Section: Medicine

Original Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON THE DIAGNOSTIC AND PROGNOSTIC VALUE OF SERUM LACTATE LEVEL IN PATIENTS DIAGNOSED WITH SEPSIS AT THE TIME OF ADMISSION

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Received *: 05/11/2025*
Received in revised form *: 20/12/2025*
Accepted *: 08/01/2026*

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DOI: 10.70034/ijmedph.2026.1.26

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (1); 145-149

ABSTRACT

Background: Sepsis and septic shock remain leading causes of morbidity and mortality worldwide. The Sepsis-3 definitions emphasize organ dysfunction assessed by the Sequential Organ Failure Assessment (SOFA) score; however, its routine application is limited in resource-constrained settings. Serum lactate, a readily available biomarker, has been recognized as an independent predictor of adverse outcomes in sepsis, but its diagnostic and prognostic utility relative to established scoring systems remains uncertain. The objective is to evaluate the diagnostic and prognostic value of serum lactate levels in patients with sepsis and septic shock, compare its performance with SOFA, qSOFA, and SIRS criteria, and assess whether the addition of serum lactate to qSOFA improves clinical utility.

Materials and Methods: This prospective observational study was conducted at a tertiary care hospital over 16 months and included 100 adult patients admitted with suspected sepsis or septic shock. Serum lactate levels were measured at admission, day 3, and day 7. SOFA, qSOFA, and SIRS scores were calculated concurrently. Patients were followed for 28-day outcomes. Diagnostic performance was assessed using sensitivity and specificity, prognostic accuracy using receiver operating characteristic curves, and survival using Kaplan–Meier analysis. Multivariable Cox regression was performed to identify independent predictors of mortality.

Results: Elevated serum lactate levels (≥2 mmol/L) demonstrated moderate diagnostic performance for sepsis and high sensitivity for septic shock but were inferior to SOFA criteria. SOFA score showed superior prognostic accuracy for 28-day mortality and prolonged ICU stay. Elevated serum lactate at admission was independently associated with increased 28-day mortality (adjusted hazard ratio 2.01; p = 0.037). The modified qSOFA score showed improved diagnostic sensitivity compared with lactate alone but did not outperform SOFA.

Conclusion: Serum lactate is a valuable prognostic marker in sepsis and septic shock but does not replace SOFA for diagnosis or risk stratification. Lactate measurement remains a useful adjunct, particularly in resource-limited settings.

Keywords: Sepsis; Septic shock; Serum lactate; SOFA score; qSOFA; Prognosis.

INTRODUCTION

Sepsis and septic shock continue to be major contributors to morbidity and mortality worldwide despite advances in critical care and antimicrobial therapy. Recognizing its global burden, the World Health Assembly declared sepsis a global health priority in 2017. To address limitations of earlier

definitions, the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) redefined sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection, operationalized as an acute increase in Sequential Organ Failure Assessment (SOFA) score of ≥2 points.[1] Septic shock was defined as a subset of sepsis characterized by the need for vasopressors to maintain mean arterial pressure ≥65 mmHg in the presence of serum lactate levels >2 mmol/L despite adequate fluid resuscitation.[2]

The SOFA score is currently regarded as the reference standard for assessing organ dysfunction and prognostication in sepsis; however, its routine application is often limited in resource-constrained settings due to the need for multiple laboratory parameters and continuous monitoring.[3,4] To facilitate early bedside risk stratification, particularly outside intensive care units, the quick SOFA (qSOFA) score was proposed as a simplified clinical tool.[2] Subsequent studies, however, have demonstrated that qSOFA has lower sensitivity for early sepsis detection when compared with SOFA and systemic inflammatory response syndrome (SIRS) criteria, raising concerns about missed or delayed diagnoses.[5-7]

