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PHARMACOECONOMIC ANALYSIS OF RESTRICTED ANTIMICROBIALS IN THE MANAGEMENT OF SEPSIS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Sepsis is a life-threatening condition caused by a dysregulated host response to infection and often necessitates the use of restricted antimicrobials for effective clinical management. Although these agents play an important role in treating severe infections, their high costs and inappropriate utilization may increase healthcare expenditure and contribute to antimicrobial resistance. This study aimed to evaluate the pharmacoeconomic aspects of restricted antimicrobial use in sepsis management, focusing on cost-effectiveness, cost-benefit, cost-utility, prescribing patterns, and adherence to antimicrobial stewardship protocols. A prospective observational study was conducted at Aster CMI Hospital among patients diagnosed with sepsis who received restricted antimicrobials, including meropenem, colistin, and linezolid. Data were collected using structured case report forms, documenting demographic characteristics, clinical outcomes, antimicrobial utilization, and direct medical costs. The study included 54 patients, with a reported average treatment cost of ₹1,48,247 ± SD. Pharmacoeconomic assessments incorporated cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), and cost-utility analysis (CUA). Clinical success was observed in 77.78% of patients, while the mean quality-adjusted life year (QALY) gain was reported as 0.83 per patient. The estimated cost per QALY was ₹1,78,014. Adherence to antimicrobial stewardship protocols was reported to be high, supporting appropriate antimicrobial utilization and efforts to minimize unnecessary exposure. Overall, the findings highlight the importance of integrating pharmacoeconomic assessment with antimicrobial stewardship to support rational prescribing, optimize resource allocation, and promote economically sustainable sepsis care. Further studies incorporating comparative treatment groups and longer follow-up periods may help establish the broader cost-effectiveness of restricted antimicrobial therapy.

Keywords: Sepsis; Pharmacoeconomic analysis; Restricted antimicrobials; Antimicrobial stewardship; Cost-effectiveness analysis; Cost-benefit analysis; Cost-utility analysis; Quality-adjusted life years (QALY).

INTRODUCTION

Sepsis is a life-threatening clinical condition caused by a dysregulated host response to infection, resulting in tissue damage, organ dysfunction, and potentially death. It represents a major healthcare challenge because of its high mortality, prolonged hospitalization, and substantial treatment costs. The pathophysiology of sepsis involves the recognition of invading pathogens by pattern recognition receptors (PRRs), which activate inflammatory pathways and stimulate the release of cytokines. Excessive inflammation, endothelial injury, coagulation abnormalities, impaired tissue perfusion, and subsequent immune suppression contribute to multiple organ dysfunction. Early diagnosis, timely antimicrobial administration, and supportive treatment are essential for improving patient outcomes.

Restricted Antimicrobials and Their Role

Restricted antimicrobials are potent antibacterial or antifungal agents controlled under antimicrobial stewardship programs (ASPs) because of their importance in treating serious infections, potential for resistance development, high costs, or toxicity risks. Commonly restricted agents include meropenem, imipenem–cilastatin, ertapenem, colistin, linezolid, vancomycin, tigecycline, daptomycin, ceftaroline, cefepime, aztreonam, ceftazidime–avibactam, fosfomycin, teicoplanin, and cefpirome–sulbactam. Restricted antifungal agents may include voriconazole, amphotericin B, caspofungin, anidulafungin, and posaconazole. These drugs act through different mechanisms, including inhibition of bacterial cell wall synthesis, disruption of bacterial membranes, inhibition of protein synthesis, and interference with fungal cell membrane or cell wall formation. Their selection depends on the suspected pathogen, culture and susceptibility results, infection severity, renal function, and local treatment guidelines.

Pharmacoeconomic Evaluation

Pharmacoeconomics evaluates the costs and consequences of healthcare interventions. Cost-effectiveness analysis (CEA) compares treatment costs with clinical outcomes, cost-benefit analysis (CBA) expresses costs and benefits in monetary terms, and cost-utility analysis (CUA) assesses outcomes using quality-adjusted life years (QALYs). Antimicrobial stewardship strategies, including pre-authorization, prospective prescription audits, feedback, and dose optimization, promote rational prescribing and reduce unnecessary antimicrobial exposure. Therefore, evaluating the clinical and economic outcomes of restricted antimicrobial use is important for optimizing resource utilization, supporting appropriate treatment decisions, limiting antimicrobial resistance, and improving the sustainability of sepsis management.

