

Prognostic significance of early (first 6 hours) versus delayed changes in serum lactate and procalcitonin in septic shock: A prospective observational cohort study.

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Abstract

Background:

Sepsis and septic shock are major causes of mortality among critically ill patients. Serum lactate and procalcitonin are important biomarkers for prognostic evaluation and monitoring treatment response.

Objective:

To assess the prognostic significance of serial changes in serum lactate and procalcitonin and their clearance in predicting outcomes in patients with sepsis and septic shock.

Methods:

This prospective observational cohort study included 100 adult intensive care unit patients with suspected or confirmed sepsis. Serum lactate was measured at admission, 6, 12, and 24 hours, while procalcitonin was measured at admission and on day 3. Lactate and procalcitonin clearance rates were calculated. Clinical severity was assessed using the Glasgow Coma Scale, Sequential Organ Failure Assessment score, and National Early Warning Score.

Results:

The mean age was 57.8 ± 13.6 years, 56% were male, and overall mortality was 21%. Non-survivors had significantly higher baseline lactate and procalcitonin levels and markedly lower clearance rates than survivors ($p < 0.0001$). Lactate levels progressively declined over 24 hours in survivors, indicating improved tissue perfusion. Procalcitonin clearance demonstrated excellent diagnostic accuracy for predicting mortality, while higher Sequential Organ Failure Assessment and National Early Warning Score values were associated with poorer outcomes.

Conclusion:

Elevated serum lactate and procalcitonin levels with reduced clearance are associated with increased mortality in sepsis and septic shock. Serial biomarker monitoring combined with clinical severity scores may improve early risk stratification and prognostic assessment.

Recommendation:

Routine serial monitoring of lactate and procalcitonin clearance should be incorporated into sepsis management to facilitate early identification of high-risk patients.

Keywords: Glasgow Coma Scale; Sequential Organ Failure Assessment; National Early Warning Score; Sepsis; Septic shock; Procalcitonin.

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Introduction

A dysregulated host response to infection can result in sepsis, a potentially fatal illness that causes organ failure, septic shock, and elevated mortality. Sepsis remains a leading cause of morbidity and mortality globally, despite improvements in intensive care and treatment approaches. Nearly 49 million sepsis cases and 11 million sepsis-related fatalities occurred worldwide in 2017, making up almost 19.7% of all deaths, according to the Global Burden of Disease Report 2020. High frequency and fatality rates among severely ill sepsis patients have also been documented in Indian studies (1).

Reducing sepsis-related complications and mortality requires early diagnosis and prompt action. Disease severity is frequently evaluated using a variety of clinical scoring systems, including APACHE II, SOFA, MEWS, and NEWS. Nonetheless, biomarkers continue to be crucial instruments for septic patients' early diagnosis, treatment response tracking, and prognosis prediction. (2). Procalcitonin (PCT) and serum lactate are two frequently utilised biomarkers that have achieved significant therapeutic value. (3). Procalcitonin, a precursor of calcitonin, is correlated with the severity of disease and rises significantly during systemic bacterial infections. Elevated PCT levels may be a helpful prognostic indicator in sepsis and have been linked to poor outcomes in critically ill individuals. (4).

Another significant biomarker that indicates tissue hypoxia, reduced perfusion, and anaerobic metabolism is serum lactate (5). Increased mortality is linked to elevated lactate levels, which are commonly seen in sepsis and septic shock. Lactate clearance and serial lactate readings have become important markers of therapy response and resuscitation effectiveness (6). While several studies have assessed the prognostic importance of lactate and procalcitonin separately, nothing is known about their combined significance and clearance patterns in Indian septic patients. Thus, the current study was conducted to assess the correlation between procalcitonin levels, serum lactate, and clinical outcomes in sepsis and septic shock patients (7).

MATERIALS AND METHODS

Study Design

This prospective observational cohort study was conducted to evaluate the prognostic significance of early (first 6 hours) and delayed changes in serum lactate and procalcitonin, as well as their clearance, in predicting clinical outcomes among patients with sepsis and septic shock.

Study Setting and Duration

The study was conducted in the Department of Critical Care Medicine, Jaypee Hospital, Noida, Uttar Pradesh, India, over one year.

Participants

A total of 100 consecutive adult patients (≥ 18 years) admitted to the Intensive Care Unit (ICU) with suspected or confirmed sepsis or septic shock were enrolled. Patients who remained in the ICU for at least 72 hours were eligible for inclusion. Patients with malignancy, chronic liver disease, chronic kidney disease, human immunodeficiency virus (HIV) infection, pregnancy, or recent surgery were excluded from the study.

