



Original Research Article

Significance of arterial lactate levels as a mortality indicator in sepsis patients

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Abstract

Background and Aims: Sepsis is a life-threatening condition resulting from infection, with a mortality rate of 10% and high morbidity. Serum lactate levels are commonly used for diagnosing septic shock and guiding fluid resuscitation. However, the value of serum lactate levels beyond the initial 6 hours of resuscitation remains under investigation, as many septic patients continue to die even after the crucial initial phase of treatment. The primary objective of this study was to assess the association between initial arterial lactate levels and 30-day outcomes in sepsis patients. Additionally, we aimed to explore the relationship between arterial lactate clearance and the initial lactate levels with the 30-day outcome in these patients.

Materials and Methods: Patients aged ≥ 18 years with sepsis diagnosed and treated according to the Sepsis Survival Campaign 2021 guidelines. Arterial lactate levels were measured at the time of admission (H0), 6 hours (H6), and 24 hours (H24) using ABG analysis. Lactate clearance was calculated at H6 and H24. Clinical data, treatment details, and 30-day mortality were recorded, with follow-up via phone for discharged patients.

Results: Lactate levels at 0, 6, and 24 hours, as well as lactate clearance at 6 and 24 hours, showed significant differences between survivors and non-survivors. Lactate clearance at 6 hours was notably higher in survivors (46.15%) compared to non-survivors (28.81%), with a similar pattern observed at 24 hours. The Area Under the Curve (AUC) of 0.847 from the ROC curve for lactate levels at 6 hours was superior to lactate values measured at 0 and 24 hours, indicating a better prognostic value at this time point.

Conclusion: Arterial lactate serves as a strong predictor of mortality in sepsis patients, with elevated lactate levels being associated with a higher risk of death. The lactate value at 6 hours, exhibiting an AUC of 0.847, provides superior prognostic accuracy when compared to measurements taken at 0 and 24 hours.

Keywords: Sepsis, Lactate, Lactate clearance.

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1. Introduction

Sepsis is an emergency and a life-threatening situation arising due to infection with a recorded mortality rate of 10% and a high morbidity.¹ Several studies have been done and guidelines have been updated for the management of sepsis, the latest being surviving sepsis campaign guidelines 2021.

Lactate was introduced into the sepsis guidelines around 2004-2008, where its initial measurement on presentation was recommended by Dellinger et al.^{2,3} Lactate can point to tissue hypoperfusion without evident hypotension in the patient. Several factors⁴ have been postulated for increase in lactate in sepsis including tissue hypoxia, altered function of the enzyme pyruvate dehydrogenase leading to an accumulation of pyruvate and resulting increased lactate production, a flawed utilization of oxygen by mitochondria,

discrepancy between oxygen delivery to tissues and consumption of oxygen and adrenergic stimulation in sepsis which leads to increased aerobic glycolysis.^{4,5}

The initial six hours are vital for resuscitation in sepsis and this period is considered as the golden hour. Serum lactate level is a part of the diagnostic criteria for septic shock and is utilized for guiding fluid therapy.^{6,7} Even with recommended treatment based on diagnostic criteria, many patients succumb to the disease. Limited studies in the Indian context address the role of serum lactate levels and lactate clearance in predicting the outcomes of sepsis patients. This study aimed to assess and compare the relationship between arterial lactate levels (initial, 6th hour, and 24th hour), lactate clearance (6th hour and 24th hour), and 30-day mortality in sepsis patients.

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2. Materials and Methods

This prospective cross-sectional study was conducted in a tertiary care hospital after obtaining Institutional Ethics Committee approval and CTRI registration (CTRI/2024/07/070338). Informed written consent was obtained from patients or legally responsible relatives of patients who satisfied the inclusion criteria.

