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Comparison of Lactate Clearance and Procalcitonin as Early Predictors of Mortality and Organ Dysfunction in Septic Patients

Ambresh Parutabad[1*], Sudha B R[2*], Brian D'mello[3]

[1]Postgraduate, Department of Emergency Medicine, The Oxford medical College Hospital and research centre, Bangalore, India

[2]Professor and HOD, Department of Emergency Medicine, The Oxford Medical College Hospital and Research Centre, Bangalore, India

[3]Assistant Professor, Department of Emergency Medicine, The Oxford Medical College Hospital and Research Centre, Bangalore, India

***Address for Correspondence:** Dr. Ambresh Parutabad, Postgraduate, Department of Emergency Medicine, The Oxford medical College hospital and research centre, Bangalore, India
E-mail: agp8358@gmail.com

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ABSTRACT

Background: Early prognostic assessment in sepsis remains crucial for optimal patient management and resource allocation. While both lactate clearance and procalcitonin have been proposed as biomarkers for sepsis prognosis, their comparative effectiveness for predicting mortality and organ dysfunction requires further investigation. To compare the prognostic value of lactate clearance and procalcitonin as early predictors of 28-day mortality and organ dysfunction in septic patients.

Methods: This prospective observational cohort study was conducted in a 20-bed intensive care unit over 12 months. Forty adult patients diagnosed with sepsis according to Sepsis-3 criteria were enrolled. Blood samples for lactate and procalcitonin measurements were collected at baseline, 6, 12, 24, and 48 hours after ICU admission.

Results: The study population had a mean age of 62.5±14.8 years with 30% mortality rate. Lactate clearance demonstrated superior prognostic performance compared to procalcitonin clearance. At 48 hours, lactate clearance achieved an area under the ROC curve of 0.88 (95% CI: 0.78-0.98) with an optimal cutoff <25% providing sensitivity 91.7% and specificity 85.7%. In contrast, procalcitonin clearance showed poor discriminatory ability across all time points (AUC range: 0.51-0.67). Survivors achieved significantly higher lactate clearance than non-survivors at 48 hours (52.1±29.6% vs. -18.3±38.7%, p<0.001).

Conclusions: Lactate clearance, particularly when assessed over 48 hours, provides superior prognostic information compared to procalcitonin clearance for predicting mortality and organ dysfunction in septic patients, supporting its prioritization in clinical decision-making and sepsis management protocols.

Key-words: Sepsis; Procalcitonin; Lactic Acid; Biomarkers; Prognosis; Mortality; Organ Dysfunction Scores; Critical Care; ROC Curve

INTRODUCTION

Sepsis remains one of the most challenging clinical conditions in modern medicine, representing a life-threatening organ dysfunction caused by a dysregulated host response to infection [1].

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Despite significant advances in critical care medicine and widespread implementation of standardized treatment protocols through the Surviving Sepsis Campaign, sepsis continues to be a leading cause of morbidity and mortality in intensive care units worldwide [2]. The condition affects more than 900,000 people annually in the United States alone, with mortality rates persisting between 20% and 36%, resulting in approximately 270,000 deaths each year [3].

The evolution of sepsis definitions, culminating in the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), has fundamentally transformed

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our understanding of this complex syndrome [4]. The current definition emphasizes organ dysfunction rather than systemic inflammation, utilizing the Sequential Organ Failure Assessment (SOFA) score as a primary diagnostic criterion. This paradigm shift reflects a deeper understanding of sepsis pathophysiology and underscores the critical importance of early recognition and intervention to prevent progressive organ failure [5].

Early identification of patients at high risk for poor outcomes remains paramount in sepsis management, as timely recognition and appropriate treatment substantially improve survival rates [6]. The heterogeneous nature of sepsis presentation, particularly in elderly and immunocompromised patients who may not manifest typical inflammatory signs, necessitates the development and validation of reliable biomarkers that can accurately predict mortality and guide therapeutic decision-making [7]. The pathophysiology of lactate elevation in sepsis is multifactorial, involving increased anaerobic production due to tissue hypoperfusion, enhanced aerobic production via stimulation of the Na-K ATPase channel, and decreased lactate clearance secondary to hepatic dysfunction [8]. Multiple studies have demonstrated a strong correlation between initial lactate levels and mortality in septic patients, with values exceeding 2.5-4.0 mmol/L consistently associated with significantly increased risk of death [9-13]. Marty et al. demonstrated that lactate clearance during the first 24 hours in the intensive care unit was the best predictor of 28-day mortality in septic patients, with survivors showing significantly higher clearance rates compared to non-survivors (42±33% vs. -17±76%, p<0.001) [13-16].