Data Collection

Baseline demographic characteristics, clinical history, comorbidities, laboratory investigations, and severity scores were recorded at admission. Serum lactate levels were measured at admission (0 hour), 6 hours, 12 hours, and 24 hours, whereas serum procalcitonin levels were measured at admission and on the third day. Absolute lactate clearance, relative lactate clearance, lactate clearance rate, and procalcitonin clearance were calculated. Clinical severity was assessed using the Glasgow Coma Scale (GCS), Sequential Organ Failure Assessment (SOFA) score, and National Early Warning Score (NEWS). Patients were followed until hospital discharge or death, and 28-day mortality was recorded as the primary clinical outcome.

Bias

To minimize selection bias, consecutive eligible patients fulfilling the inclusion criteria were recruited during the study period. Standardized protocols were used for patient assessment, specimen collection, laboratory investigations, and biomarker estimation. Clinical data were collected prospectively using a predefined data collection form to minimize information bias, and all laboratory investigations were performed in the same hospital laboratory using standardized procedures.

Study Size

A total of 100 patients were included in the study. The sample size was determined based on the expected number of eligible patients admitted during the study period and the feasibility of prospective recruitment within the available study duration. This sample size was considered adequate to evaluate the association between serial biomarker changes and clinical outcomes in patients with sepsis and septic shock.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). The normality of continuous variables was assessed using the **Kolmogorov–Smirnov test**. Continuous variables with normal distribution were expressed as mean $\pm$ standard deviation (SD), whereas non-normally distributed variables were presented as median with interquartile range (IQR). Categorical variables were expressed as frequencies and percentages. Comparisons between groups were performed using the independent Student's *t*-test or Mann–Whitney *U* test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables, as appropriate. Correlation and regression analyses were performed to evaluate the relationship between biomarker kinetics and clinical outcomes. Receiver operating characteristic (ROC) curve analysis was performed to determine the predictive performance of lactate clearance and procalcitonin clearance for mortality. A two-tailed *p*-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee.

Written informed consent was obtained from all participants before enrollment.

Results

A total of 100 patients with suspected or confirmed sepsis admitted to the intensive care unit were included in the study. Their demographic characteristics, clinical severity scores, laboratory parameters, biomarker kinetics, and clinical outcomes were analyzed.

The study was conducted in the Department of Critical Care Medicine of Jaypee Hospital, Noida, Uttar Pradesh. 100 patients with suspected / diagnosis of sepsis with age ≥ 18 years were included in the study. Lactate and procalcitonin clearance in septic patients were determined, and their association in predicting the outcome on the 28th day after admission was identified, and the results are as follows.

The mean age of the study population was **57.8 $\pm$ 13.6 years**, with a median age of **57.5 years** (IQR: 48–66 years). The participants ranged from **28 to 86 years**, indicating that sepsis predominantly affected middle-aged and elderly patients.

Table 1: Age distribution.

Variable	Mean $\pm$ SD	Median(25th-75th percentile)	Range
Age(years)	57.8 $\pm$ 13.6	57.5(48-66)	28-86

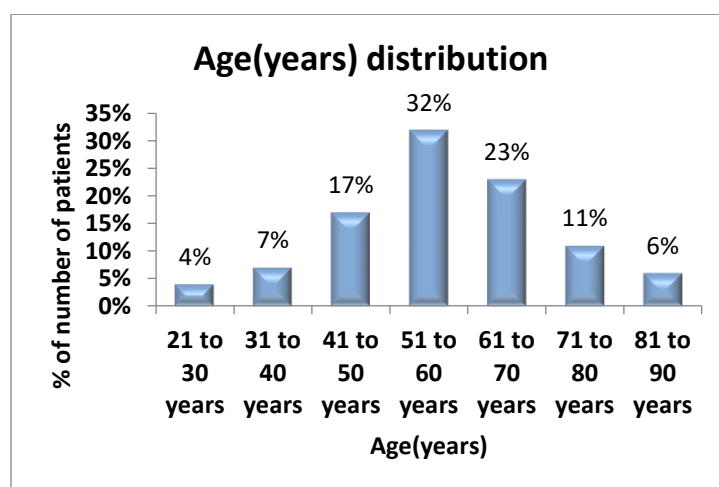


Figure 1: Age distribution.

Among the 100 patients, **56% were male**, and **44% were female**, demonstrating a slight male predominance in the study population.

Table 2: Gender distribution.

