

Prognostic Value of Serial Serum Lactate and Lactate Clearance in Paediatric Shock: A Prospective Observational Study

FATEMA HUDA¹, VINOD INGALE², MOHAMMAD HASEEB³, IMTIYAZ AHMAD⁴

ABSTRACT

Introduction: Paediatric shock remains a major cause of morbidity and mortality in intensive care units. Early identification of children at high-risk of adverse outcomes is crucial. Serum lactate and lactate clearance have emerged as potential biomarkers of tissue hypoxia and adequacy of resuscitation, but data in paediatric shock across diverse aetiologies remain limited.

Aim: To evaluate the prognostic significance of serial serum lactate levels and lactate clearance at 6, 12, and 24 hours in predicting mortality among children with shock.

Materials and Methods: This prospective observational study was conducted over six months (April 2024 to September 2024) in the Paediatric Intensive Care Unit (PICU) of MGM Medical College and Hospital, Aurangabad, Maharashtra, India. Total 100 children aged 1 month to 18 years admitted with clinical shock and an initial serum lactate level ≥ 2 mmol/L were enrolled. Serum lactate levels were measured at admission and at 6, 12, and 24 hours. Lactate clearance was calculated for each

interval. The primary outcome was survival status at hospital discharge. Comparisons between survivors and non-survivors were performed using the independent t-test/Mann-Whitney U test and Chi-square/Fisher's-exact test as appropriate. ROC analysis was used to assess prognostic performance.

Results: A total of 100 children were included; out of them, 72 survived and 28 died (mortality 28%). Non-survivors had significantly higher serum lactate levels at admission and at all subsequent time points ($p < 0.01$). Lactate clearance was significantly lower in non-survivors than survivors at 6, 12, and 24 hours (13.4%, 22.4%, and 26.9% vs. 20.7%, 37.9%, and 55.2%, respectively; $p < 0.001$). Persistently elevated lactate levels and poor lactate clearance were associated with increased mortality.

Conclusion: Serial serum lactate measurements and lactate clearance during the first 24 hours of PICU admission are valuable prognostic markers in paediatric shock. Low lactate clearance identifies children at higher risk of mortality and may aid in early risk stratification and monitoring of resuscitation.

Keywords: Critical illness, Haemodynamic instability, Paediatric intensive care, Prognostic biomarkers, Tissue hypoperfusion

INTRODUCTION

Paediatric shock is a life-threatening emergency characterised by inadequate tissue perfusion and oxygen delivery, leading to cellular hypoxia, metabolic derangements, multi-organ dysfunction and death if not promptly managed [1]. Despite advances in critical care, shock continues to contribute substantially to PICU mortality, particularly in low- and middle-income countries [2].

Early recognition of high-risk patients and timely assessment of response to therapy are essential components of shock management. Among various biomarkers, serum lactate has gained attention as an indicator of tissue hypoxia and impaired oxygen utilisation [3]. Elevated lactate levels and persistent hyperlactatemia have been associated with increased severity of illness and mortality in critically ill patients [4,5]. More recently, lactate clearance, the reduction in serum lactate over time, has been proposed as a dynamic marker reflecting adequacy of resuscitation and recovery from shock [6-9].

While several studies in adults and children have demonstrated the prognostic value of serum lactate and lactate clearance, most evidence is limited to septic shock [4-6,10], and data on lactate measurements and lactate clearance in paediatric shock remain scarce [3,6,10]. Furthermore, evidence regarding the optimal timing of lactate assessment is limited [8,11,12]. Therefore, the present study was undertaken to evaluate the prognostic value of

serial serum lactate levels and lactate clearance at 6, 12, and 24 hours in children with shock and to assess their association with mortality.

MATERIALS AND METHODS

The present study was a prospective observational study conducted over six months (April 2024 to September 2024) in the PICU of MGM Medical College and Hospital, Ch Sambhajinagar, Maharashtra, India. The study was approved by the Institutional Ethics Committee of MGM Medical College and Hospital, Chhatrapati Sambhajinagar (Ethical clearance number: MGM-ECRHS/2023/43).

Inclusion criteria: The study included children aged one month to 18 years who were admitted to the PICU with a clinical diagnosis of shock. Patients were eligible for enrolment if their initial serum lactate level at admission was ≥ 2 mmol/L.

Shock was defined clinically based on signs of impaired tissue perfusion, including tachycardia, prolonged capillary refill time (> 3 seconds), weak peripheral pulses, altered mental status, hypotension (age-specific), or requirement of fluid resuscitation or vasoactive support [1].