MATERIALS AND METHODS

Research Design- This was a prospective, observational cohort study conducted in the intensive care unit (ICU) of a tertiary care teaching hospital for 12 months from January 2023 to December 2023. The study was designed to evaluate and compare the prognostic value of lactate clearance and procalcitonin as early predictors of mortality and organ dysfunction in patients diagnosed with sepsis. The ICU was a 20-bed mixed medical-surgical unit equipped with advanced monitoring capabilities and staffed by board-certified intensivists and trained nursing personnel providing 24-hour coverage. Adult patients aged 18 years or older who were admitted to the ICU with a diagnosis of sepsis according to the Sepsis-3 criteria were considered eligible for inclusion. Sepsis was defined as life-threatening organ dysfunction caused by a dysregulated host response to infection, with organ dysfunction identified by an increase in Sequential Organ Failure Assessment (SOFA) score of 2 points or more from baseline.

Inclusion Criteria

- Adult patients aged 18 years or older.
- Admitted to the ICU with a diagnosis of sepsis according to Sepsis-3 criteria.
- Presence of life-threatening organ dysfunction indicated by an increase in SOFA score of ≥2 points from baseline.

Exclusion Criteria

- Age <18 years.
- Pregnancy.
- Known terminal illness with expected survival <24 hours.
- Cardiopulmonary resuscitation (CPR) within 24 hours before ICU admission.
- Chronic kidney disease requiring dialysis.

Statistical Analysis- All statistical analyses were performed using SPSS version 28.0 (IBM Corporation, Armonk, NY, USA) and R statistical software version 4.3.0. A two-tailed p-value of less than 0.05 was considered statistically significant for all analyses. Bonferroni correction was applied for multiple comparisons when appropriate. All confidence intervals were calculated at the 95% level.

Ethical Approval- The study protocol was reviewed and approved by the Institutional Ethics Committee and the Hospital Research Review Board before patient enrolment.

RESULTS

The study enrolled 40 septic patients admitted to the intensive care unit, with an overall 28-day mortality rate of 30% (12 patients). Table 1 demonstrates significant differences in baseline characteristics between survivors and non-survivors. Non-survivors were significantly older (70.8±15.6 years vs. 58.9±13.2 years, p=0.02), had higher APACHE II scores (28.2±6.8 vs. 19.8±5.9, p=0.001), and presented with higher initial SOFA scores (11.8±3.2 vs.

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7.5±2.8, p<0.001). These findings are consistent with established literature showing that advanced age and higher severity scores are associated with poor outcomes in sepsis.

Table 1: Baseline Characteristics of Study Population (n=40)

Variable	All Patients (n=40)	Survivors (n=28)	Non-survivors (n=12)	p-value
Demographics				
Age (years), mean±SD	62.5±14.8	58.9±13.2	70.8±15.6	0.02*
Male gender, n (%)	24 (60.0)	17 (60.7)	7 (58.3)	0.88
BMI (kg/m²), mean±SD	26.4±4.7	26.8±4.9	25.5±4.2	0.42
Comorbidities, n (%)				
Diabetes mellitus	16 (40.0)	10 (35.7)	6 (50.0)	0.39
Hypertension	22 (55.0)	14 (50.0)	8 (66.7)	0.31
Chronic kidney disease	8 (20.0)	4 (14.3)	4 (33.3)	0.16
COPD	11 (27.5)	6 (21.4)	5 (41.7)	0.18
Source of Infection, n (%)				
Respiratory	18 (45.0)	11 (39.3)	7 (58.3)	0.25
Urogenital	9 (22.5)	8 (28.6)	1 (8.3)	0.15
Abdominal	8 (20.0)	6 (21.4)	2 (16.7)	0.73
Skin/soft tissue	3 (7.5)	2 (7.1)	1 (8.3)	0.89
Other/unknown	2 (5.0)	1 (3.6)	1 (8.3)	0.52
Severity Scores				
APACHE II score, mean±SD	22.4±7.1	19.8±5.9	28.2±6.8	0.001*
Initial SOFA score, mean±SD	8.7±3.4	7.5±2.8	11.8±3.2	<0.001*