Serum lactate has long been recognized as a key biomarker in sepsis, reflecting tissue hypoperfusion and altered cellular metabolism. Multiple studies have consistently shown an association between elevated serum lactate levels and increased mortality, independent of hypotension, shock, or overt organ failure.[8-11] Both single lactate measurements at admission and serial lactate clearance have demonstrated prognostic value in patients with severe sepsis and septic shock.[12-14] Consequently, lactate estimation has been incorporated into international sepsis management guidelines and is widely used in emergency and critical care settings.[15]

Given the limitations of existing clinical scoring systems and the relative simplicity of lactate estimation, there is growing interest in evaluating whether serum lactate alone, or in combination with qSOFA, could serve as a practical alternative for diagnosis and prognostication, particularly in resource-limited environments. This study was therefore undertaken to evaluate the diagnostic and prognostic utility of serum lactate levels, compare their performance with SOFA, qSOFA, and SIRS criteria, and assess whether the addition of lactate to qSOFA improves clinical utility.

MATERIALS AND METHODS

This prospective observational study was conducted at a tertiary care teaching hospital and included adult patients admitted with suspected sepsis or septic shock. Participants were recruited from the multidisciplinary intensive care unit and general medicine wards over a period of 16 months, from July 2019 to October 2020. Patients aged 18 years and above with a clinical suspicion of sepsis or septic shock at the time of admission were eligible for inclusion. Pregnant or lactating women and patients receiving medications known to independently elevate serum lactate levels, including metformin, antiretroviral therapy, antitubercular therapy, valproic acid, or those with ethylene glycol, methanol, or ethanol intoxication, were excluded to minimize confounding.

The sample size was calculated using the Cochran formula based on the estimated prevalence of sepsis-related admissions, yielding a minimum required sample of 82 participants; however, a total of 100 patients were enrolled to enhance the statistical robustness and generalizability of the study findings. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants or their legally authorized representatives. The study was registered with the Clinical Trials Registry–India (CTRI/2020/01/022823).

Baseline demographic characteristics, comorbidities, and clinical and laboratory parameters required for the calculation of Sequential Organ Failure Assessment (SOFA), quick SOFA (qSOFA), and systemic inflammatory response syndrome (SIRS) criteria were recorded at admission. Serum lactate levels were measured from arterial blood samples obtained as part of routine clinical care using a Radiometer ABL800 BASIC™ analyzer. Lactate measurements were performed at admission, on day 3, and on day 7 of hospitalization. Patients were followed until death, discharge, or completion of 28 days of hospitalization, and for those discharged earlier, outcome status at 28 days was ascertained telephonically.

The primary outcomes assessed were 28-day all-cause mortality and successful treatment with discharge, while secondary outcomes included duration of ICU stay, prolonged ICU stay defined as more than 72 hours, time to outcome, requirement of vasopressor support, requirement of respiratory support, and decision for palliative care. Data were entered into Microsoft Excel and analyzed using SPSS version 22.0 (IBM SPSS Statistics, Somers, NY, USA).. Continuous variables were expressed as mean with standard deviation or median as appropriate, and categorical variables were expressed as frequencies and percentages. Comparisons between groups were performed using the independent Student's t test for continuous variables and the Chi-square test for categorical variables. Diagnostic performance was evaluated using sensitivity and specificity, while prognostic accuracy was assessed using receiver operating characteristic curve analysis with estimation of area under the curve. Survival analysis was conducted using Kaplan–Meier curves with log-rank testing, and multivariable Cox proportional hazards regression was used to adjust for potential confounders. A two-sided p value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 adult patients admitted with suspected sepsis were included in the analysis, with a median age of 67 years and a male predominance (59%). Most participants were aged 50–70 years (35%) or older than 70 years (44%), and 71% were admitted to the ICU through the emergency department. Hypertension (54%) and diabetes mellitus (53%) were the most common comorbidities, and 34% of patients had three or more comorbid conditions. At admission, 31% of patients fulfilled SOFA criteria for septic shock, and elevated serum lactate levels (≥2 mmol/L) were observed in 51% of participants. By day 28, 41% of patients had died, 39% were discharged following successful treatment, and 20% were managed with palliative intent, while 79% experienced a prolonged ICU stay exceeding 72 hours [Table 1].