Exclusion criteria: Children who had received definitive treatment at another hospital prior to referral, absence of initial serum lactate measurement, known chronic liver disease, inborn errors

of metabolism, post-cardiac arrest status, and other conditions known to significantly affect lactate metabolism or clearance were excluded.

Sample size: A formal sample size calculation was not performed prior to the study. All eligible patients admitted during the study period were consecutively enrolled.

Study Procedure

After obtaining written informed consent from parents or guardians, demographic data, clinical details, and type of shock (septic, hypovolemic, or cardiogenic) were recorded. Subjects with shock were classified into subtypes based on predefined clinical and investigational criteria [2]. Septic shock was diagnosed in the presence of suspected or confirmed infection with signs of circulatory dysfunction, in accordance with paediatric surviving sepsis campaign recommendations. Hypovolemic shock was defined by a history of fluid loss (e.g., diarrhoea, vomiting, or haemorrhage), clinical signs of dehydration, and haemodynamic improvement following fluid resuscitation. Cardiogenic shock was diagnosed based on clinical features of myocardial dysfunction (e.g., gallop rhythm, hepatomegaly, pulmonary oedema) supported by investigations such as chest radiography and echocardiography, where available.

In cases with overlapping features, classification was based on the predominant clinical aetiology as determined by the treating paediatric intensivist.

Serum lactate was measured using venous blood samples at the following time points:

- At PICU admission (0 hour)
- 6 hours post-admission
- 12 hours post-admission
- 24 hours post-admission

Serum lactate levels were measured using 2 mL peripheral venous blood samples collected at all predefined study time points. Analysis was performed using the ABL800 FLEX blood gas analyser. The normal reference range for serum lactate was 0.5–2.0 mmol/L. The same sampling technique was employed consistently throughout the study to minimise analytical variability. Peripheral venous sampling was selected because it is less invasive and more practical for serial monitoring in paediatric patients.

Lactate Clearance (LC) was calculated using the formula:

Lactate clearance (%) = $\frac{\{(\text{Initial lactate} - \text{Follow-up lactate}) / \text{Initial lactate}\} \times 100$

Lactate clearance was calculated for the intervals 0–6 hours (LC_{0-6}), 0–12 hours (LC_{0-12}), and 0–24 hours (LC_{0-24}).

All patients received standard treatment for shock according to institutional PICU protocols. Management included fluid resuscitation, vasoactive support, antimicrobial therapy for suspected sepsis, respiratory support, and other supportive measures as indicated. As this was an observational study, interventions were not protocolised specifically for research purposes.

The primary outcome of the study was survival status at hospital discharge, categorised as survivor or non-survivor. The secondary

outcome assessed was the duration of hospital stay, which was recorded for all enrolled patients.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 25.0. Continuous variables were expressed as mean $\pm$ Standard Deviation (SD) or median with interquartile range, as appropriate. Normality of data was assessed prior to analysis. Comparisons between survivors and non-survivors were made using the independent two-sample t-test or Mann-Whitney U test for continuous variables. Categorical variables were analysed using the Chi-square test or Fisher's-exact test. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic and Clinical characteristics: Out of the 100 patients included in the study, 58 were male (58%) and 42 were female (42%), resulting in a male-to-female ratio of 1.38:1. The median age was 5.4 years (IQR: 3.2–8.9 years). Of the 100 enrolled patients, septic shock was the most common subtype, accounting for 44 patients (44%), followed by hypovolemic shock in 30 patients (30%) and cardiogenic shock in 26 patients (26%). Mortality was 28% as 28 of the enrolled cases died and 72 survived. There was no statistically significant association between type of shock and survival outcome ($\chi^2=0.657$, $df=2$, $p=0.720$; Fisher's-exact test $p=0.749$) [Table/Fig-1].

Characteristics	n (%)
Sex	
Male	58 (58.0)
Female	42 (42.0)
Age (year), median (IQR)	5.4 (IQR: 3.2–8.9)
Shock category	
Septic shock	44 (44.0)
Hypovolemic shock	30 (30.0)
Cardiogenic shock	26 (26.0)
Outcome	
Survived	72 (72.0)
Died	28 (28.0)