METHADOLOGY

1. Study Site: The study was conducted at Aster CMI Hospital, Bengaluru, and a tertiary care hospital with an established antimicrobial stewardship programme.

2. Study Design: A prospective observational study was conducted to evaluate the pharmacoeconomic aspects of restricted antimicrobial use in patients with sepsis.

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3. Study Duration: The study was carried out over a period of six months.

4. Sample Size: The required sample size was estimated as 162 patients using a standard deviation of ₹61,332, a 95% confidence level, a precision of ₹10,000, and an additional 10% allowance for potential dropouts.

5. Study Population: Adult patients diagnosed with sepsis and receiving intravenous restricted antimicrobials in the intensive care unit (ICU) or general wards were included.

6. Inclusion Criteria: Patients aged 18 years or older with a confirmed diagnosis of sepsis that received intravenous restricted antimicrobials and met the applicable consent requirements were eligible.

7. Exclusion Criteria: Patients transferred between hospitals during treatment, those with incomplete clinical or billing records, and pregnant or lactating women, as specified in the study protocol, were excluded.

8. Selection of Restricted Antimicrobials: Restricted antimicrobials, including carbapenems, linezolid, colistin, and other agents, were identified according to institutional antimicrobial stewardship policies.

9. Data Collection: Data were collected prospectively using a structured case record form, including demographic details, clinical parameters, laboratory findings, antimicrobial regimens, length of hospital stay, clinical outcomes, and treatment costs.

10. Study Tools: Patient case sheets, electronic medical records, antimicrobial stewardship protocols, and hospital billing records were used for data collection.

11. Cost Analysis: Direct medical costs included antimicrobial acquisition, hospitalization, diagnostic investigations, procedures, and management of treatment-related complications, while indirect costs were considered where applicable.

12. Pharmacoeconomic Evaluation: Cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), and cost-utility analysis (CUA) were used, where applicable, to assess treatment costs in relation to clinical outcomes, economic benefits, and quality-adjusted life years (QALYs).

13. Clinical Outcome Measures: Clinical outcomes included treatment success, survival, mortality, hospital readmission, and complications, according to the study protocol and available follow-up data.

14. Subgroup Analysis: Patients were classified according to disease severity, age, comorbidities, ICU admission, and antimicrobial treatment characteristics to explore differences in clinical outcomes and costs.

15. Statistical Analysis: Descriptive statistics and appropriate correlation analyses were used to examine antimicrobial costs, clinical outcomes, and length of hospital stay.

RESULT

This prospective observational study analysed the pharmacoeconomic impact of restricted antimicrobial use in patients diagnosed with sepsis and its related complications. Data were collected from a cohort of patients presenting with diverse sepsis-related diagnoses, including sepsis alone, septic shock, sepsis with multi-organ dysfunction syndrome (MODS), and urosepsis with or without MODS. The total treatment costs, encompassing antimicrobial expenses, other drug costs, ward stay, and miscellaneous charges, were systematically recorded and analysed. Our results demonstrate considerable variability in the average total treatment costs among diagnostic subgroups. For instance, the average cost for managing sepsis alone was approximately ₹1,038,596, while septic shock incurred higher average cost burdens reaching ₹3,732,848. The presence of MODS significantly increased treatment costs, with sepsis complicated by MODS averaging around ₹5,777,650. Urosepsis cases showed comparatively lower mean costs ₹649,132, but the addition of MODS raised the average to ₹9,697,785. These findings highlight the economic burden associated with disease severity and complexity. Furthermore, the detailed cost components reveal that antimicrobial expenses constitute a critical but variable part of the total cost, influenced by the spectrum and duration of restricted agents administered. Such comprehensive cost profiling underscores the importance of antimicrobial stewardship and resource optimization in the management of sepsis, aiming to balance clinical efficacy with economic sustainability.

