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ORIGINAL ARTICLE

An Observational Study to Assess the Efficacy of Antibiotics in Sepsis at a Tertiary Care Hospital

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Abstract

Background: Sepsis is a life-threatening condition characterized by organ dysfunction because of dysregulated host response to infection, which continues to challenge clinical management. **Objective:** To assess the pharmacotherapeutic efficacy of antibiotics in sepsis patients admitted in the hospital. **Methodology:** This prospective observational study evaluated the clinical effectiveness of antibiotic therapy in 80 adult sepsis patients admitted to a tertiary care centre. The study assessed multiple outcome measures, including trends in inflammatory biomarkers, hemodynamic stabilisation and morality rate, to provide a detailed and insightful evaluation of treatment response. SPSS (version 27) and Microsoft Excel were used for the statistical analysis, and P <0.005 set as significance level. **Findings:** The results indicated significant improvements in clinical parameters. There was a notable reduction in inflammatory markers, with C- reactive protein (CRP) and procalcitonin levels decreasing significantly (*p* <0.01). Hemodynamic parameters show a remarkable improvement, with increased mean arterial pressure and better lactate clearance (*p* < 0.05). These findings highlight how important it is for the prompt administration of antibiotic therapy in reducing inflammation and bringing back the stability in sepsis patients. However, a high mortality rate of 33.7% was observed in the study. **Novelty**: This study emphasizes the importance of prompt antibiotic treatment in sepsis by showing significant improvement in SIRS (systemic inflammatory response syndrome) criteria and other inflammatory markers by discharge. It indicates that in order to improve the patient outcome a need for faster diagnostic tools and better antibiotic management is necessary.

Keywords: Sepsis; Antibiotic management; Antibiotic efficacy; Biomarkers; Mortality rate

1 Introduction

Sepsis can be defined as life-threatening organ dysfunction resulting from a dysregulated host response to infection. It is a major cause of death in intensive care units worldwide. Sepsis globally results in an annual death toll of 11 million [(1)]. The evolving

understanding of its pathophysiology has refined our approach in management of sepsis, though fundamental concepts of systemic inflammation and organ failure remain central to its definition. The pathophysiological process starts with that of a complex interaction between microbial pathogens and body's immune system. Pattern recognition receptors recognise pathogen-associated molecular patterns and cause the massive release of inflammatory mediators like TNF-α, IL-6, and interferons. The storm of cytokine release induces endothelial injury, microvascular thrombosis, and distributive shock, which ultimately results in tissue hypoxia and cellular dysfunction. The coagulation and complement systems get activated, whereas anti-inflammatory responses try to restore homeostasis, tending to result in paradoxical immunosuppression. Over the years, diagnostic paradigms for sepsis detection and treatment have undergone significant changes, with a combination of laboratory tests, culture tests, vital signs monitoring and current sepsis guidelines such as SIRS criteria and SOFA score help in early detection and understanding the severity of sepsis in patients. However, the large amount of heterogeneity in the studies needs to be considered when interpreting the information. Referring to a paper published in March 2020, it was observed that Procalcitonin and C-reactive protein aid to diagnosis and guide to antibiotic use in cases of sepsis, with procalcitonin being more specific to bacterial infections. It is noticed that if a procalcitonin measurement demonstrates a drop to below 0.5 ng/mL or about an 80% decline from the highest value, suggest stopping antibiotics. In closing, biomarkers can help guide decisions, but clinical judgment is also important when stopping or de-escalating treatment[(2)]. Prehospital lactate clearance is directly linked with reduced mortality in patients with septic shock[(3)]. Antibiotics are the most crucial when it comes to sepsis management. The mortality risk increases with delays in delivery over an hour, especially after three hours from the identification of the infection[(4)].