**Statistically significant (p<0.05)*

Table 2 reveals distinct patterns in biomarker evolution between survivors and non-survivors. Initial lactate levels were significantly higher in non-survivors (6.3±3.1 mmol/L vs. 4.2±2.1 mmol/L, p=0.018), and this difference persisted throughout the study period. Initial procalcitonin concentrations were higher in non-survivors but did not reach statistical significance (13.5±18.2 ng/mL vs. 6.8±8.9 ng/mL, p=0.146). However, significant differences emerged at 24 hours (12.8±16.4 ng/mL vs. 5.2±7.1 ng/mL, p=0.049) and 48 hours (10.7±13.2 ng/mL vs. 3.8±5.6 ng/mL, p=0.029), suggesting that procalcitonin clearance patterns may be more informative than initial values for prognostication.

Table 2: Laboratory Parameters and Biomarker Levels Over Time

Parameter	Time Point	All Patients (n=40)	Survivors (n=28)	Non-survivors (n=12)	p-value
Lactate (mmol/L)					
	0 hours	4.8±2.6	4.2±2.1	6.3±3.1	0.01*
	6 hours	3.9±2.4	3.2±1.8	5.7±2.9	0.003*
	24 hours	3.1±2.2	2.4±1.5	4.8±2.8	0.002*
	48 hours	2.6±1.9	2.0±1.3	4.1±2.4	0.003*
Procalcitonin (ng/mL)					
	0 hours	8.7±12.4	6.8±8.9	13.5±18.2	0.14
	6 hours	9.2±13.1	7.1±9.4	14.2±19.6	0.16
	24 hours	7.4±10.8	5.2±7.1	12.8±16.4	0.04*
	48 hours	5.9±8.9	3.8±5.6	10.7±13.2	0.02*
Other Laboratory Values (at admission)					

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White blood cell count (×10³/μL)	14.8±8.7	13.9±7.9	16.8±10.2	0.35
C-reactive protein (mg/L)	186.4±112.7	168.2±98.4	228.9±138.5	0.14
Creatinine (mg/dL)	1.8±1.2	1.5±0.9	2.6±1.5	0.01*
Bilirubin (mg/dL)	2.1±1.8	1.7±1.4	3.2±2.2	0.02*

**Statistically significant (p<0.05)*

Table 3 summarizes the clinical outcomes and healthcare resource utilization patterns. Non-survivors had significantly longer ICU stays (12.5 vs. 7.0 days, p=0.045), required mechanical ventilation more frequently (100% vs. 71.4%, p=0.029), and needed longer duration of ventilatory support (10.5 vs. 5.0 days, p=0.031). The vasopressor-free days in the first week were significantly fewer in non-survivors (1.2±2.1 vs. 4.1±2.6 days, p=0.002), indicating more severe and persistent hemodynamic instability. The need for renal replacement therapy was significantly higher in non-survivors (41.7% vs. 10.7%, p=0.022), reflecting the higher incidence of acute kidney injury and its association with poor outcomes in sepsis.

Table 3: Clinical Outcomes and Resource Utilization

Outcome	All Patients (n=40)	Survivors (n=28)	Non-survivors (n=12)	p-value
Mortality				
28-day mortality, n (%)	12 (30.0)	0 (0.0)	12 (100)	-
ICU mortality, n (%)	10 (25.0)	0 (0.0)	10 (83.3)	<0.001*
Hospital mortality, n (%)	11 (27.5)	0 (0.0)	11 (91.7)	<0.001*
Length of Stay				
ICU LOS (days), median (IQR)	8.5 (5.0-14.0)	7.0 (4.0-12.0)	12.5 (6.8-18.3)	0.045*
Hospital LOS (days), median (IQR)	16.0 (9.0-28.0)	15.0 (8.3-25.8)	18.5 (7.3-29.8)	0.634
Interventions				
Mechanical ventilation, n (%)	32 (80.0)	20 (71.4)	12 (100)	0.029*
Ventilator days, median (IQR)	6.0 (3.0-12.0)	5.0 (2.0-9.8)	10.5 (5.3-16.8)	0.031*
Vasopressor use, n (%)	35 (87.5)	23 (82.1)	12 (100)	0.125
Vasopressor-free days (first 7 days)	3.2±2.8	4.1±2.6	1.2±2.1	0.002*
Renal replacement therapy, n (%)	8 (20.0)	3 (10.7)	5 (41.7)	0.022*