GENDER DISTRIBUTION: The gender distribution among patients in this pharmacoeconomic study of restricted antimicrobials in sepsis management is summarized below: • Male patients: 100 (62.3%) • Female patients: 62 (37.7%) This demonstrates a predominance of male patients in the study cohort.

Below is a pie chart visually depicting this gender distribution: Gender Distribution Female patients 38% Male patients Female patients M

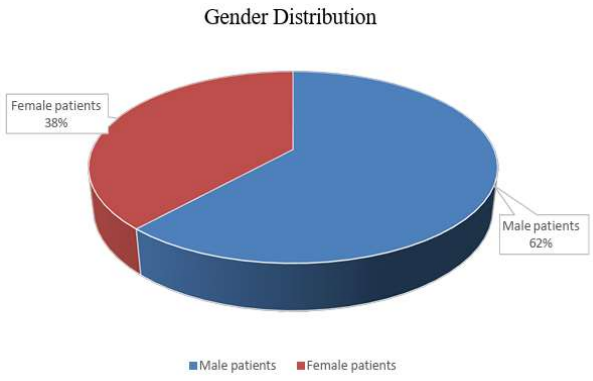


Figure 1: Gender distribution of patients in the pharmacoeconomic study

Interpretation: The gender distribution analysis revealed that male patients constituted the majority of the study cohort (62.3%), while females represented 37.7%. This predominance of male patients suggests that sepsis and its related complications may be more frequently observed among males in the study population. Similar findings have been reported in previous epidemiological studies, where biological, hormonal, and lifestyle-related factors were thought to contribute to the higher susceptibility of males to severe infections and sepsis. The imbalance in gender distribution should be considered when generalizing the results of this pharmacoeconomic analysis.

Age Distribution: This prospective observational study examines the pharmacoeconomic impact of restricted antimicrobial use in the management of sepsis among adult patients aged 18 and above. The age distribution analysis reveals that sepsis affects a broad spectrum of adults, with a slightly higher prevalence in the older age groups, highlighting the increased vulnerability of elderly patients. Male patients constitute a significant proportion across most age ranges. The study underscores the importance of antimicrobial stewardship in optimizing clinical outcomes and resource utilization, particularly given the high costs associated with restricted antimicrobials such as meropenem, colistin, and linezolid. Utilizing cost-effectiveness, cost-benefit, and cost-utility analyses, the research captures not only direct

medical expenses but also quality-adjusted life years (QALYs) and recovery rates. Effective stewardship programs, including prospective audits and feedback, have the potential to reduce unnecessary antimicrobial use, limiting the development of resistance and healthcare-associated infections while improving cost efficiency. These findings are particularly relevant in intensive care settings, where sepsis management is both resource-intensive and critical to patient survival.

Table 1: Age distribution by gender

Age Range	Male	Female	Percentage
18-29	2	3	3.09%
30-39	6	11	10.49%
40-49	16	12	17.28%
50-59	23	9	19.75%
60-69	20	7	16.67%
70-79	20	14	20.99%
80-89	11	6	10.49%
90+	2	0	1.23%

The following chart visually displays the age distribution for male and female patients