Even with the advances in the use of antibiotics to treat sepsis, disputes have continued with regard to the best antimicrobial therapy (or combinations of therapy) with resultant impact on patient outcomes. In addition, we have evidence that the use of medicinal plant, such as *Coptis teeta*, exhibits strong antibiotic properties and is effective in treating both curable and life-threatening illnesses[(5)]. Also, another study suggested that *Lactuca virosa* has the potential to provide novel anti-bacterial agent(s). They demonstrated a very strong level of antibacterial activity for the extract, especially against *Bacillus cereus* and *Streptococcus* mutans[(6)].

In conclusion, several studies have shown that early antibiotic administration is associated with lower mortality rates, however other studies argue to have found no significant correlation between early therapy and patient outcomes. Thus, the present study is designed to evaluate the efficacy of antibiotic treatment in sepsis patients. Specifically, it seeks to assess how stronger diagnostic tools are used for more accurate and quick detection of sepsis and how the use of broad-spectrum antibiotics influences patient survival, disease progression, and overall recovery in both sepsis and septic shock cases.

2 Methodology

This prospective observational study was conducted in the Department of General Medicine and the ICU at MVJ Medical College and Research Hospital over six months (March–August 2024), following ethical approval from the Institutional Ethics Committee (No. MVJMC&RH/IEC-118/2024) on 21/02/2024. Using a standardised formula ($n = [Z^2 \times P(1\text{-}P)]/d^2$, where $Z = 1.96$, $P = 0.5$, $d = 0.052$), we calculated a required sample size of 80 participants. Adult patients (≥ 18 years) diagnosed with sepsis or septic shock were enrolled after obtaining informed consent, excluding pregnant women and unwilling participants. Data were collected using a structured proforma capturing demographics, clinical presentation, laboratory results, antibiotic regimens, and outcomes (particularly mortality). Statistical analysis was performed using Microsoft Excel and SPSS version 27, with skewed data reported as median and categorical variables as percentages. ROC curve analysis was used to determine predictive accuracy (AUC), with significance set at $p < 0.05$. The study maintained methodological rigour through a prospective design, standardised protocols, and ethical compliance.

3 Results and Discussion

3.1 Sociodemographic profile

The study was carried out among 80 adult sepsis patients in ICU (intensive care unit). Out of 80 sepsis patients analysed, the majority of the patients belonged to age group of 71-80 years.

3.2 Clinical outcome

In this study, we assessed clinical outcome in terms of mortality rate, and it was found that 27 sepsis patients out of 80 were deceased.

