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PATTERNS OF ANTIMICROBIAL USE, THEIR ADVERSE EFFECTS AND COST ANALYSIS IN THE CCU OF A TERTIARY CARE TEACHING HOSPITAL IN EASTERN INDIA: AN OBSERVATIONAL STUDY

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Abstract

Background: Antimicrobial agents are extensively used in Critical Care Units (CCUs) for the management of severe bacterial infections. However, irrational prescribing contributes to antimicrobial resistance, adverse drug reactions (ADRs), and increased healthcare costs. ***Objectives:*** To evaluate the patterns of antimicrobial use, analyse antimicrobial sensitivity and resistance patterns, assess adverse drug reactions, and perform cost analysis among CCU patients in a tertiary care teaching hospital in Eastern India. ***Methods:*** A cross-sectional observational study was conducted in the CCU over a period of 18 months. A total of 196 adult patients requiring antimicrobial therapy with a CCU stay ≥96 hours were included. Data regarding demographic profile, clinical diagnosis, antimicrobial prescribing pattern, microbiological reports, adverse drug reactions, and cost of therapy were collected and analysed using appropriate statistical methods. ***Results:*** Sepsis (27.6%) and pneumonia (21.4%) were the most common indications for antimicrobial therapy. Empirical therapy was initiated in 65.3% of patients. Culture positivity was observed in 49% cases, with Gram-negative organisms predominating; Klebsiella pneumoniae (27.1%) was the most frequent isolate. High resistance to third-generation cephalosporins was noted, while carbapenems and colistin retained good sensitivity. Adverse drug reactions occurred in 28.6% of patients, with nephrotoxicity being clinically significant. A considerable proportion of patients incurred high antimicrobial costs, particularly those receiving reserve antibiotics. ***Conclusion:*** The study highlights substantial antimicrobial use, significant resistance patterns, notable ADR incidence, and considerable economic burden in the CCU, underscoring the need for robust antimicrobial stewardship programs.

Keywords: Antimicrobial utilization, Critical Care Unit, Drug resistance, Adverse drug reactions, Cost analysis.

INTRODUCTION

Antimicrobial agents remain one of the most frequently prescribed classes of drugs in critical care settings worldwide. Patients admitted to Critical Care Units (CCUs) are at increased risk of severe infections due to underlying comorbidities, invasive procedures, mechanical ventilation, prolonged hospitalization, and immunological compromise. Early initiation of broad-spectrum antimicrobial therapy is often lifesaving in critically ill patients with sepsis, septic shock, and severe pneumonia [1]. However, inappropriate or excessive antimicrobial use contributes significantly to antimicrobial resistance (AMR), adverse drug reactions (ADRs), and escalating healthcare costs [2].

Globally, antimicrobial resistance has emerged as a major public health threat. The World Health Organization (WHO) has recognized AMR as one of the top ten global health challenges of the 21st century [3]. Intensive care units represent epicenters for the emergence and spread of multidrug-resistant (MDR) organisms due to high antimicrobial consumption and selective pressure [4]. Studies such as the EPIC II study have demonstrated that nearly 70% of ICU patients receive at least one antimicrobial agent during their stay, highlighting the magnitude of exposure in critical care environments [5]. In low- and middle-income countries, including India, the burden of resistant Gram-negative

pathogens is particularly alarming, with increasing reports of extended-spectrum beta-lactamase (ESBL)-producing organisms, carbapenem-resistant Enterobacteriaceae (CRE), and methicillin-resistant Staphylococcus aureus (MRSA) [6].

In India, irrational prescribing practices, over-the-counter availability of antibiotics, lack of uniform antimicrobial stewardship programs, and limited microbiological support contribute significantly to the AMR crisis [7]. Data from the Indian Council of Medical Research (ICMR) surveillance network indicate high resistance rates to third-generation cephalosporins and fluoroquinolones among common pathogens isolated from ICU patients [8]. Consequently, reserve antibiotics such as carbapenems, colistin, and linezolid are increasingly used, further accelerating resistance development and increasing treatment costs.

Apart from resistance, antimicrobial therapy is associated with a spectrum of adverse drug reactions, ranging from mild gastrointestinal intolerance to severe nephrotoxicity, hepatotoxicity, hypersensitivity reactions, and hematological abnormalities. Critically ill patients are particularly vulnerable due to altered pharmacokinetics, polypharmacy, organ dysfunction, and prolonged drug exposure [9]. Monitoring ADRs in CCU settings is therefore essential to ensure patient safety and optimize therapeutic outcomes. Drug-related nephrotoxicity, especially with aminoglycosides and colistin, has been widely reported in ICU-based studies, emphasizing the need for dose adjustment and therapeutic drug monitoring [10].