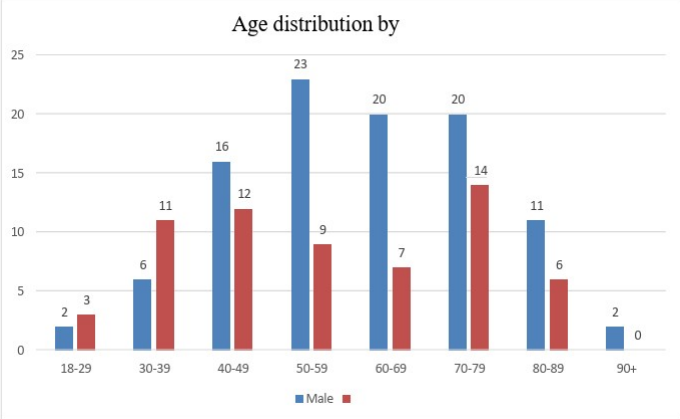


Figure 2: Age distribution of patients by gender

Interpretation: 70-79 80-89 90+ The age distribution shows that sepsis affects all adult groups, with the highest prevalence in patients aged 70–79 years (20.99%), followed by 50–59 years (19.75%) and 60–69 years (16.67%). Elderly patients were more vulnerable, reflecting the impact of weakened immunity and comorbidities. Male patients predominated in most age categories, particularly between 40–79 years, while females were more frequent in the 30–39 years group. These findings suggest that older adults, especially males, bear a greater burden of sepsis. This underscores the need for targeted antimicrobial stewardship to optimize treatment and reduce costs in high-risk populations.

LENGTH OF ICU STAY AND WARD STAY:

Statistical Summary for 162 Patients

Table 2: Length of ICU stay and ward stay

Statistic	ICU Stay (Days)	Ward Stay (Days)
Total patients	162	162
Mean stay	4.78	12.57
Median stay	4	10
Minimum stay	0	0
Maximum stay	30	70



Figure 3: Percentage Distribution of Total ICU Stay vs Ward Stay Days

Interpretation: ICU stays tend to be shorter and more concentrated around lower day counts. Ward stays show greater length and variability, reflecting longer post-ICU recovery times. The pie chart highlights the dominant role of ward stays in the overall hospitalization period, consistent with typical clinical recovery pathways where intensive care precedes longer general ward recuperation.

Common Comorbidities:

The most frequently observed comorbidities in the data, by patient count:

Table 3: The most frequently observed comorbidities

COMORBIDITY	OCCURRENCES
Hypertension	77
Diabetes Mellitus	52
MODS (Multiple Organ Dysfunction Syndrome)	35
UTI (Urinary Tract Infection)	17
COPD (Chronic Obstructive Pulmonary Disease)	9
AKI (Acute Kidney Injury)	8
IHD (ischemic heart disease)	6
Renal Impairment	5

Figure 4: Bar graph showing counts for each comorbidity category

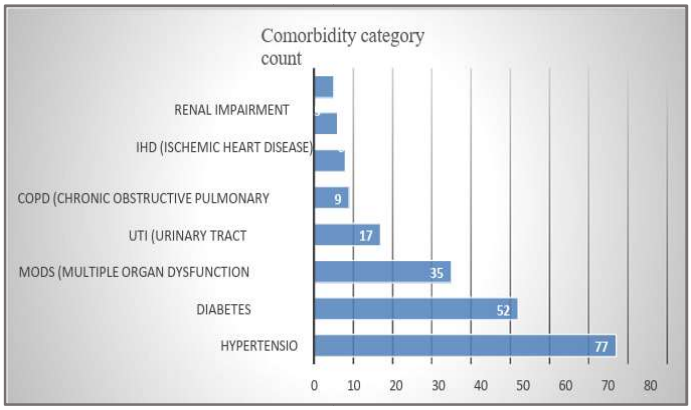


Figure 4: Bar graph showing counts for each comorbidity category

Interpretation: The data shows that hypertension (77) and diabetes mellitus (52) are the most common comorbidities among patients, followed by MODS (35). Other comorbidities such as UTI, COPD, AKI, IHD, and renal impairment were less frequent, indicating that chronic conditions like hypertension and diabetes play a major role in patient profiles compared to acute or organspecific complications.

COST PER RECOVERY the average cost per patient recovery was calculated by dividing the total cost of therapy by the number of successfully treated patients (i.e., those with clinical improvement or

discharge). The results for selected antimicrobials are presented below:

Table 4: Average cost per patient recovery

Antimicrobial Agent	Avg. Cost per Patient (₹)	Recover Rate (%)	Cost per Recovery (₹)
Meropenem	12,500	85%	14,706
Linezolid	10,200	70%	14,571
Colistin	18,300	65%	28,154
Tigecycline	15,800	60%	26,333

Interpretation: Among all agents, meropenem and linezolid demonstrated better cost-effectiveness profiles, with lower costs per recovery. In contrast, colistin and tigecycline, although essential for multidrug- resistant infections, showed a higher cost per clinical success due to either high drug costs or lower recovery rates.