Gender	Frequency	Percentage
Female	44	44%
Male	56	56%
Total	100	100%

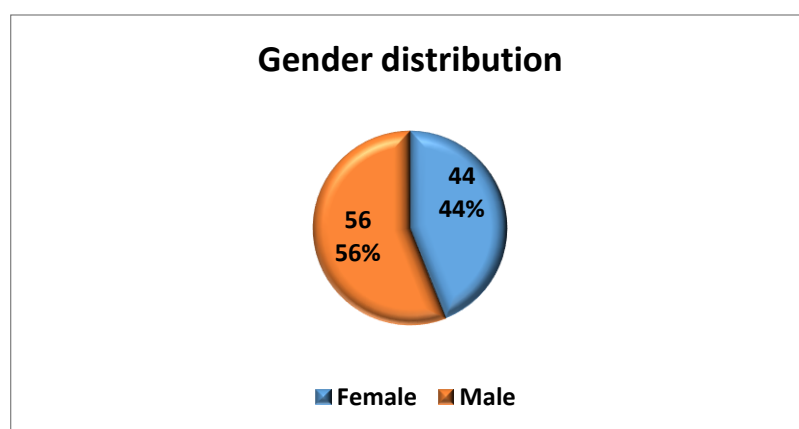


Figure 2: Gender distribution

The mean Glasgow Coma Scale (GCS) score was 13.04 ± 2.23 . Most patients (67%) had mild neurological impairment (GCS 13–15), whereas 28% and 5% had moderate and severe impairment, respectively.

Table 3: Glasgow Coma Scale distribution

Glasgow Coma Scale	Frequency	Percentage
Mild head insult {13 to 15}	67	67%
Moderate head insult {9 to 12}	28	28%
Severe head insult {≤8}	5	5%
Mean $\pm$ SD	13.04 ± 2.23	
Median(25th-75th percentile)	13(12-15)	
Range	6-15	

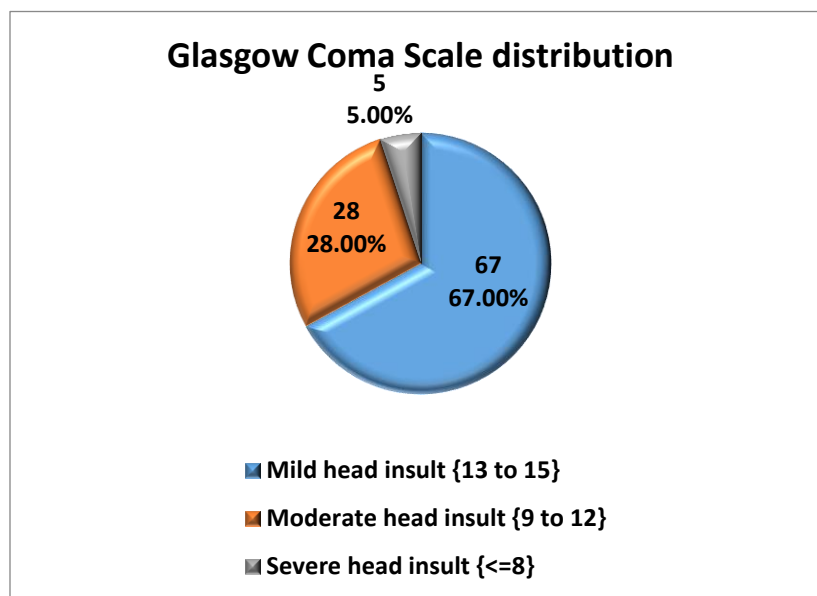


Figure 3: Glasgow Coma Scale distribution

The baseline laboratory investigations showed leukocytosis with a mean total leukocyte count of $16,570.9 \pm 7,651.17$ cells/mm³. The mean serum creatinine was 2.13 ± 1.05 mg/dL, suggesting renal dysfunction in many patients,

while abnormalities in liver function tests and coagulation parameters reflected the multisystem involvement commonly observed in sepsis.

Table 4: Descriptive statistics of investigations

Investigations	Mean $\pm$ SD	Median (25th-75th percentile)	Range
Complete blood count			
Hemoglobin(g/dL)	10.87 $\pm$ 1.69	11(9.7-12)	6.9-14.6
Total leukocyte count(cells/mm ³)	16570.9 $\pm$ 7651.17	16500(10495-21205)	1400-34000
Platelet count(cells/mm ³)	209.11 $\pm$ 91.66	220(129.5-280)	26-483
Serum electrolytes			
Serum sodium(mmol/L)	134.13 $\pm$ 4.38	134.5(130-138)	125-148
Serum potassium(mmol/L)	4.1 $\pm$ 0.54	4(3.775-4.4)	2.9-5.5
Kidney function test parameters			
Urea(mg/dL)	59.29 $\pm$ 36.9	48(32-72.75)	16-205
Serum creatinine(mg/dL)	2.13 $\pm$ 1.05	1.87(1.328-2.812)	0.63-5
Liver function test parameters			
Total bilirubin(mg/dL)	1.45 $\pm$ 0.73	1.4(0.975-1.868)	0.28-4.63
Albumin(g/dL)	3.32 $\pm$ 0.49	3.38(2.938-3.62)	2.2-4.4
SGOT(U/L)	145.67 $\pm$ 585.95	34(27.5-68)	15-4669
SGPT(U/L)	86.43 $\pm$ 252.79	33.5(25.75-65.75)	11-2018
Coagulation parameters			
PT(seconds)	17.02 $\pm$ 7.3	14(12.6-17)	11-48.1
INR	1.19 $\pm$ 0.5	1.1(0.92-1.31)	0.46-3.99