Elevated serum lactate levels (≥2 mmol/L) demonstrated moderate diagnostic performance for sepsis when compared with SIRS criteria, with a sensitivity of 60.7% and specificity of 64.1%, and this association was statistically significant ($p = 0.016$). However, when compared with SOFA criteria for sepsis, serum lactate levels showed lower sensitivity (53.8%) and the association did not reach statistical significance ($p = 0.07$). For the diagnosis of septic shock, elevated serum lactate levels exhibited very high sensitivity (100%) when compared with both SOFA-defined septic shock and SIRS-defined severe sepsis, though specificity remained moderate, and these associations were statistically significant ($p < 0.001$) [Table 2].

The modified qSOFA score (qSOFA with added serum lactate) demonstrated improved diagnostic performance for sepsis compared with serum lactate alone, with sensitivities of 59.3% and 70.5% when compared with SOFA and SIRS criteria, respectively, and both associations were statistically significant. For the diagnosis of septic shock, modified qSOFA also showed high sensitivity (>93%) with moderate specificity, and all comparisons with SOFA and SIRS reference standards were statistically significant ($p < 0.001$) [Table 2].

At admission, the prognostic accuracy of clinical markers for 28-day mortality was highest for the SOFA score (AUROC 0.54), followed by serum lactate (AUROC 0.47), modified qSOFA (AUROC 0.47), and qSOFA score (AUROC 0.43). For the prediction of prolonged ICU stay, SOFA score again demonstrated superior discriminatory ability (AUROC 0.60), whereas serum lactate, qSOFA, and modified qSOFA showed limited prognostic performance. For the outcome of successful discharge, serum lactate and qSOFA scores demonstrated marginally higher AUROC values than SOFA score, although overall discriminatory capacity remained modest across all markers [Table 3].

On multivariable Cox proportional hazards regression analysis adjusted for age and comorbidities, elevated serum lactate levels (≥2 mmol/L) at admission emerged as an independent predictor of 28-day mortality, with an adjusted hazard ratio of 2.01 (95% CI 1.04–3.86; $p = 0.037$). The number of comorbidities did not independently predict mortality after adjustment [Table 4].

Table 1: Baseline clinical characteristics and outcomes of patients admitted with suspected sepsis (n = 100)

Characteristic	n (%) / Mean (SD)
Age (years)	
Median age	67
<30 years	5 (5.0)
30–50 years	16 (16.0)
50–70 years	35 (35.0)
>70 years	44 (44.0)
Sex	
Male	59 (59.0)
Female	41 (41.0)
Source of ICU admission	
Emergency department	71 (71.0)
In-hospital transfer	29 (29.0)
Comorbidities	
Hypertension	54 (54.0)
Diabetes mellitus	53 (53.0)
Cardiac disease	29 (29.0)
Renal disease	18 (18.0)
Respiratory disease	14 (14.0)
Liver disease	12 (12.0)
≥3 comorbidities	34 (34.0)
No comorbidity	22 (22.0)
Clinical status at admission	
Septic shock (SOFA criteria)	31 (31.0)
Elevated serum lactate (≥2 mmol/L)	51 (51.0)
Vasopressor support required	44 (44.0)
Respiratory support required	28 (28.0)
Outcomes	
28-day mortality	41 (41.0)
Successful discharge	39 (39.0)

Palliative care	20 (20.0)
Prolonged ICU stay (>72 h)	79 (79.0)
Mean ICU stay (days)	5.6

Table 2: Diagnostic performance of serum lactate and modified qSOFA score for sepsis and septic shock