Sepsis diagnosis was made using the standard criteria established in the Sepsis Survival Campaign 2021 guideline, with treatment carried out in accordance with the same guideline, based on the clinical condition of the patient. Detailed clinical history, including demographic characteristics, hospitalization details, comorbidities, vital signs such as blood pressure, temperature, respiratory rate, laboratory results, APACHE II scores, and Glasgow Coma Scale (GCS) assessments, were recorded within the first 24 hours of sepsis and septic shock diagnosis. The APACHE II score, commonly used in intensive care units, classifies disease severity and is measured within 24 hours of admission. The GCS is used to assess consciousness impairment in patients with traumatic brain injury or other acute medical illnesses.

Arterial lactate levels were measured through arterial blood gas (ABG) analysis at the time of initial admission (H0), at the 6th hour (H6), and at the 24th hour (H24). ABG was recorded using the GEM3500 ABG machine. Arterial lactate clearance was calculated and recorded at the 6th and 24th hour using the formula:

Arterial Lactate Clearance = $[(\text{Initial lactate} - \text{Follow-up lactate}) / \text{Initial lactate}] \times 100\%$.

The antibiotic treatment received by patients, their need for ventilation, and their discharge and 30-day mortality status were also recorded. Follow-up data was collected by phone if patients were discharged.

Inclusion criteria included patients aged ≥ 18 years with a diagnosis of septic shock admitted to the ICU. Exclusion criteria included patients who refused participation, were unable to complete the 6th hour follow-up for lactate levels, had an initial lactate level < 2 mmol/L, had a history of major surgery, polytrauma, HIV, malignancy, pregnancy, or were on biguanides or salicylates (**Figure 1**).