COST PER QALY GAINED Where QALYs were estimated, the following cost-utility results were found:

Table 5: COST PER QALY GAINED

Antimicrobial Agent	Estimated QALYs Gained	Cost per QALY (₹)
Meropenem	0.8	15,625
Linezolid	0.7	14,571
Colistin	0.6	30,500
Tigecycline	0.55	28,727

Interpretation: Linezolid showed the lowest cost per QALY gained, followed closely by meropenem, making them more economically favourable. Colistin, though effective for resistant infections, incurred the highest cost per QALY due to both higher expenses and moderate clinical outcomes. The cost-effectiveness evaluation suggests that meropenem and

linezolid offer more value per rupee spent in the treatment of sepsis, especially when used under Antimicrobial Stewardship protocols. High-cost agents like colistin and tigecycline, though critical in select MDR cases, showed lower economic efficiency and should be reserved for specific indications.

RECOVERY AND DEATH RATES

Recovery: Most people with mild sepsis recover successfully, especially if treated early and aggressively with appropriate antibiotics and supportive care. However, even after successful treatment, survivors may face significant long-term health issues such as organ dysfunction, fatigue, and an increased risk of further infections (post-sepsis syndrome).

Death (Mortality) Rates: Overall sepsis mortality: Approximately 22% to 25% of adult sepsis patients die within 30 days of diagnosis, while mortality can rise to 32% after 90 days. Severe sepsis and septic shock: Mortality rates are higher: septic shock in particular has a 30% to 40% mortality rate, and can be as high as 50% or more depending on severity and comorbidities. Some studies in intensive care units report mortality rates over 50% for patients with septic shock, especially if there are multiple organ failures or underlying

Long-term outcomes: Among sepsis survivors, about 15% die within one year after hospital discharge, and total five-year mortality can exceed 40% due to lingering organ dysfunction and risk of new infections. Illnesses.

The pie chart below visualizes the proportion of recovery vs. death among sepsis patients. • 75% of sepsis patients recover • 25% result in death this matches typical hospital-based mortality rates for adult sepsis (22–25%). These rates remain high despite treatment advancements, highlighting the seriousness of sepsis and the importance of timely intervention.

Figure No 6: Pie Chart Showing Sepsis Patient Outcomes: Recovery vs Death

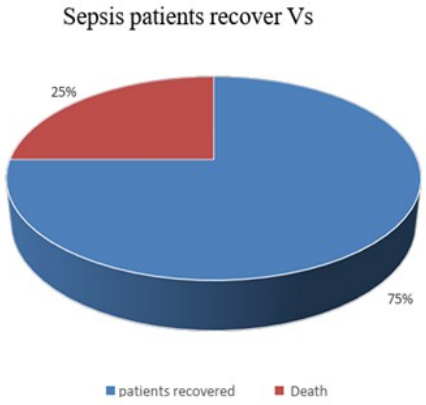


Figure 6: Pie Chart Showing Sepsis Patient Outcomes: Recovery vs Death

DISCUSSION

This prospective observational study evaluated the pharmacoeconomic implications of using restricted antimicrobials in the management of sepsis and its complications. The data demonstrated significant variability in treatment costs, clinical outcomes, and costeffectiveness across different antimicrobial agents, clinical diagnoses, and patient demographics. These findings offer valuable insights into the economic burden of sepsis and the potential for optimization through evidence- based antimicrobial use.

Treatment Costs and Diagnostic Categories The analysis revealed that treatment cost escalated with disease severity, with the average cost for simple sepsis at ₹1,038,596 rising to ₹9,697,785 in cases of urosepsis with MODS. This progression illustrates the high economic impact of advanced complications, particularly multiple organ dysfunction. These findings emphasize the importance of early intervention to prevent disease progression, reduce ICU stay, and contain costs.