**Statistically significant (p<0.05)*

Table 4 presents the results of multivariate logistic regression analysis to identify independent predictors of 28-day mortality. After adjusting for confounding variables, lactate clearance at both 24 hours (<20%) and 48 hours (<25%) emerged as independent predictors of mortality, with odds ratios of 12.4 (95% CI: 1.87-82.1, p=0.009) and 18.7 (95% CI: 2.41-145.0, p=0.005), respectively. The maximum SOFA score also remained an independent predictor (OR 1.35, 95% CI: 1.02-1.78, p=0.03).

Table 4: Multivariate Analysis for 28-Day Mortality Predictors

Variables	Univariate Analysis		Multivariate Analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Age (per year)	1.08 (1.01-1.16)	0.029*	1.05 (0.96-1.14)	0.285
APACHE II score (per point)	1.22 (1.08-1.38)	0.002*	1.15 (0.98-1.35)	0.092
Initial SOFA score (per point)	1.52 (1.18-1.96)	0.001*	1.28 (0.91-1.81)	0.158
Initial lactate (per mmol/L)	1.34 (1.05-1.71)	0.019*	1.12 (0.78-1.61)	0.542
Lactate clearance 24h <20%	8.67 (1.56-48.2)	0.014*	12.4 (1.87-82.1)	0.009*

Lactate clearance 48h <25%	15.2 (2.89-79.8)	0.001*	18.7 (2.41-145)	0.005*
PCT clearance 48h <30%	2.84 (0.68-11.9)	0.15	-	-
Maximum SOFA score (per point)	1.48 (1.19-1.84)	<0.001*	1.35 (1.02-1.78)	0.03*

**Statistically significant (p<0.05); OR=Odds Ratio; CI=Confidence Interval; PCT=Procalcitonin*

Table 5 provides a comprehensive comparison of the discriminatory performance of various predictors for 28-day mortality. Lactate clearance at 48 hours demonstrated the highest AUC of 0.88, followed closely by the maximum SOFA score (AUC 0.91). The optimal cutoff for 48-hour lactate clearance (<25%) showed excellent sensitivity (91.7%) and specificity (85.7%), with a high negative predictive value (96%), making it particularly useful for ruling out poor outcomes. In comparison, procalcitonin levels showed modest discriminatory ability, with the best performance observed at 48 hours (AUC 0.72).

Table 5: ROC Analysis for Predicting 28-Day Mortality

Predictor	Time Point	AUC (95% CI)	Optimal Cutoff	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Lactate Level							
0 hours		0.72 (0.56-0.87)	>5.2 mmol/L	75.0	71.4	52.9	87.0
24 hours		0.79 (0.66-0.92)	>3.8 mmol/L	83.3	78.6	62.5	91.7
Lactate Clearance							
0-24 hours		0.85 (0.72-0.97)	<20%	83.3	82.1	66.7	92.0
0-48 hours		0.88 (0.78-0.98)	<25%	91.7	85.7	73.3	96.0
Procalcitonin Level							
0 hours		0.62 (0.43-0.81)	>12.5 ng/mL	58.3	75.0	50.0	80.8
48 hours		0.72 (0.56-0.89)	>8.0 ng/mL	75.0	75.0	56.3	87.5
SOFA Score							
Initial		0.84 (0.72-0.97)	>10 points	83.3	82.1	66.7	92.0
Maximum		0.91 (0.82-0.99)	>12 points	91.7	85.7	73.3	96.0

AUC=Area Under Curve; PPV=Positive Predictive Value; NPV=Negative Predictive Value

DISCUSSION

This prospective observational study of 40 septic patients showed that lactate clearance, especially over 24–48 hours, is a superior predictor of 28-day mortality and organ dysfunction compared to procalcitonin clearance. Lactate clearance at 48 hours demonstrated an AUC of 0.887, with <25% cutoff yielding 91.7% sensitivity and 85.7% specificity. Similarly, Marty *et al.* reported 24-hour lactate clearance as the strongest mortality predictor (AUC=0.79) in severe sepsis and septic shock [11]. A retrospective cohort study by Chertoff *et al.* examined lactate clearance measured 24-48 hours after initiation of treatment in nonsurgical septic patients and found that patients with lower lactate clearance had significantly higher 30-day mortality rates and increased requirements for vasopressors [17].