The mean Sequential Organ Failure Assessment (SOFA) score was 6.59 ± 3.63 . Most patients (61%) had SOFA scores between 0 and 6, while higher scores were observed in patients with greater disease severity.

Table 5: SOFA score distribution.

SOFA score	Frequency	Percentage
0 to 6	61	61%
7 to 9	18	18%
10 to 12	10	10%
13 to 14	8	8%
15	1	1%
16 to 24	2	2%
Mean $\pm$ SD	6.59 ± 3.63	
Median(25th-75th percentile)	5.5(4-8)	
Range	1-16	

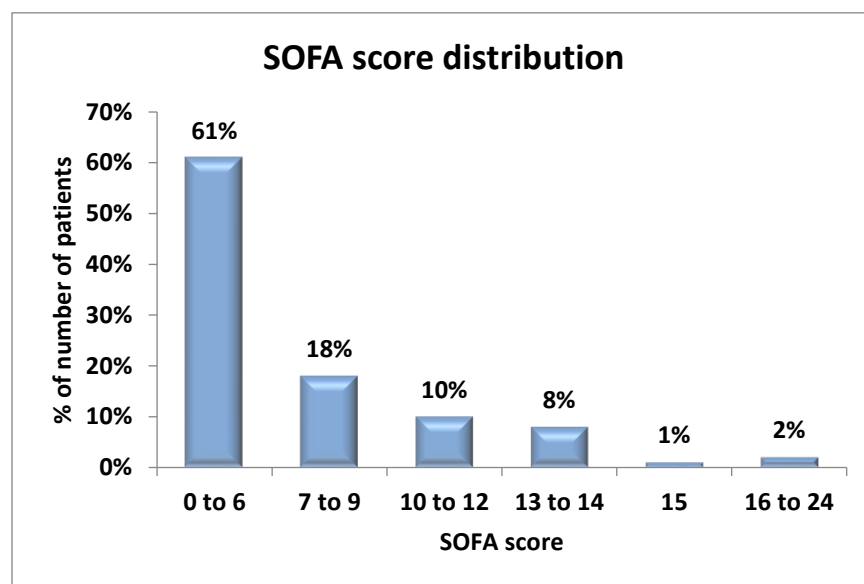


Figure 4: SOFA score distribution.

The mean National Early Warning Score (NEWS) was 7.01 ± 4.21 . Nearly half of the patients (45%) were categorized as high risk (NEWS ≥ 7), indicating severe clinical illness at presentation.

Table 6: NEWS score distribution

NEWS score	Frequency	Percentage
Low risk{0 to 4}	33	33%
Medium risk{5 to 6}	22	22%
High risk{ ≥ 7 }	45	45%
Mean $\pm$ SD	7.01 ± 4.21	
Median(25th-75th percentile)	6(4-10)	
Range	0-17	

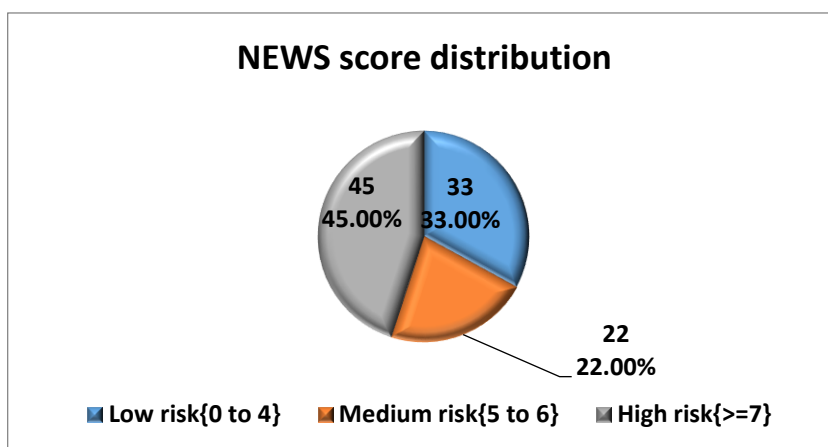


Figure 5: NEWS score distribution

Serum lactate levels showed a progressive decline from admission to 24 hours, decreasing from 5.01 ± 3.12 mmol/L at baseline to 2.59 ± 3.32 mmol/L at 24 hours, suggesting improvement in tissue perfusion following treatment.