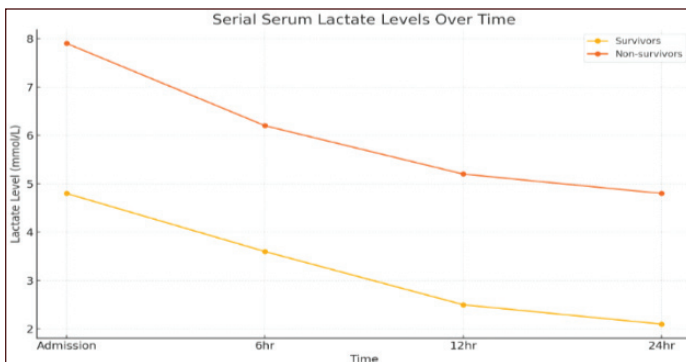
[Table/Fig-1]: Baseline characteristics of the study population (N=100). IQR: Interquartile range

Lactate levels and lactate clearance: Lactate levels were measured at four intervals: admission, six hours, 12 hours, and 24 hours post-admission. Serum lactate levels were significantly higher among non-survivors at all measured time points. At admission, the mean serum lactate level was 6.7 ± 1.1 mmol/L in non-survivors compared to 2.9 ± 0.6 mmol/L in survivors ($p=0.001$). At 6 hours, lactate levels decreased to 5.8 ± 1.0 mmol/L in non-survivors and 2.3 ± 0.5 mmol/L in survivors ($p=0.002$). At 12 hours, the mean lactate level was 5.2 ± 1.0 mmol/L among non-survivors and 1.8 ± 0.5 mmol/L among survivors ($p=0.001$). By 24 hours, survivors showed near normalisation of lactate levels (1.3 ± 0.3 mmol/L), whereas non-survivors continued to have elevated levels (4.9 ± 0.9 mmol/L), with the difference remaining statistically significant ($p=0.001$) [Table/Fig-2,3].

All values are expressed as mean $\pm$ Standard Deviation (SD). Comparisons between survivors and non-survivors were performed using the independent samples t-test. The p-values <0.05 were considered statistically significant.

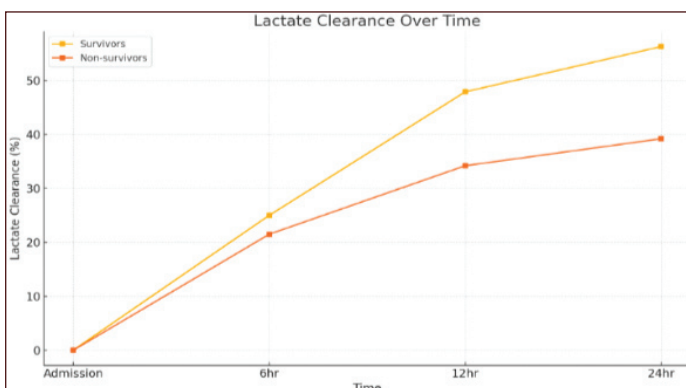
Parameters	Categories	Lactate level	p-value
Admission Lactate (mmol/L)	Survivors	2.9±0.6	0.001
	Non-survivors	6.7±1.1	
6-hour Lactate (mmol/L)	Survivors	2.3±0.5	0.002
	Non-survivors	5.8±1.0	
12-hour Lactate (mmol/L)	Survivors	1.8±0.5	0.001
	Non-survivors	5.2±1.0	
24-hour Lactate (mmol/L)	Survivors	1.3±0.3	0.001
	Non-survivors	4.9±0.9	
LC_06h (%)	Survivors	20.7	0.001
	Non-survivors	13.4	
LC_12h (%)	Survivors	37.9	0.001
	Non-survivors	22.4	
LC_24h (%)	Survivors	55.2	0.001
	Non-survivors	26.9	

[Table/Fig-2]: Comparison of serum lactate levels (mmol/L) and Lactate Clearance (LC) (%) at 6, 12, and 24 hours between survivors and non-survivors.



[Table/Fig-3]: Serial serum lactate levels over time, showing the trend of lactate levels in survivors vs. non-survivors.

