nausea, and vomiting, with piperacillin-tazobactam showing a higher incidence of nausea and vomiting. In contrast, cefoperazone-sulbactam was associated with more cases of urticaria and anaemia.

CONTRIBUTION OF AUTHORS

Research concept – Amit Singhal, Ankur Singh, Sanjay Kumar Verma

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Final approval – Ajay Kestwal, Sumit Singhal

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