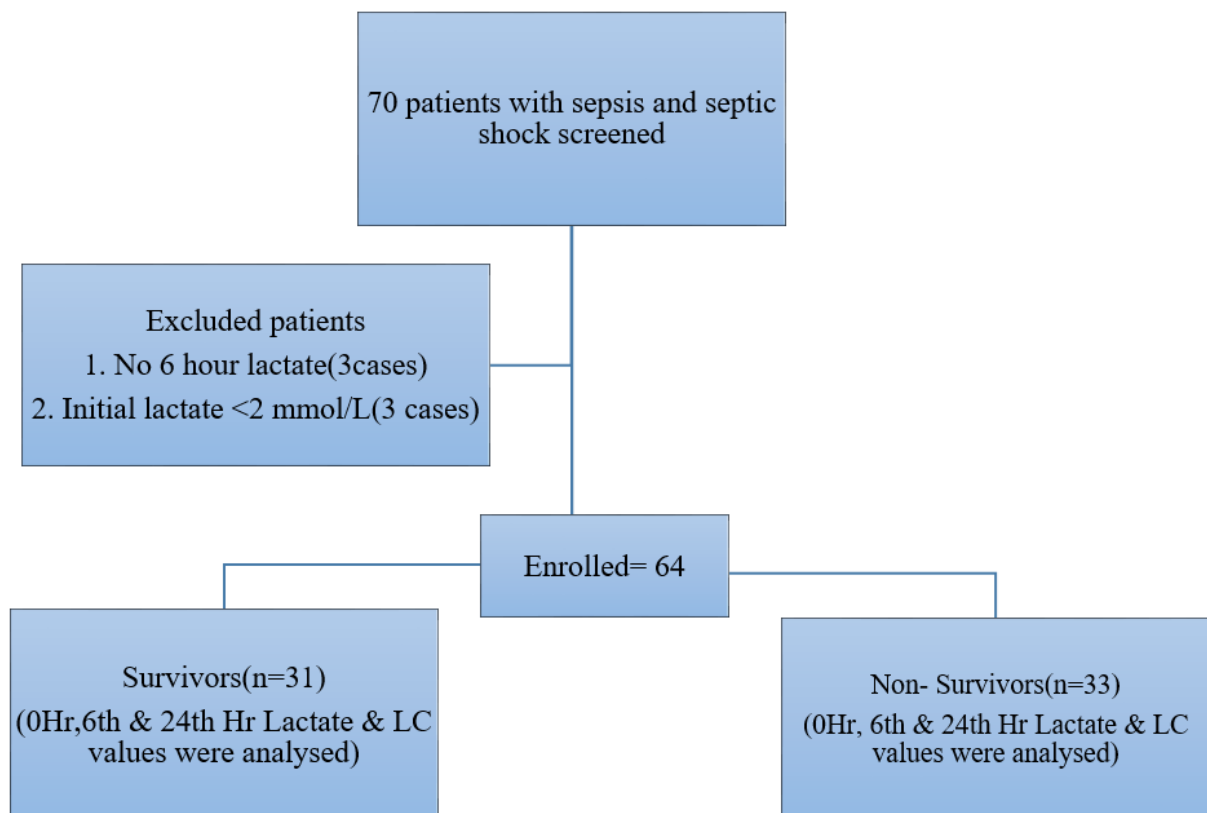


Figure 1: Consort diagram

Sample size was estimated using the sensitivity of serum lactate at Day 0 (83%) from a study by Chaudhari et al.⁸ with the formula:

$$n = [Z_{\alpha/2} * Sn * (1 - Sn)] / (d^2 * p)$$

Where:

n = sample size

$Z_{\alpha/2}$ = standard normal value at the 95% confidence level (1.96)

Sn = sensitivity = 0.83

1-Sn = 0.17

d = desired absolute precision = 2% (0.02)

p = prevalence = 23.5% (0.235)

Substituting these values: n=58 subjects. Considering a 10% non-response rate, the final sample size taken as 58+5.8=64 subjects were included in the study.

Data were analysed using SPSS version 21 and Epi-info version 7.2.1. Categorical data were presented as frequencies and proportions, while continuous variables were represented as means \pm SD or medians with IQR. Normality was tested using Kolmogorov–Smirnov and Shapiro–Wilk tests. Chi-

square or Fischer's exact test was used for categorical comparisons, and the independent t-test/Mann–Whitney test for quantitative variables. The optimal cut-off values for blood lactate and lactate clearance associated with 30-day mortality were determined using ROC curves. Sensitivity, specificity, PPV, and NPV were calculated, with a p-value <0.05 considered statistically significant.

3. Results

A total of 64 patients were included in the study, with a mean age of 53.48 ± 13.76 years. **Table 1** presents the demographic details. The gender distribution showed that 25.0% of participants were female and 75.0% were male. Regarding Glasgow Coma Scale (GCS) scores, 28.1% had a score of 15, indicating the highest level of consciousness. Other notable GCS scores included 15.6% with scores of 6 and 7, 9.4% with a score of 10, and 7.8% each with scores of 8, 12, and 13. The median GCS score was 10.

For the Acute Physiology and Chronic Health Evaluation (APACHE) scores, 18.8% of patients had a score of 12, 14.1% had a score of 10, and 12.5% had a score of 8. The median APACHE score was 12, with a range from 6 to 24, reflecting the wide variation in illness severity. A majority of subjects (76.6%) required inotropic support, and 59.4% needed mechanical ventilation. The ICU/hospital mortality rate was 48.4%, with 51.6% surviving.

Table 1: Association of factors with mortality

		Mortality				p value
		Yes		No		
		Count	Row N %	Count	Row N %	
Age	<30 years	3	75.0%	1	25.0%	0.576
	31 to 40 years	5	62.5%	3	37.5%	
	41 to 50 years	9	52.9%	8	47.1%	
	51 to 60 years	3	30.0%	7	70.0%	
	61 to 70 years	9	47.4%	10	52.6%	
	>70 years	2	33.3%	4	66.7%	
Gender	Female	6	37.5%	10	62.5%	0.312
	Male	25	52.1%	23	47.9%	
GCS Classification	14-15 (Mild)	6	33.3%	12	66.7%	0.045*
	9-13 (Moderate)	6	35.3%	11	64.7%	
	3-8 (Severe)	19	65.5%	10	34.5%	
APACHE Score	<8	3	17.6%	14	82.4%	0.003*
	>8	28	59.6%	19	40.4%	
Inotrope support	No	2	13.3%	13	86.7%	0.002*
	Yes	29	59.2%	20	40.8%	
Mechanical Ventilation (MV)	MV	26	68.4%	12	31.6%	<0.001*
	No MV	5	19.2%	21	80.8%	