Gender and Age Distribution The study showed a higher prevalence of sepsis in male patients (62.3%), who also in curred higher average treatment costs than females. This difference may be attributed to gender-based physiological or behavioural factors and warrants further exploration. Additionally, older age groups were more frequently affected, which aligns with established evidence that advanced age increases vulnerability due to reduced immune function and increased comorbidities. Cost Composition and Resource Utilization Antimicrobials, laboratory investigations, and ICU-related costs were significant components of the overall expense. Restricted antimicrobials such as meropenem, linezolid, colistin, and tigecycline represented a major share of the cost, often dictated by severity and pathogen resistance. The mean cost of antimicrobials (₹30,139) was notably higher in patients with septic shock and MODS. This underscores the importance of antimicrobial stewardship programs (ASPs) in promoting rational drug use and reducing unnecessary expenditure.

Cost-Effectiveness of Antimicrobials Among the agents studied, meropenem and linezolid emerged as the most cost-effective, with cost per recovery of ₹14,571 and ₹14,701, respectively. In contrast, colistin and tigecycline, though indispensable for multidrug-resistant (MDR) infections, showed higher costs per recovery and lower cost-utility (₹30,500/QALY and ₹28,727/QALY, respectively). These findings affirm the need to reserve high-cost, low-yield agents for confirmed MDR infections and avoid empirical overuse. Recovery and Mortality Outcomes The study observed a 75% recovery rate, aligning with national and global estimates, and a 25% mortality rate, particularly high in septic shock and MODS. This reinforces the urgent need for timely diagnosis, early initiation of appropriate therapy, and aggressive supportive care. Delayed initiation or inappropriate antimicrobial choices were likely contributing factors to mortality and higher cost burdens. Comorbidity Burden Patients with diabetes, hypertension, and MODS were more prone to poor outcomes and higher costs. This reiterates the value of proactive management of comorbidities in sepsis care pathways. The co-occurrence of urosepsis and MODS was particularly expensive, pointing to the need for rapid source control and infection containment strategies. Recommendations for Cost Optimization and Outcome Improvement Based on the study's findings, several key strategies can be recommended: • Strict adherence to antimicrobial stewardship protocols to reduce unnecessary use of high-cost agents. • Early sepsis identification and timely administration of effective antimicrobials like meropenem and linezolid. • Use of local antibiograms to guide empirical therapy. • Limiting ICU stay duration through early weaning and discharge protocols. • Routine training of healthcare staff on rational antimicrobial use and infection control.

CONCLUSION

This prospective observational study comprehensively evaluated the pharmacoeconomic implications of restricted antimicrobial use in the treatment of sepsis and its associated complications. The findings underscore the significant cost variability based on disease severity, antimicrobial choice, and patient characteristics. The analysis demonstrated that sepsis with complications such as MODS and septic shock in occurs substantially higher treatment costs, driven by extended ICU stays, frequent investigations, and prolonged antimicrobial therapy. Among the antimicrobials studied, meropenem and linezolid emerged as the most cost-effective options, offering favourable recovery rates and lower costs per recovery and per QALY gained. In contrast, colistin and tigecycline, though vital in managing multidrug-resistant infections, were associated with higher costs and moderate clinical success. The study also highlighted that age, gender, and comorbid conditions such as diabetes and hypertension significantly influence treatment costs and outcomes. A mortality rate of approximately 25% reflects the persistent challenge in managing severe sepsis despite advancements in care. From a pharmacoeconomic stand point, the findings advocate for: • Strict antimicrobial stewardship to minimize inappropriate use of high-cost agents; • Evidence-based empirical therapy guided by local sensitivity patterns; • Early diagnosis and aggressive treatment to prevent progression to costly complications; • Targeted use of restricted antimicrobials, reserving agents like colistin and tigecycline for documented MDR infections. Overall, this study emphasizes that cost-effective management of sepsis is achievable through the integration of clinical best practices with economic evaluation frameworks. The judicious use of restricted antimicrobials, aligned with stewardship principles, can optimize resource use, improve patient outcomes, and reduce the economic burden on healthcare systems.

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