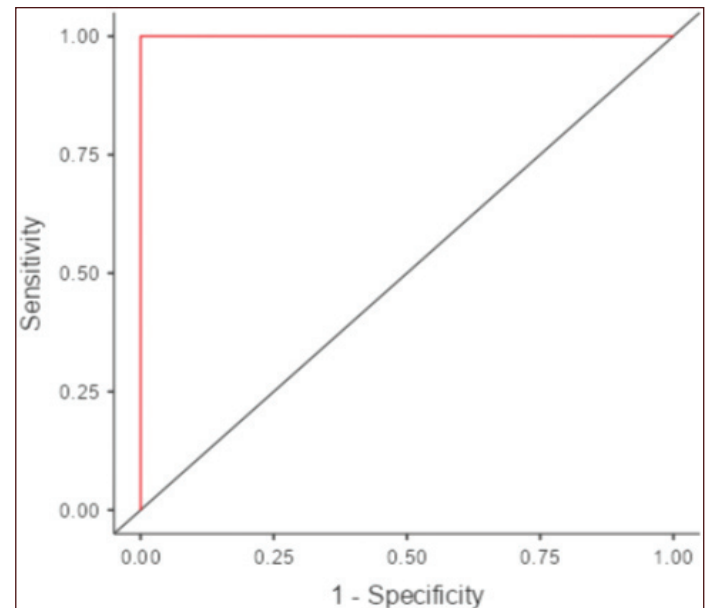
Lactate clearance values at 6, 12, and 24 hours were significantly higher among survivors as compared to non-survivors. At six hours, the mean lactate clearance was 13.4% in non-survivors and 20.7% in survivors; at 12 hours, 22.4% vs. 37.9%; and at 24 hours, 26.9% vs. 55.2%, respectively. In all three time points, the differences were statistically significant ($p < 0.001$) [Table/Fig-2,4].



[Table/Fig-4]: Lactate clearance over time, illustrating how effectively each group cleared lactate at 6, 12, and 24 hours.

Due to complete separation of predictor values by outcome (i.e., no overlap between the groups), logistic regression could not estimate valid coefficients. Receiver Operating Characteristic (ROC) analysis demonstrated excellent discriminatory ability of serum lactate levels and lactate clearance for predicting mortality, with an Area Under Curve (AUC) of 1.0, sensitivity of 100%, and specificity of 100%. However, an optimal biomarker cut-off value was not calculated. Furthermore, due to near-complete separation of values between

survivors and non-survivors in this relatively small sample, the observed ROC performance may have been overestimated and should therefore be interpreted with caution [Table/Fig-5].



[Table/Fig-5]: Receiver Operating Characteristic (ROC) curves for prediction of mortality in paediatric shock: (a) ROC curve for 24-hour serum lactate level; (b) ROC curve for 24-hour lactate clearance; Both parameters demonstrated excellent discriminatory performance with an AUC of 1.00, which may reflect complete data separation in this sample.

DISCUSSION

The present study underscores the prognostic value of serum lactate levels and lactate clearance in paediatric shock patients, where elevated lactate levels correlate with higher mortality rates. In the present cohort, non-survivors demonstrated significantly higher lactate levels, reflecting persistent tissue hypoxia and poor oxygen delivery. High initial lactate levels were consistently linked to worse outcomes, as was lower lactate clearance, which indicates inadequate metabolic adaptation to shock.

Comparatively, the study by Jat KR et al., in a North Indian PICU with septic shock patients found a mortality rate of 50%, with 79.3% of cases involving septic shock [13]. Their study established a lactate threshold of >45 mg/dL (approximately 5 mmol/L; 1 mmol/L $\approx$ 9 mg/dL) as a critical predictor of mortality, with odds ratios ranging from 6.7 to 12.5 and a negative predictive value of 83%, demonstrating that patients below this threshold had a significantly lower risk of mortality. In the present study, we included patients presenting with various shock types and introduced a 6, 12 and 24-hour post-admission measurement, which may capture critical early trends in lactate levels and help tailor interventions.

Nazir M et al., studied 112 paediatric patients with septic shock, the primary outcome variable of 60-day mortality rate was 31.25% [10]. Only lactate clearance at six and 24 hour was significantly associated with mortality, with odds of 0.97 (95% CI, 0.951-0.981; $p < 0.001$) and 0.975 (95% CI, 0.964-0.986; $p < 0.001$), respectively. They reported odds ratios less than one for lactate clearance, indicating that higher lactate clearance is associated with reduced odds of mortality. This reflects a protective effect, where each incremental increase in lactate clearance corresponds to improved survival. Similarly, Yue C et al., retrospective analysis of 12,213 paediatric ICU patients in China found that admission lactate levels independently predicted all-cause mortality [14]. Out of the 12,213 patients, 755 (6.18%) died, with an adjusted odds ratio of 1.14 (95% CI: 1.12-1.17) per unit increase in lactate. Their study controlled for confounding factors

such as acid-base disorders, inflammation, and organ dysfunction, suggesting that admission lactate consistently predicts mortality risk across diverse patient profiles. These findings align with the present study, reinforcing the utility of lactate as a reliable and independent mortality indicator in critically ill children.

In the study by Gorgis N et al., study of 74 paediatric patients with severe sepsis or septic shock, they observed a mortality rate of 10.5% [15]. Their study found that initial lactate (LO) levels were significantly associated with Paediatric Risk of Mortality III (PRISM III) scores, where each 1 mmol/L increase in LO correlated with a 1.12-unit increase in PRISM-III ($p=0.003$). However, LO did not independently predict mortality in their cohort. Their findings underscore the role of early lactate levels as a severity indicator rather than a direct mortality predictor, reinforcing the need for larger, multicentre studies to validate early lactate's prognostic utility.