The lactate level at 0 hours had a mean of 3.1 ± 1 and 5.3 ± 2.68 mmol/L in survivors and non survivors respectively. Lactate level at 6 hours had mean of 1.76 ± 0.89 mmol/L and 3.69 ± 1.92 mmol/L and lactate clearance mean was $45.75 \pm 10.57\%$ and $31.4 \pm 10.4\%$ respectively in survivors and non survivors. Lactate level at 24 hours had a mean of 1.02 ± 0.66 mmol/L and 2.65 ± 1.5 mmol/L and lactate clearance at 24 hours had a mean of $68.8 \pm 10.9\%$ and 49.5 ± 16.92 survivors and non survivors respectively (**Figure 2**).

Arterial lactate clearance at 6hrs in survivors had median of 46.15% [41.46-54.55] and in non-survivors had a median of 28.81% [23.81-41.67]. Arterial lactate clearance at 24hrs in survivors had median of 70.73% [65.38-77.78] and in non-survivors had a median of 47.62% [38.98-67.27] ($p < 0.001$) as shown in **Figure 3**.

The ROC curve comparing lactate levels and lactate clearance at different time points in predicting 30-day mortality is shown in **Figure 4**. The areas under the curve

(AUC) for various lactate measurements and lactate clearance are presented in **Table 2**. Lactate levels at 0 hours, 6 hours, and 24 hours, along with lactate clearance at 6 and 24 hours, all demonstrated significant predictive value for 30-day mortality ($p < 0.001$).

Table 3 shows the prognostic value of lactate and lactate clearance. The sensitivity, specificity, and predictive values for each criterion are provided for lactate levels at 0 hours, 6 hours, and 24 hours, as well as for lactate clearance at 6 and 24 hours. Notably, lactate levels at 0 hours >3.7 , 6 hours >2.1 , and 24 hours >1 were associated with sensitivity values of 74.19%, 77.42%, and 80.65%, respectively. Lactate clearance at 6 hours $\leq 32.14\%$ and at 24 hours $\leq 54.35\%$ showed sensitivity values of 64.52% and 54.84%, with high specificity (90.91% and 93.94%, respectively), making them strong predictors of 30-day mortality.