The primary objective of the present study was to evaluate the patterns of antimicrobial use in combating bacterial infections among patients admitted to the Critical Care Unit (CCU) of a tertiary care teaching hospital, along with a detailed cost analysis of the antimicrobials prescribed during their CCU stay. The secondary objectives were to analyse the antimicrobial sensitivity and drug resistance patterns of the isolated pathogens and to assess the adverse effects associated with antimicrobial therapy. Collectively, these objectives aimed to provide a comprehensive evaluation of antimicrobial utilization, microbiological trends, safety profile, and economic burden in the CCU setting, thereby generating evidence to support rational prescribing practices and strengthen antimicrobial stewardship initiatives.

MATERIALS AND METHODS

STUDY DESIGN: Cross-sectional study.

STUDY TYPE: Observational study.

STUDY POPULATION: Patients admitted to the Critical Care Unit (CCU) of JNM Hospital, Kalyani, who required antimicrobial therapy for the management of bacterial infections and had a CCU stay of ≥ 96 hours.

STUDY SETTING: Department of Pharmacology and the Critical Care Unit (CCU), Department of Medicine, College of Medicine & JNM Hospital, Kalyani.

STUDY PERIOD: 1st July 2024 to 31st December 2025.

- Data collection period: 12 months
- Data analysis period: 6 months

SAMPLE SIZE: The calculated sample size was 196 patients.

INCLUSION CRITERIA

1. Patients of either gender aged ≥ 18 years admitted to the CCU during the study period.
2. Patients with a CCU stay of ≥ 96 hours.

EXCLUSION CRITERIA

1. Patients with diagnosed psychiatric illness.
2. Patients with confirmed viral, fungal, or parasitic infections.
3. Patients with tubercular pneumonia (TB).
4. Patients seropositive for Human Immunodeficiency Virus (HIV), Hepatitis B, or Hepatitis C infection.
5. Patients with diagnosed malignancy.
6. Pregnant and lactating women.
7. Patients receiving immunosuppressive therapy.
8. Patients with chronic hepatic or renal impairment.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS software version 27.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The unpaired t-test was used to compare continuous variables between independent groups, and the paired t-test was applied for within-group comparisons. Categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant.

RESULTS

Table 1: Sociodemographic Characteristics of Study Participants (n = 196)

The majority of study participants belonged to the age group 51–60 years (24.5%), followed closely by 61–70 years (22.4%). Nearly half of the patients (46.9%) were between 51–70 years of age. The age distribution was statistically significant (p = 0.021). A significant male predominance was observed, with 63.3% males and 36.7% females (p = 0.004). Most patients were from rural areas (60.2%) compared to urban areas (39.8%), which was also statistically significant (p = 0.018).

Table 1: Sociodemographic Characteristics of Study Participants (n = 196)

Variable	Category	Frequency (n)	Percentage (%)	p-value
Age Group (years)	≤30	18	9.2	**0.021**
	31–40	26	13.3	
	41–50	34	17.3	
	51–60	48	24.5	
	61–70	44	22.4	
	>70	26	13.3	
Gender	Male	124	63.3	**0.004**
	Female	72	36.7	
Residence	Rural	118	60.2	**0.018**
	Urban	78	39.8	

Table 2: Clinical Profile and Comorbidities of Study Participants (n = 196)

	Variable	Frequency (n)	Percentage (%)	p-value
Provisional Diagnosis	Sepsis / Septic shock	54	27.6	**0.001**
	Pneumonia (CAP/HAP)	42	21.4	
	Acute exacerbation of COPD	28	14.3	
	UTI	22	11.2	
	Acute febrile illness	18	9.2	
	Post-operative infections	16	8.2	
	Others	16	8.1	
Comorbidities	Diabetes mellitus	62	31.6	**0.032**
	Hypertension	56	28.6	
	Chronic lung disease	34	17.3	
	AKI	22	11.2	
	IHD	20	10.2	
	No comorbidity	38	19.4	

Table 3: Clinical Presentation and Hospital Stay (n = 196)

Variable		Frequency (n)	Percentage (%)	p-value
Clinical Features	Fever	148	75.5	<0.001
	Breathlessness	132	67.3	<0.001
	Cough with expectoration	96	49	0.041
	Altered sensorium	58	29.6	0.087
	Hypotension/Shock	64	32.7	0.063
	Oliguria	46	23.5	0.091
	Tachycardia	118	60.2	0.022
	Oxygen requirement	104	53.1	0.038
Duration of Hospital Stay	≤5 days	32	16.3	0.015
	6–10 days	74	37.8	
	11–15 days	48	24.5	
	16–20 days	26	13.3	
	>20 days	16	8.1	