The present study findings on lactate clearance also align with current literature indicating its importance as a recovery marker in shock. Patients with higher lactate clearance demonstrated better survival rates, emphasising that rapid normalisation of lactate levels is associated with improved outcomes. In the present study, ROC analysis yielded AUC values approaching 1.0, which likely reflects near-complete separation of lactate values between outcome groups rather than true perfect discrimination. Such findings are recognised in smaller datasets and may result in overestimation of predictive performance. Therefore, these results should be interpreted cautiously, and larger studies are needed to validate the discriminatory ability of lactate and lactate clearance. Additionally, the present study observed that prolonged hospital stays correlated with elevated lactate levels, suggesting lactate clearance could be an essential marker to guide interventions and predict recovery time. These findings highlight serum lactate and lactate clearance as critical metrics in managing paediatric shock, potentially improving therapeutic strategies and survival rates in this vulnerable population.

The present study has several strengths. It employed a prospective design with serial measurement of lactate at clinically relevant time intervals, allowing dynamic assessment of patient response to resuscitation. Inclusion of multiple types of shock enhances the applicability of findings across a broader paediatric population. Additionally, the use of lactate clearance as a functional marker provides clinically meaningful insight beyond single time-point measurements.

From a clinical perspective, serial lactate measurement and lactate clearance may serve as useful bedside tools for monitoring response to resuscitation and early risk stratification in paediatric shock. Failure of lactate reduction during the first 24 hours may help identify high-risk patients requiring escalation of care. However, factors such as resource availability and cost should be considered, particularly in resource-limited settings.

Limitation(s)

The present study has certain limitations. Being a single-centre study, the findings may not be generalisable. A formal sample size calculation was not performed prior to the study, and the relatively modest sample size may have limited the robustness of subgroup analyses, particularly across different shock aetiologies. Illness severity scores such as PRISM or Paediatric Logistic Organ Dysfunction (PELOD) were not included, which could have provided better risk adjustment and outcome assessment. In addition, management strategies, including fluid resuscitation, vasoactive

support, and other therapeutic interventions, were not protocolised and may have influenced lactate clearance and clinical outcomes. Since septic, hypovolemic, and cardiogenic shock have distinct pathophysiological mechanisms, subgroup analysis based on shock type could not be performed because of the limited sample size. Therefore, it remains unclear whether lactate clearance has similar prognostic performance across different shock aetiologies. Finally, the near-complete separation of lactate values between survivors and non-survivors may also have resulted in overestimation of ROC performance measures.

CONCLUSION(S)

Serial serum lactate measurements and lactate clearance during the first 24 hours of PICU admission are valuable prognostic tools in paediatric shock. Elevated lactate levels and poor lactate clearance are associated with increased mortality. Incorporating lactate clearance into routine monitoring may aid in early identification of high-risk children and guide ongoing resuscitative efforts. Larger multicentric studies are needed to validate these findings and improve generalisability. Future research should incorporate illness severity scores and aim to define standardised lactate clearance cut-offs. Interventional studies evaluating lactate-guided resuscitation and long-term outcome assessments are also warranted.

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PARTICULARS OF CONTRIBUTORS:

1. Senior Resident, Department of Paediatrics, Mahatma Gandhi Mission's (MGM) Medical College and Hospital, A Constituent Unit of MGM Institute of Health Sciences, Ch Sambhajinagar, Maharashtra, India.
2. Associate Professor, Department of Paediatrics, Mahatma Gandhi Mission's (MGM) Medical College and Hospital, a Constituent Unit of MGM Institute of Health Sciences, Ch Sambhajinagar, Aurangabad, Maharashtra, India.
3. Professor, Department of Paediatrics, Mahatma Gandhi Mission's (MGM) Medical College and Hospital, a Constituent Unit of MGM Institute of Health Sciences, Ch Sambhajinagar, Aurangabad, Maharashtra, India.
4. Resident, Department of Paediatrics, Mahatma Gandhi Mission's (MGM) Medical College and Hospital, a Constituent Unit of MGM Institute of Health Sciences, Ch Sambhajinagar, Aurangabad, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Mohammad Haseeb,
P No. 98, N 13, CIDCO, Himayat Baugh, Aurangabad-431001, Maharashtra, India.
E-mail: mohdhaseeb181@gmail.com

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