Diagnostic marker	Reference standard	Sensitivity (%)	Specificity (%)	p value
Serum lactate ≥2 mmol/L	SOFA (sepsis)	53.8	77.8	0.070
Serum lactate ≥2 mmol/L	SIRS (sepsis)	60.7	64.1	0.016*
Serum lactate ≥2 mmol/L	SOFA (septic shock)	100.0	71.0	<0.001*
Serum lactate ≥2 mmol/L	SIRS (severe sepsis)	100.0	77.8	<0.001*
Modified qSOFA ≥2	SOFA (sepsis)	59.3	77.8	0.032*
Modified qSOFA ≥2	SIRS (sepsis)	70.5	66.7	<0.001*
Modified qSOFA ≥2	SOFA (septic shock)	93.5	60.9	<0.001*
Modified qSOFA ≥2	SIRS (severe sepsis)	94.6	66.7	<0.001*

Modified qSOFA = qSOFA score with addition of serum lactate level.
Chi-square test

Table 3. Prognostic accuracy (AUROC) of clinical markers at admission for key outcomes

Marker	28-day mortality AUROC (95% CI)	Prolonged ICU stay AUROC (95% CI)	Discharge AUROC (95% CI)
Serum lactate	0.47 (0.35–0.59)	0.53 (0.40–0.66)	0.52 (0.40–0.63)
qSOFA score	0.43 (0.32–0.55)	0.43 (0.29–0.57)	0.58 (0.46–0.70)
SOFA score	0.54 (0.42–0.66)	0.60 (0.47–0.74)	0.47 (0.36–0.59)
Modified qSOFA	0.47 (0.36–0.59)	0.50 (0.35–0.64)	0.54 (0.42–0.66)

AUROC = Area under receiver operating characteristic curve.
Prolonged ICU stay defined as >72 hours.

Table 4. Multivariable Cox proportional hazards regression for predictors of 28-day mortality

Variable	Adjusted Hazard Ratio (aHR)	95% CI	p value
Elevated serum lactate (≥2 mmol/L)	2.01	1.04–3.86	0.037
Number of comorbidities	0.57	0.27–1.21	0.143

Model adjusted for age >65 years and number of comorbidities.
aHR = adjusted hazard ratio; CI = confidence interval.

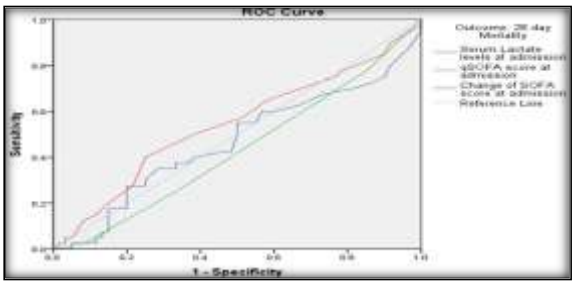

Figure 1: AUROCs for discriminatory capacity for 28 day mortality for serum lactate levels, qsofa score and change of sofa score at admission

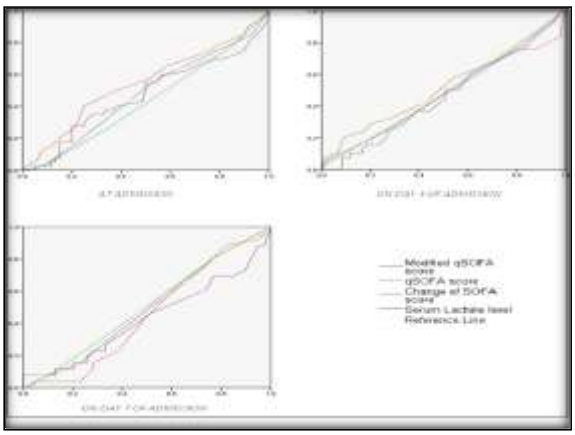

Figure 2: AUROCs for discriminatory capacity for 28 day mortality for modified qsofa score, serum lactate levels, QSOFA score and change of sofa score at admission, day 3 and day 7