Table 7: Descriptive statistics of Lactate(mmol/L).

Lactate(mmol/L)	Mean $\pm$ SD	Median (25th-75th percentile)	Range
At 0 hour	5.01 ± 3.12	3.85(2.8-6.075)	1.8-15
At 6 hours	4.01 ± 2.94	3(2-4.6)	1.3-14.2
At 12 hours	3.23 ± 3.01	2(1.4-3.525)	0.8-14
At 24 hours	2.59 ± 3.32	1.2(0.7-2.1)	0.4-14.2

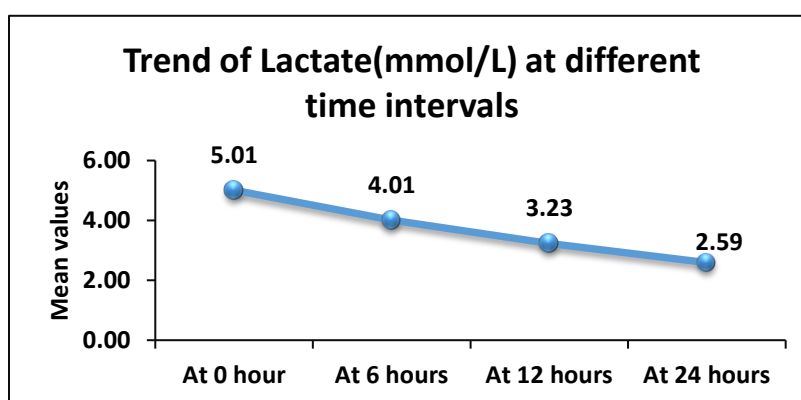


Figure 6: Descriptive statistics of Lactate(mmol/L) at 0 hour, at 6 hours, at 12 hours and at 24 hours.

The mean absolute lactate clearance was 2.42 ± 1.86 mmol/L, while the mean relative lactate clearance was $58.57 \pm 29.76\%$, indicating considerable variation in metabolic recovery among patients.

Table 8: Descriptive statistics of lactate clearance

Lactate clearance	Mean $\pm$ SD	Median (25th-75th percentile)	Range
Absolute lactate clearance(mmol/L)	2.42 $\pm$ 1.86	2.2(1.7-3)	-2.4-9.8
Lactate clearance rate(%/hour)	2.44 $\pm$ 1.24	2.88(2.34-3.24)	-1.56-3.68
Relative lactate clearance (%)	58.57 $\pm$ 29.76	69.23(56.625-77.805)	-37.5-88.37

The mean serum procalcitonin level decreased from **30.83 $\pm$ 32.95 ng/mL** at admission to **16.00 $\pm$ 28.71 ng/mL** on day 3, reflecting a reduction in systemic inflammatory response during treatment.

Table 9: Descriptive statistics of Procalcitonin(ng/mL).

Procalcitonin(ng/mL)	Mean $\pm$ SD	Median (25th-75th percentile)	Range
At 0 hour	30.83 $\pm$ 32.95	18(6.532-39.608)	1.49-100
At 3rd day	16 $\pm$ 28.71	3.18(1.492-8.1)	0.04-100

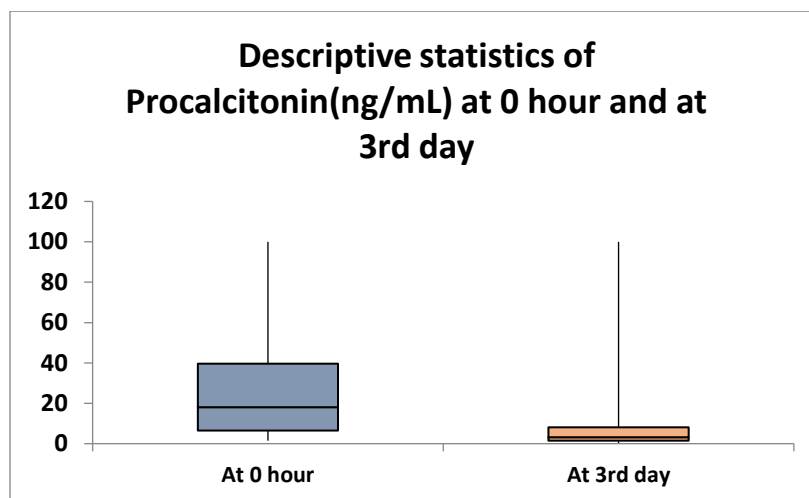


Figure 7: Descriptive statistics of Procalcitonin(ng/mL) at 0 hour and at 3rd day

The mean procalcitonin clearance was **67.58 $\pm$ 29.12%**, demonstrating substantial improvement in inflammatory status among survivors.