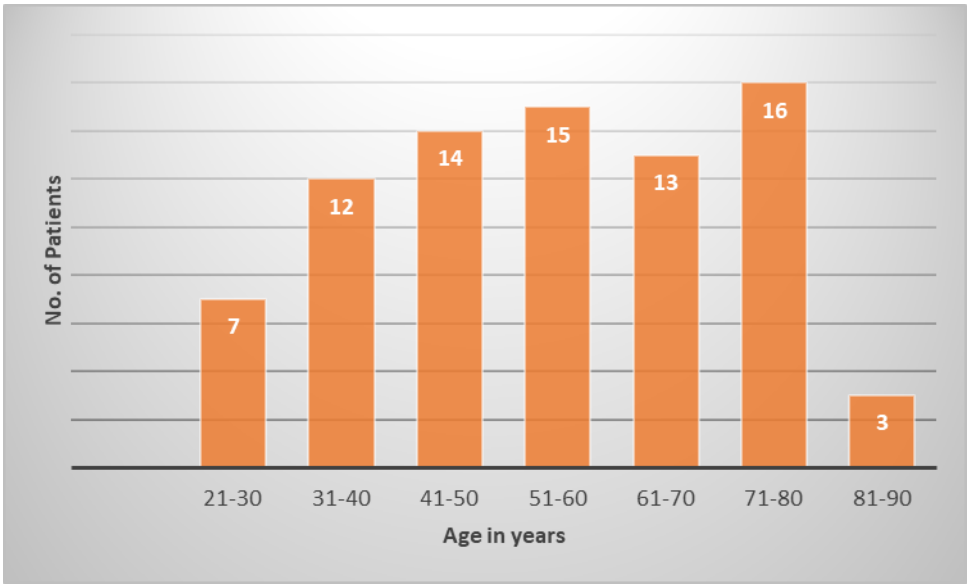

Fig 1. Distribution of age among sepsis patients

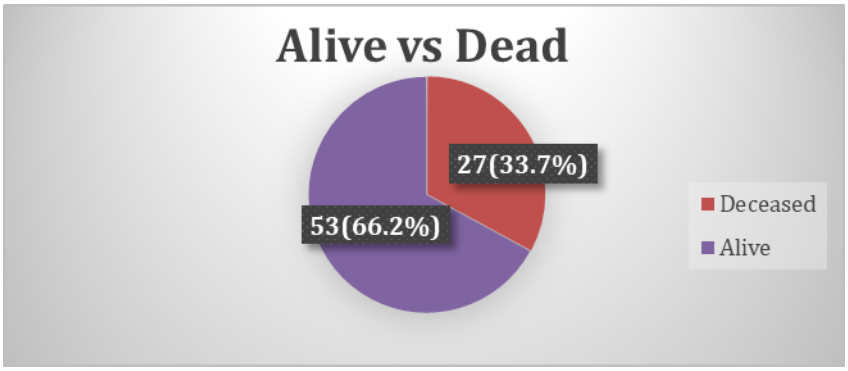

Fig 2. Distribution of clinical outcomes among sepsis patients

3.3 Prescription pattern of antibiotics

In the present study we analysed several classes of antibiotics where Cephalosporins, Carbapenem and Nitroimidazole class were being the most utilized.

3.4 Biomarkers

The laboratory results show significant changes in several parameters from admission to discharge. Haemoglobin levels increased from 8.7 g/dL to 12.6 g/dL, indicating improved anaemia. Neutrophil counts decreased from 72% to 57%, suggesting a reduction in inflammation or infection. Red blood cell count, platelet levels, and packed cell volume all rose, reflecting better overall haematological health. C-reactive protein and procalcitonin, markers of inflammation, decreased substantially, from 15 mg/L to 8.95 mg/L and 5.9 ng/mL to 0.09 ng/mL, respectively, indicating reduced inflammatory response. Erythrocyte sedimentation rate also fell from 34 mm/hr to 13 mm/hr.

Blood pressure improved notably, with systolic and diastolic values increasing from 100/60 mmHg to 130/70 mmHg, reflecting better cardiovascular stability. Pulse rate and respiratory rate also decreased, aligning with improved clinical status. Temperature normalized from 100.5°F to 98.4°F, and oxygen saturation improved from 90% to 96%. pH levels corrected from 7.1 to 7.356, and lactate levels dropped from 4.18 mmol/L to 0.9 mmol/L, suggesting better metabolic balance.

Table 1. Prescription Pattern of Antibiotics

Sl. No	Antibiotics	Number	Percentage	Total
1	**Aminoglycosides**			
1a.	Amikacin	4	5%	5% (n=4)
2	**Cephalosporins**			
2a.	Cefoperazone	8	10%	43.8% (n=35)
2b.	Ceftriaxone	14	17.5%	
2c.	Cefoperazone + Sulbactam	7	8%	
2d.	Cefotaxime	6	7.5%	
3	**Tetracycline**			23.8% (n=19)
3a.	Doxycycline	19	23.8%	
4	**Penicillin**			
4a.	Piperacillin	20	25%	35%(n=28)
4b.	Amoxicillin	8	10%	
5	**Sulfonamides**			7.5% (n=6)
5a.	Sulfamethoxazole + Trimethoprim	6	7.5%	
6	**Carbapenem**			41.3% (n=33)
6a.	Meropenem	33	41.3%	
7	**Beta lactamase inhibitor**			25% (n=20)
7a.	Tazobactam	20	25%	
8	**Glycopeptides**			16.3% (n=13)
8a.	Vancomycin	13	16.3%	
9	**Nitroimidazole**			33.8% (n=27)
9a.	Metronidazole	27	33.8%	
10	**Macrolides**			17.5% (n=14)
10a.	Azithromycin	14	17.5%	