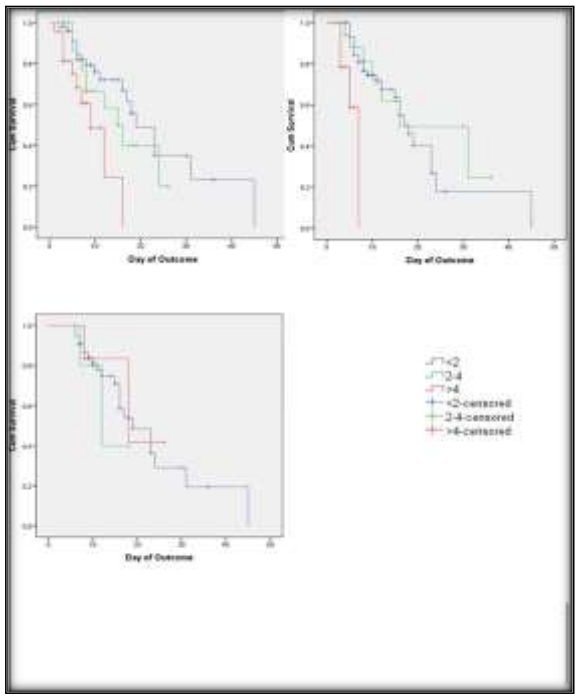

Figure 3: Kaplan- meier survival plots and log rank comparisons for serial serum lactate measurements

DISCUSSION

In this prospective observational study, elevated serum lactate levels at admission demonstrated moderate diagnostic performance for sepsis and high

sensitivity for septic shock, but were inferior to SOFA criteria for diagnosing sepsis. These findings are consistent with Sepsis-3 recommendations, which emphasize organ dysfunction rather than isolated biochemical abnormalities for defining sepsis.[1,2] The modest diagnostic accuracy of lactate alone for sepsis observed in the present study is comparable to earlier reports highlighting the nonspecific nature of hyperlactatemia in critically ill patients.[8,9]

When compared with SIRS criteria, serum lactate showed similar diagnostic performance, supporting prior evidence that SIRS lacks specificity and may overestimate sepsis burden.[6,16] The modified qSOFA score demonstrated improved diagnostic sensitivity compared with serum lactate alone; however, its performance remained inferior to SOFA. These findings align with large cohort studies indicating that qSOFA, even with additional parameters, cannot fully replace SOFA for diagnostic purposes.[7,17]

From a prognostic standpoint, SOFA score at admission demonstrated superior discriminatory ability for predicting 28-day mortality and prolonged ICU stay, reaffirming its role as the most robust prognostic tool in sepsis.[3,4,7] Nevertheless, elevated serum lactate levels remained independently associated with mortality after adjustment for confounders, consistent with previous studies identifying lactate as an independent predictor of adverse outcomes.[10-13] Notably, lower lactate thresholds appeared to improve sensitivity for outcome prediction, a finding supported by Howell et al. and Mikkelsen et al., suggesting that clinically significant hypoperfusion may occur even at lactate levels below traditional cut-offs.[10,11]

Survival analysis demonstrated that elevated lactate levels at admission and on day 3 were significantly associated with increased mortality, whereas serial SOFA, qSOFA, and modified qSOFA scores were not. This observation supports earlier evidence that persistent hyperlactatemia and impaired lactate clearance are strong predictors of mortality in sepsis.[12-14] Additionally, the need for vasopressor support, respiratory support, and persistent septic shock were strongly associated with poor survival, consistent with existing critical care literature.[2,15]

Overall, while serum lactate and modified qSOFA provide valuable prognostic information, they do not outperform SOFA score. However, lactate measurement remains a useful adjunct, particularly in settings where comprehensive organ dysfunction scoring may not be feasible.

CONCLUSION

Serum lactate is a useful and readily available biomarker that provides important prognostic information in patients with sepsis and septic shock. Although elevated lactate levels demonstrate high sensitivity for septic shock and are independently associated with increased mortality, they are inferior to the SOFA score for the diagnosis and overall risk stratification of sepsis. The addition of lactate to qSOFA modestly improves diagnostic sensitivity but does not replace comprehensive organ dysfunction assessment. Serum lactate measurement should therefore be used as an adjunct to established scoring systems, particularly in resource-limited settings.

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