Table 10: Descriptive statistics of procalcitonin clearance (%).

Variable	Mean $\pm$ SD	Median (25th-75th percentile)	Range
Procalcitonin clearance(%)	67.58 $\pm$ 29.12	79.04(66.672-85.79)	0-98.9

Absolute lactate clearance showed a significant positive correlation with ICU stay duration (**r = 0.318, p = 0.001**), whereas relative lactate clearance was not significantly associated with ICU stay (**p = 0.925**).

Table 11: Correlation of lactate clearance and Procalcitonin clearance (%) with duration of ICU stay(days).

Variables	Absolute lactate clearance(mmol/L)	Relative lactate clearance (%)
Duration of ICU stay(days)		
Correlation coefficient	0.318	0.01
P value	0.001	0.925

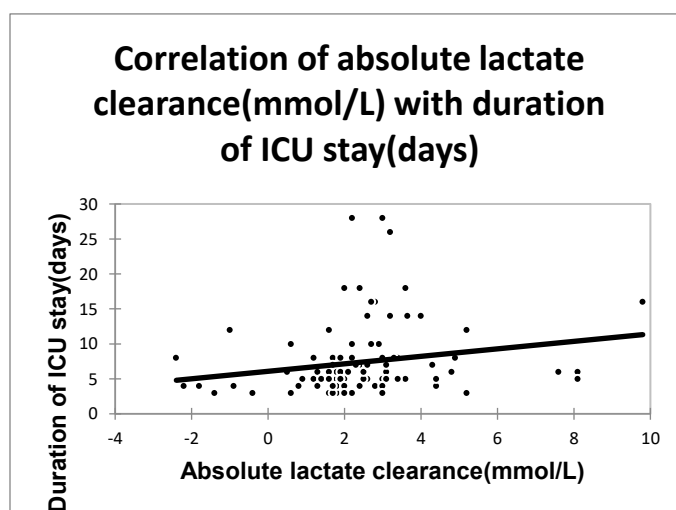


Figure 8: Correlation of absolute lactate clearance(mmol/L) with duration of ICU stay(days).

Patients who died had significantly higher admission serum lactate levels than survivors (9.09 ± 3.54 vs. 3.92 ± 1.85 mmol/L, $p < 0.0001$), indicating that elevated baseline lactate was strongly associated with mortality.

Table 12: Association of Lactate(mmol/L) at 0 hours with mortality.

Lactate(mmol/L) at 0 hours	Survived(n=79)	Died(n=21)	Total	P value
Mean $\pm$ SD	3.92 ± 1.85	9.09 ± 3.54	5.01 ± 3.12	
Median(25th-75th percentile)	3.7 (2.6-4.4)	8.6 (6.4-12.4)	3.85 (2.8-6.075)	$<.0001^*$
Range	1.8-12.2	4.2-15	1.8-15	

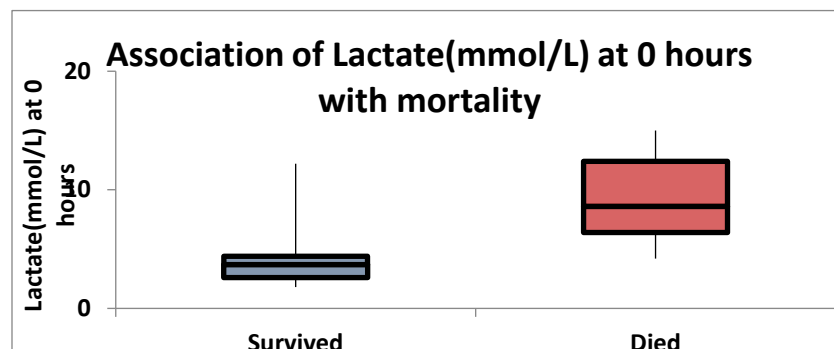


Figure 9: Association of Lactate(mmol/L) at 0 hours with mortality. (non-parametric variable, Box-whisker plot)

Table 13: Association of procalcitonin clearance (%) with mortality.