Table 2. Comparison of Various Parameters on Admission VS Discharge [median]

Variables	Admission	Discharge	P- value
Haemoglobin [g/dl]	8.7 [7.2-11.7]	12.6 [9.0-14.3]	0.000
Neutrophil [%]	72.00 [68.00-81.00]	57.00 [49.00-72.00]	0.000
Red Blood Cell [million cells/microliter]	3.12 [2.7-3.8]	4.23 [3.35-4.9]	0.000
Platelet [platelets per microliter]	2.57 [2.0-3.2]	3.16 [2.25-4.9]	0.000
Eosinophil [%]	3 [1-4]	2 [1-3]	0.001
Leukocyte [cells/μL]	12000 [8700-14400]	10000 [7300-11300]	0.000
Packed Cell Volume [%]	30 [26-36]	39.3 [32.6-43.0]	0.000
C reactive protein [mg/L]	15 [11.6-31.82]	8.95 [5.45-24.325]	0.010
Procalcitonin [ng/ml]	5.9 [3.4-9.3]	0.09 [0.05-1.0]	0.000
Erythrocyte Sedimentation Rate [mm/hr]	34 [24-65]	13 [8-32]	0.000
Systolic Blood Pressure [mm/hg]	100 [80-120]	130[110 -150]	0.000
Diastolic Blood Pressure [mm/hg]	60 [50-70]	70 [60-80]	0.000
Pulse [bpm]	100 [90-111]	90 [78-100]	0.000
Temperature [F]	100.5 [98.6-102]	98.400 [97.5- 99.9]	0.000
Respiratory rate [breath per minute]	24 [20-27]	17 [14-22]	0.000
SPO2 [%]	90 [86-97]	96 [90-98]	0.000
pH	7.1 [6.854-7.34]	7.356 [7.1- 7.4]	0.000
Lactate [mmol/L]	4.18 [3.1-5.9]	0.9 [0.68-4.9]	0.000
Potassium [mmol/L]	4.6 [4- 5.7]	4.350 [3.9-5.025]	0.269

3.5 ROC Analysis for Laboratory Parameters

In this observational study various laboratory parameters were evaluated for their ability to predict patient outcomes. C-Reactive Protein (CRP) had AUC of 0.996, demonstrating strong diagnostic performance, with sensitivity of 96.2%, specificity 96.1% and the cut-off value >14.30mg/L.

Table 3. Cut-off and AUC for Laboratory parameters

Variables	AUC	Sensitivity	Specificity	Cut off
Neutrophil	0.897	0.846	0.824	>65.5 %
Leucocyte	0.81	0.769	0.725	>10,350 cells/μL
C-reactive protein (CRP)	0.996	0.962	0.961	>14.30mg/L
Procalcitonin (PCT)	0.786	0.615	0.759	>0.255ng/mL
Erythrocyte sedimentation rate (ESR)	0.994	0.923	0.961	>24mm/h
Lactate	0.907	0.923	0.882	>1.10mmol/L
Potassium	0.834	0.769	0.647	>4.35mmol/L