Table 4: Microbiological Profile (n = 196)

Variable	Frequency (n)	Percentage (%)	p-value
Culture sent	164	83.7	<0.001
Culture positive	96	49	
Culture negative	68	34.7	
Culture not sent	32	16.3	
MDR organisms isolated	38	19.4	0.009

Table 5: Organism-wise Distribution (n = 96 culture-positive cases)

Organism	Frequency	Percentage (%)	p-value
Klebsiella pneumoniae	26	27.1	0.003
Escherichia coli	22	22.9	
Acinetobacter baumannii	16	16.7	
Pseudomonas aeruginosa	14	14.6	
Staphylococcus aureus	12	12.5	
Enterococcus spp.	6	6.2	

Table 6: Antibiotic Sensitivity Pattern and Prescribing Pattern (n = 196)

Antibiotic	Sensitive n (%)	Resistant n (%)	p-value
Piperacillin-Tazobactam	58 (60.4)	38 (39.6)	0.041
Ceftriaxone	42 (43.8)	54 (56.2)	0.018
Cefepime	46 (47.9)	50 (52.1)	0.029
Meropenem	72 (75.0)	24 (25.0)	<0.001
Imipenem	70 (72.9)	26 (27.1)	<0.001
Colistin	88 (91.7)	8 (8.3)	<0.001
Vancomycin†	16 (88.9)	2 (11.1)	0.002
Linezolid†	17 (94.4)	1 (5.6)	0.001

Table 7: Adverse Drug Reactions and Cost Analysis (n = 196)

(a) Adverse Drug Reactions

ADR	Frequency (n)	Percentage (%)	p-value
GI upset	18	9.2	0.031
Nephrotoxicity	14	7.1	
Hepatotoxicity	10	5.1	
Skin rash	8	4.1	
Thrombocytopenia	6	3.1	
No ADR	140	71.4	

(b) Cost Analysis

Variable		Frequency (n)	Percentage (%)	p-value
Daily Cost (INR)	<500	34	17.3	0.022
	500–1000	68	34.7	
	1001–2000	56	28.6	
	>2000	38	19.4	
Total Cost During CCU Stay (INR)	<5000	42	21.4	0.017
	5001–10000	64	32.7	
	10001–20000	52	26.5	
	>20000	38	19.4	