Procalcitonin clearance (%)	Survived(n=79)	Died(n=21)	Total	P value
Mean $\pm$ SD	81.76 $\pm$ 8.9	14.24 $\pm$ 10.33	67.58 $\pm$ 29.12	
Median (25th-75th percentile)	82.48(76.59-87.69)	14.28(6-18)	79.04(66.672-85.79)	<.0001*
Range	50.81-98.9	0-38.65	0-98.9	

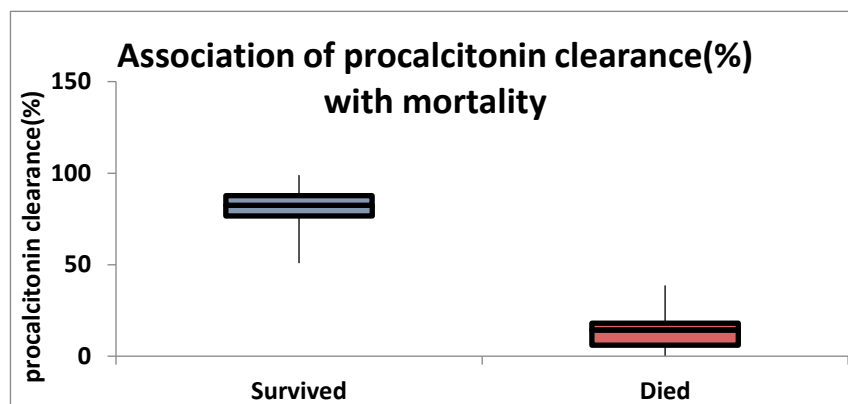


Figure 10: Association of procalcitonin clearance (%) with mortality. (non-parametric variable, Box-whisker plot)

Table 14: -Association of Procalcitonin(ng/mL) at 0 hour with mortality.

Procalcitonin(ng/mL) at 0 hour	Survived(n=79)	Died(n=21)	Total	P value
Mean $\pm$ SD	20.21 $\pm$ 21.95	70.76 $\pm$ 37.08	30.83 $\pm$ 32.95	
Median (25th-75th percentile)	11.5 (5.455-27.3)	100 (44.5-100)	18 (6.532-39.608)	<.0001*
Range	1.49-100	4.1-100	1.49-100	

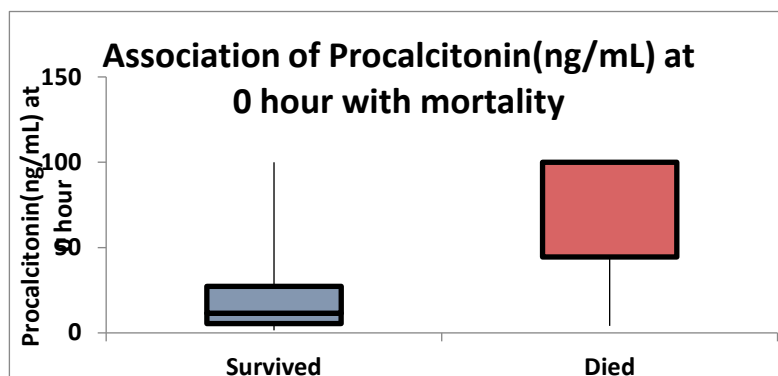


Figure 11:-Association of Procalcitonin(ng/mL) at 0 hour with mortality. (non-parametric variable, Box-whisker plot)

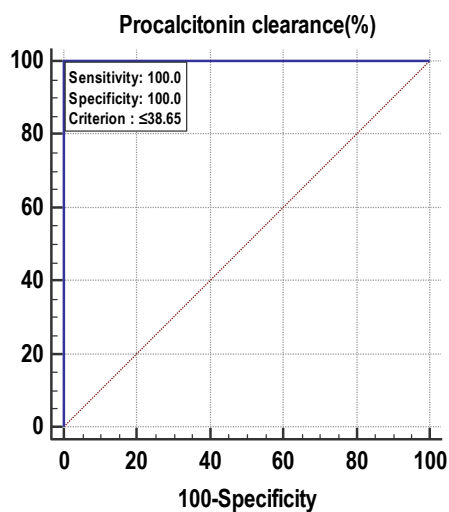


Figure 12: Receiver operating characteristic curve of lactate clearance rate for predicting mortality.

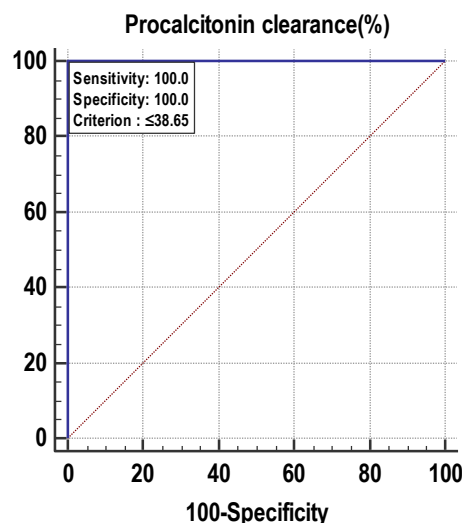


Figure 13: Receiver operating characteristic curve of Procalcitonin clearance for predicting mortality.