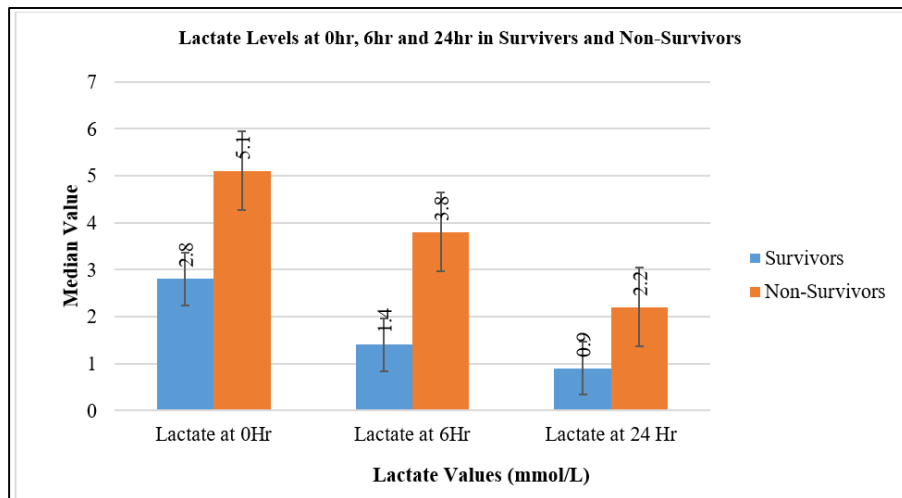


Figure 2: Lactate levels - comparison between survivors and non-survivors

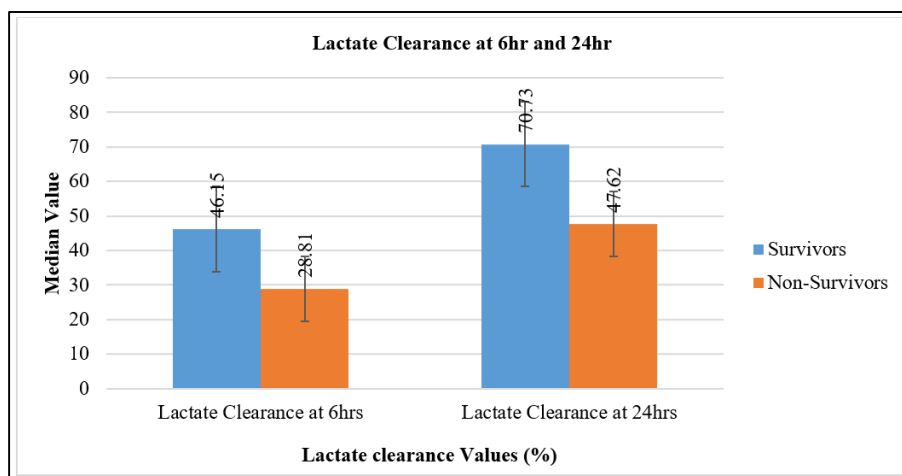


Figure 3: Lactate clearance - Comparison between survivors and non-survivors

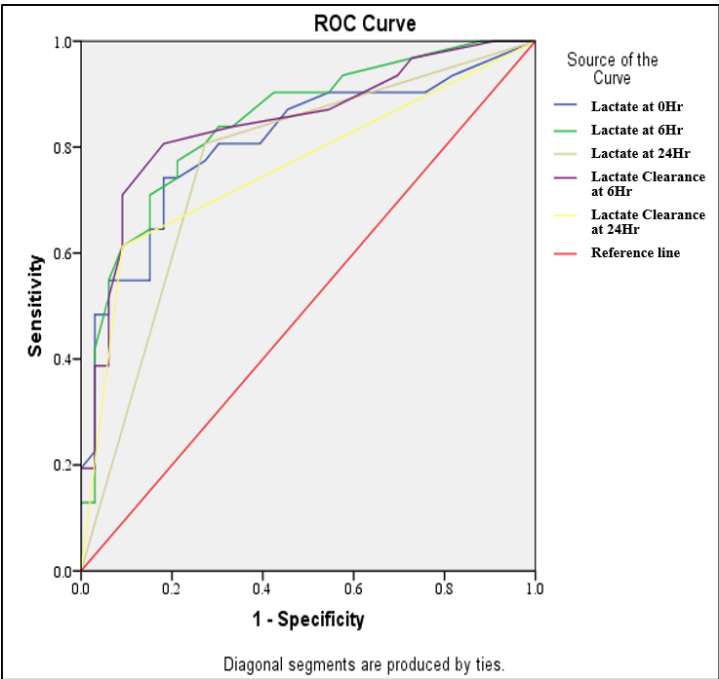


Figure 4: ROC curve comparing lactate and lactate clearance in predicting mortality at different periods of follow-up

Table 2: Predictive value of each variable for 30th day mortality

Test Result Variable(s)	Area	P value	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
Lactate at 0Hr	0.811	<0.001*	.701	.921
Lactate at 6Hr	0.847	<0.001*	.751	.943
Lactate clearance at 6Hr	0.767	<0.001*	.646	.887
Lactate at 24Hr	0.845	<0.001*	.745	.945
Lactate clearance at 24Hr	0.761	<0.001*	.639	.883

Table 3: Prognostic value of lactate and lactate clearance in predicting 30th day mortality