3.6 Discussion

Sepsis is one of the many medical crises. It's a group of physiological and pathological host dysfunctions caused by a serious infection [7]. In a tertiary care hospital, this study assesses how well antibiotics work to treat sepsis. Sepsis can be divided into five stages based on its symptoms. In stage 1, the infection is contained, and its spread is stopped by a localized response at the site of injury. In Stage 2, in order to maintain immunological balance a compensatory Anti-inflammatory Response syndrome (CARS) begins. With worsening endothelial dysfunction and coagulation dysregulation, stage 3 represents a shift toward a dominant proinflammatory SIRS response. In stage 4, SIRS is replaced by CARS, which leads to a relative immunosuppressive state. Stage 5 is defined by dysregulation of the CARS and SIRS responses [8]. Antibiotic use is important in the treatment of sepsis. Current guidelines and previous studies showed that IV fluid resuscitation and early antibiotic treatment are essential to improve survival. These procedures are essential to manage sepsis and are needed to provide effective care [9]. This study showed how antibiotics are used in different classes. Several categories showed high usage: 43.8% participants used cephalosporins, followed by carbapenems (41.3%), nitroimidazoles (33.8%), penicillin (35%) and beta-lactamase inhibitors (25%). Alternatively lower usage was seen in the class of glycopeptides, aminoglycosides and sulfonamides. The most commonly used antibiotics for sepsis patients were carbapenems and third-generation cephalosporins, as per recent epidemiology study by Abe T et al [10]. The most common antibiotics administered were meropenem (21.33%) and Piperacillin-tazobactam (18.67%), according to another type of study carried out by Vanlalpeka HS *et al.,* [11] in southern India. Significant clinical improvement on discharge was seen in elevated haemoglobin, platelets, RBCs and PCV levels (packed cell volume). Patients' lab values returned to normal after treatment indicating and highlighting the efficacy of antibiotics in treating the infection. In this study we used ROC analysis to see how accurate different lab tests were at diagnosing diseases. The area under the curve for the leucocyte count was 0.81 with a cut-off of >10,350 cells/μL (sensitivity 76.9% and specificity 72.5%). CRP did very well, with an AUC of 0.996, a cut-off value of >14.30 mg/L, and a sensitivity of 96.2% and a specificity of 96.1%. A study by Yu G *et al.,* [12] found out that the lactate area score was higher (AUC [95% CI]: 0.596 [0.532 to 0.659], 0.635 [0.572 to 0.698], and 0.659 [0.597 to 0.720] in the non-surviving sepsis group. When and how well broad-spectrum antibiotics are given for sepsis are very important. Most of the evidence for the recommendation to give these antibiotics within an hour comes from studies that looked at a wide range of patient groups. Taking into account the research by Kollef MH *et al.,* [13] the timing of antibiotic administration in patients with potentially fatal conditions like sepsis and septic shock is one of the most important factors affecting survival for this population and it was further noticed that a person's mortality rate can double or even triple if antibiotic medication is not administered promptly for severe illnesses. Our study highlights the several precipitating factors which could aid in the early intervention of antibiotics and increase its efficiency.

4 Conclusion

This observational study shows the therapeutic effectiveness of different antibiotics during the course of treatment for sepsis. The study highlights the importance of giving broad-spectrum antibiotics within the first hour of sepsis diagnosis. Patients on administration of antibiotics demonstrated a statistically significant improvement in their body temperature, heart rate,

respiratory rate and white blood cells (SIRS criteria) with a p- value below 0.05 when discharged. The patients also had desirable clinical improvements in their haemoglobin, red blood cell (RBC) count, and platelet count, which showed that their oxygenation, clotting function, and nutritional status had all improved by time they were discharged. An overall 66.2% survival rate was seen by the end of the study. Whereas, the 33.7% mortality rate is mainly attributed to several contributing factors such as late diagnosis, delayed initiation of antibiotic therapy, severity of sepsis and advanced patient age. The ROC analysis showed that biomarkers like CRP, lactate levels and ESR having AUC of 0.996, 0.907 and 0.994 respectively have strong diagnostic performance in the early detection of sepsis. This helped in early diagnosis and treatment of sepsis. Ongoing monitoring of lab parameters is crucial for making effective treatment adjustments. Since there is no follow up of the patients once discharged, long-term effects of treatment in the sepsis survivors remains unknown. Future research should aim to fine-tune antibiotic regimens based on age, immune status and other genetic factors, and find not only stronger but faster diagnostic tools for early detection of sepsis to improve patient outcomes and lower sepsis-related deaths.

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