Figure: 1. Clinical Profile and Comorbidities of Study Participants

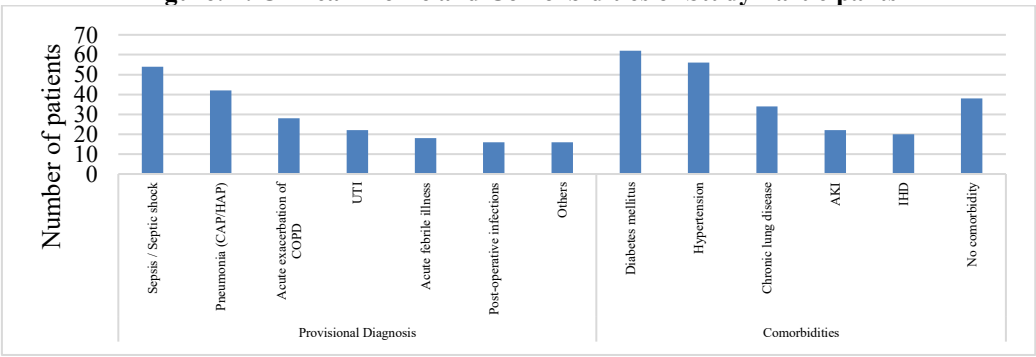

Figure: 2. Antibiotic Sensitivity Pattern and Prescribing Pattern

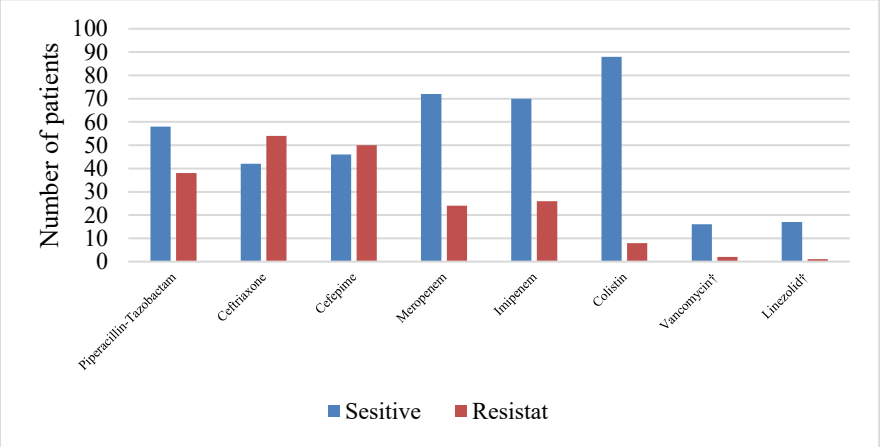

Table 2: Clinical Profile and Comorbidities of Study Participants (n = 196)
Sepsis/septic shock (27.6%) was the most common provisional diagnosis at CCU admission, followed by pneumonia (21.4%). Together, these two conditions accounted for nearly half of the admissions requiring antimicrobial therapy. The distribution of provisional diagnoses was statistically significant ($p = 0.001$).

Among comorbidities, diabetes mellitus (31.6%) was most prevalent, followed by hypertension (28.6%). A notable proportion (19.4%) had no known comorbidity. The distribution of comorbid conditions showed statistical significance ($p = 0.032$).

Table 3: Clinical Presentation and Hospital Stay (n = 196)
Fever (75.5%) was the most common presenting symptom, followed by breathlessness (67.3%) and tachycardia (60.2%). These findings were statistically significant ($p < 0.001$ and $p = 0.022$ respectively). Respiratory manifestations such as cough with expectoration (49.0%) and oxygen requirement (53.1%) were also common.

Regarding duration of hospital stay, most patients (37.8%) stayed for 6–10 days, while 24.5% stayed for 11–15 days. Overall, 62.3% had a hospital stay between 6–15 days. The association between duration categories was statistically significant ($p = 0.015$).

Table 4: Microbiological Profile (n = 196)
Culture specimens were sent in 83.7% of patients, which was statistically significant ($p < 0.001$). Among them, 49.0% were culture positive, while 34.7% were culture negative. Multidrug-resistant (MDR) organisms were isolated in 19.4% of cases, which showed statistical significance ($p = 0.009$). This highlights a considerable burden of resistant infections in the CCU setting.

Table 5: Organism-wise Distribution (n = 96 culture-positive cases)
Among culture-positive isolates, *Klebsiella pneumoniae* (27.1%) was the most common pathogen, followed by *Escherichia coli* (22.9%) and *Acinetobacter baumannii* (16.7%). Gram-negative organisms predominated overall. The distribution of organisms was statistically significant ($p = 0.003$), indicating a higher prevalence of certain pathogens in CCU infections.

Table 6: Antibiotic Sensitivity Pattern and Prescribing Pattern (n = 196)
High resistance rates were observed for third-generation cephalosporins such as ceftriaxone (56.2%) and cefepime (52.1%), which were statistically significant. In contrast, carbapenems (meropenem 75.0%, imipenem 72.9%) and colistin (91.7%) retained high sensitivity ($p < 0.001$). For Gram-positive isolates, vancomycin and linezolid demonstrated excellent sensitivity (88.9% and 94.4% respectively).

These findings indicate significant antimicrobial resistance, particularly against commonly used cephalosporins, necessitating rational antibiotic use in CCU practice.

Table 7: Adverse Drug Reactions and Cost Analysis (n = 196)
Adverse drug reactions (ADRs) were observed in 28.6% of patients. Gastrointestinal upset (9.2%) was the most common ADR, followed by nephrotoxicity (7.1%) and hepatotoxicity (5.1%). The association was statistically significant ($p = 0.031$).

Regarding cost analysis, the majority of patients (34.7%) incurred a daily antimicrobial cost between ₹500–1000 (p = 0.022). For total antimicrobial expenditure during CCU stay, 32.7% spent between ₹5001–10,000, while 19.4% incurred costs exceeding ₹20,000 (p = 0.017). Higher costs were associated with prolonged hospitalization and use of reserve antibiotics such as carbapenems and colistin.

DISCUSSION

The present cross-sectional observational study evaluated antimicrobial utilization, microbiological profile, resistance pattern, adverse drug reactions, and cost implications among CCU patients. The majority of patients in our study belonged to the age group 51–70 years (46.9%), which is consistent with findings reported by Patel et al. [11], who observed that elderly patients constituted the largest proportion of critically ill individuals requiring antimicrobial therapy. Similar age predominance was also reported by Singh et al. [12], highlighting increased susceptibility to infections due to immunosenescence and multiple comorbidities in older adults.