Discussion

The current prospective observational study assessed the predictive importance of procalcitonin levels and serum lactate kinetics in patients hospitalised to the intensive care unit with sepsis and septic shock. There were 100 patients in all, with a mean age of 57.8 ± 13.6 years and a male predominance of 56%. The majority of patients were between the ages of 51 and 60, which is indicative of older people's heightened vulnerability to serious infections and organ failure (8).

Many patients had moderate to high SOFA and NEWS scores, indicating a severe illness load at presentation, according to clinical severity assessment. Despite careful management, the study's total death rate of 21% demonstrated the seriousness of sepsis(9). From admission to 24 hours, serial lactate tests showed a progressive decrease, suggesting that survivors' tissue perfusion had improved. Absolute and relative lactate clearance was considerably higher in patients who survived than in those who did not. On the other hand, non-survivors' consistently high lactate levels indicated prolonged tissue hypoxia, poor perfusion, and a poor reaction to resuscitation. Patients who passed away had considerably higher baseline lactate levels, highlighting the significance of early lactate estimation in prognostic assessment (10).

Additionally, procalcitonin levels demonstrated a strong predictive value. Survivors showed a significant decrease in

procalcitonin levels over time, while non-survivors had significantly higher mean procalcitonin levels. Among those who did not survive, procalcitonin clearance was considerably lower, indicating ongoing systemic inflammation and unchecked infection. Procalcitonin clearance is one of the best prognostic indicators in the current study because receiver operating characteristic analysis showed that it has great sensitivity and specificity for predicting death. (11).

Absolute lactate clearance and length of ICU stay were found to be positively correlated, suggesting that delayed metabolic recovery may increase the need for critical care. Relative lactate clearance, however, did not significantly correlate with length of stay in the intensive care unit. The efficacy of severity measures like SOFA and NEWS in early risk classification was further supported by their substantial correlation with death. The current study's results highlight the fact that dynamic biomarker monitoring has more prognostic value than isolated baseline measures. Clinicians can determine high-risk patients, gauge therapy response, and direct prompt therapeutic measures by serially evaluating lactate and procalcitonin (12).

Generalizability

Although this study was conducted at a single tertiary care center, the study population comprised adult patients with sepsis and septic shock managed in a critical care setting

similar to those encountered in many tertiary hospitals. Therefore, the findings may be generalizable to comparable intensive care units with similar patient characteristics and treatment protocols. However, differences in patient demographics, healthcare resources, and institutional practices may limit the applicability of these findings to other settings. Future multicenter studies involving larger and more diverse populations are warranted to validate the findings and improve their external validity.

Conclusion

Lactate clearance indicated adequate tissue perfusion and responsiveness to resuscitation, whereas procalcitonin clearance showed greater diagnostic accuracy for death prediction among the biomarkers examined. Severe systemic inflammation and persistent organ dysfunction were suggested by persistently high biomarker values. In critically sick septic patients, serial biomarker monitoring combined with clinical severity scores such as SOFA, NEWS, and GCS can improve early risk categorisation, optimise therapy choices, and improve patient management. To confirm these results and develop standardised prognostic cutoff values, more multicentric research with bigger sample sizes is advised.

Limitations

The present study has several limitations. The study's single-center methodology and relatively limited sample size may restrict the generalizability of the findings. In addition, patients were recruited from a single tertiary care hospital, which may not fully represent other healthcare settings. Long-term follow-up beyond the study period was not performed, and other inflammatory biomarkers were not evaluated. Therefore, multicenter studies with larger sample sizes and longer follow-up are recommended to further validate the prognostic utility of serial lactate and procalcitonin measurements in patients with sepsis and septic shock.

Recommendation

Routine serial monitoring of lactate and procalcitonin clearance is essential in sepsis therapy, as they are robust predictors of outcomes. Patients exhibiting inadequate clearance necessitate prompt and intensive intervention. Integrating these indicators with clinical severity scores can enhance risk evaluation and provide prompt treatments to mitigate mortality.

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Author Contributions

Mohammad Shoaib: Conceptualization, study design, patient recruitment, data collection, data interpretation, manuscript drafting, and final approval of the manuscript.

Sourabh Kumar: Study supervision, methodology, data analysis, critical revision of the manuscript for important intellectual content, and final approval.

Ritwik Chakraborty: Data interpretation, statistical analysis, literature review, manuscript editing, and final approval.

Shalendra Goel: Study supervision, critical review of the manuscript, administrative support, and final approval of the manuscript.

All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

List of Abbreviations:

APACHE II	Acute Physiology and Chronic Health Evaluation II
SOFA	Sequential Organ Failure Assessment
MEWS	Modified Early Warning Score
NEWS	National Early Warning Score
SD	Standard Deviation
ICU	Intensive Care Unit

Conflict of interest

The author declares no conflict of interest

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