Arnold *et al*., in a meta-analysis of 927 septic patients, reported that lactate clearance was associated with a relative risk of mortality of 0.41 (95% CI, 0.28 to 0.60), with sensitivity of 0.67 and specificity of 0.73 [18]. A recent study by Park *et al*. examined 6,734 septic patients and found that serial evaluation of lactate levels combined with SOFA scores (Lac-SOFA) improved predictive accuracy, with AUC values increasing from 0.656 at initial assessment to 0.78 by day 3 when combined with lactate measurements [19].

Sugimoto *et al*. found that lactate clearance was more predictive of mortality in non-pneumonia sepsis cases compared to pneumonia cases, possibly due to different pathophysiological mechanisms of lactate production and clearance in pulmonary versus other infections [20]. Braun *et al*., in a prospective ICU cohort study, found that while initial lactate levels were better mortality predictors (AUC 0.69) compared to procalcitonin (AUC 0.55), procalcitonin kinetics showed only modest

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improvement (AUC 0.66) compared to lactate kinetics (AUC 0.73) [21].

Schuetz *et al*. demonstrated that a procalcitonin decrease of >80% from baseline to day 4 was associated with two-fold higher mortality when this target was not achieved (20% vs 10%, p=0.001) in a multicentre study of 858 severe sepsis patients [22]. Xie *et al*. developed a prediction model combining serial interleukin-6, lactate, and procalcitonin measurements, achieving AUC values of 0.849 in the training cohort and 0.828 in the validation cohort for 28-day mortality prediction [23].

Liu *et al.,* in an extensive retrospective analysis of the MIMIC III database including 12,086 septic patients, found that lactate had superior discriminative power compared to qSOFA and showed similar discriminative ability to SOFA scores for mortality prediction [24]. Park *et al*. developed a combined Lac-SOFA score that demonstrated superior predictive accuracy compared to SOFA alone, with AUC values improving from 0.781 for SOFA alone to 0.797 for the combined score at day 3 [19-23]. This challenges the traditional focus on early lactate measurements and supports recent calls for prolonged lactate monitoring as recommended by the Surviving Sepsis Campaign guidelines [24-29].

CONCLUSIONS

Our study provides compelling evidence that lactate clearance, particularly when assessed over 48 hours, offers superior prognostic value compared to procalcitonin clearance for predicting mortality and organ dysfunction in septic patients. The excellent discriminatory performance, wide availability, and cost-effectiveness of lactate measurements support its continued emphasis in sepsis management protocols. While procalcitonin remains valuable for infection diagnosis and antibiotic stewardship, our findings suggest that lactate clearance should be prioritized for prognostic assessment and clinical decision-making in sepsis care. These results contribute to the growing body of evidence supporting extended lactate monitoring in sepsis management and may inform future guideline recommendations and clinical practice protocols. Further research is needed to validate these findings in larger populations and to explore the potential benefits of lactate clearance-guided therapeutic interventions.

CONTRIBUTION OF AUTHORS

Research concept – Dr. Ambresh Parutabad, Dr. Sudha B R
Research design – Dr. Ambresh Parutabad
Supervision – Dr. Sudha B R
Materials – Dr. Ambresh Parutabad, Dr. Sudha B R
Data collection – Dr. Brian D'mello
Data analysis and interpretation – Dr. Brian D'mello
Literature search – Dr. Ambresh Parutabad
Writing article – Dr. Ambresh Parutabad, Dr. Sudha B R, Dr. Brian D'mello
Critical review – Dr. Sudha B R
Article editing – Dr. Ambresh Parutabad, Dr. Sudha B R, Dr. Brian D'mello
Final approval – Dr. Ambresh Parutabad, Dr. Sudha B R, Dr. Brian D'mello

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