A significant male predominance (63.3%) was observed in our study, comparable to the findings of Sharma et al. [13], who reported 61% male admissions in their ICU antimicrobial utilization study. This may be attributed to higher prevalence of risk factors such as smoking, occupational exposure, and delayed healthcare-seeking behavior among males in the Indian setting. Rural predominance (60.2%) in our study aligns with the findings of Das et al. [14], who documented increased referrals from rural areas to tertiary care centers, reflecting disparities in primary healthcare infrastructure.

Sepsis and pneumonia together accounted for nearly half of CCU admissions in the present study. Similar trends were reported by Vincent et al. [15] in the EPIC II study, where respiratory infections were the leading cause of ICU infections globally. An Indian multicentric study by Chatterjee et al. [16] also identified sepsis as the most common indication for broad-spectrum antimicrobial use in critical care units.

Diabetes mellitus was the most frequent comorbidity (31.6%) in our cohort. This finding corroborates observations by Mohanty et al. [17], who reported diabetes as a significant risk factor for severe infections and prolonged antimicrobial therapy in ICU settings. Hyperglycemia impairs neutrophil function and cellular immunity, predisposing to complicated infections.

Regarding microbiological profile, culture positivity was 49%, comparable to findings by Gupta et al. [18], who reported 45–52% culture positivity in ICU patients. Gram-negative organisms predominated in our study, with Klebsiella pneumoniae and Escherichia coli being the most common isolates. Similar organism distribution was noted in the ICMR Antimicrobial Resistance Surveillance Report [19], which documented Gram-negative bacilli as predominant ICU pathogens across India.

A concerning finding was the high prevalence of multidrug-resistant (MDR) organisms (19.4%). This is in line with the study by Tiwari et al. [20], who reported MDR rates ranging from 18–25% in tertiary care ICUs. Resistance to third-generation cephalosporins observed in our study mirrors national resistance trends, likely due to overuse and empirical prescribing practices. However, carbapenems and colistin retained relatively good sensitivity, similar to observations by Gupta et al. [18]. The preserved sensitivity of vancomycin and linezolid for Gram-positive isolates is also consistent with prior ICU-based antimicrobial surveillance studies [13].

Empirical antimicrobial therapy was initiated in 65.3% of patients in our study, comparable to the 60–70% empirical initiation rate reported by Singh et al. [12]. This reflects the urgency of treatment in critically ill patients, although it underscores the need for timely de-escalation based on culture results to prevent resistance development.

Adverse drug reactions were observed in 28.6% of patients, with nephrotoxicity being clinically significant. Similar findings were reported by Sharma et al. [13], where nephrotoxicity was primarily associated with aminoglycosides and colistin use. This emphasizes the importance of renal function monitoring during antimicrobial therapy in CCU patients.

Cost analysis in the present study revealed substantial expenditure, particularly in patients receiving reserve antibiotics and prolonged therapy. Comparable economic burdens were documented by Mohanty et al. [17], who reported significantly higher antimicrobial costs in patients with MDR infections and extended ICU stay.

Overall, the findings of the present study align with national and international literature, highlighting the predominance of Gram-negative infections, significant antimicrobial resistance, high empirical antibiotic use, and considerable economic burden in CCU settings. These findings reinforce the urgent need for antimicrobial stewardship programs, routine antibiogram surveillance, and rational prescribing strategies to combat the growing threat of antimicrobial resistance.

CONCLUSION

The present study demonstrated a high burden of infectious diseases requiring antimicrobial therapy among CCU patients, with sepsis and pneumonia being

the leading indications. Gram-negative organisms, particularly Klebsiella pneumoniae and Escherichia coli, predominated, and a considerable proportion of multidrug-resistant isolates was observed. Significant resistance to third-generation cephalosporins was noted, while carbapenems and colistin retained comparatively better sensitivity. Empirical antimicrobial therapy was initiated in the majority of cases, reflecting the urgency of critical care management. Adverse drug reactions were observed in nearly one-third of patients, with nephrotoxicity being clinically important. Additionally, substantial antimicrobial-related expenditure was documented, especially among patients requiring prolonged CCU stay and reserve antibiotics.Overall, the findings emphasize the urgent need for strengthened antimicrobial stewardship programs, regular antibiogram surveillance, rational prescribing practices, and continuous monitoring of drug safety to optimize therapeutic outcomes and reduce antimicrobial resistance in critical care settings.

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