	Criterion	Sensitivity	95% CI	Specificity	95% CI	+PV	-PV
Lactate at 0Hr	>3.7	74.19	55.4 - 88.1	81.82	64.5 - 93.0	79.3	77.1
Lactate at 6Hrs	>2.1	77.42	58.9 - 90.4	78.79	61.1 - 91.0	77.4	78.8
Lactate at 24Hrs	>1	80.65	62.5 - 92.5	81.82	64.5 - 93.0	80.6	81.8
Lactate Clearance at 6hours (%)	≤32.14	64.52	45.4 - 80.8	90.91	75.7 - 98.1	87.0	73.2
Lactate Clearance at 24hours (5%)	≤54.35	54.84	36.0 - 72.7	93.94	79.8 - 99.3	89.5	68.9

4. Discussion

This study included 64 patients admitted to the ICU with sepsis, diagnosed according to the Sepsis Guidelines 2021, and resuscitation was carried out following the recommended protocol. Lactate levels were obtained from arterial blood gas analysis, which has been shown to correlate well with venous lactate levels in some studies.⁹⁻¹¹ However, a study by Theeravit et al. found poor correlation when lactate levels exceeded 4 mmol/L. They emphasized that arterial lactate levels are more reliable for assessing lactate kinetics,

including absolute values and clearance rates, especially in sepsis patients.^{12,13} Severe sepsis and shock often lead to disproportionate blood flow and significant variations in microcirculation, which renders venous lactate levels less reliable for lactate assessment.¹⁴

Patient with higher APACHE II score (>8), who required inotropic support and mechanical ventilation within the 24 hours had significantly higher mortality rate. Significantly high mortality rate and high morbidity have been observed in patients in septic shock with a high q-SOFA score.^{8,15}

Elevated APACHE II scores, which assess the severity of illness, are associated with increased mortality risk, and studies have shown APACHE II to be as predictive of mortality as the more complex APACHE III score.¹⁶

Previous research has shown that elevated serum lactate is associated with poor outcomes even when there is no organ dysfunction.¹⁷ Initial lactate of > 4 mmol/L and lactate clearance of < 20% is associated with mortality.¹⁸ In our study initial lactate levels more than 3.7 mmol/L had a sensitivity of 74% and specificity of 81%. The area under ROC curve at 0 hour was 0.811. Arterial lactate level at 0 hours in survivors had a median of 2.80 [2.60–3.60] and non-survivors had median of 5.10 [3.60–6.00] ($p < 0.001$) which is similar to the study by Ryoo et al.¹⁵ A study by Filho RR et al., concluded that an initial lactate cut-off of 2.5 mmol/L provided the maximum ROC area (0.70) for predicting 28-day mortality.¹⁹ In our study, the cutoff of >3.7 mmol/L at 0 hours demonstrated a stronger predictive ability with an ROC area of 0.81 for 30-day mortality. These results further reinforce the utility of lactate as an early predictor of mortality in sepsis patients.

Lactate levels more than 2.1 mmol at 6 hours had sensitivity of 77.4 and specificity 78.8 in predicting mortality and AUC of 0.847 in the ROC curve which was highest among the factors studied in this study. Arterial lactate level in survivors at 6 hours had a median of 1.40 [1.20–2.10] and non-survivors it was 3.80 [2.20–4.40] ($p < 0.001$). These findings were similar to a study by Şeyhögü et al.²⁰ Patients who survived at 24hrs had a median arterial lactate level of 0.90 [0.60–1.00] and non-survivors had median of 2.20 [1.20–3.80] ($p < 0.001$). As compared to previous studies^{18,15,21} initial and delayed lactate levels were notably linked to mortality.

Lactate clearance was low in non-survivors compared to survivors in both at 6 and 24hrs in our study. This shows that inability to attain good lactate clearance during early stage of resuscitation can result in higher mortality rates. Therefore serial lactate guided management can definitely improve outcomes in sepsis patients.²³ When the lactate clearance is delayed, higher is the chance of organ dysfunction.^{24,25} Some studies have shown that rather than the initial lactate levels, the lactate clearance at sixth hour has more value in predicting mortality.²⁰ Lactate clearance value has also been studied as a predictor of 24hour mortality.²⁶ In our study, a lactate level of >2.1 mmol/L at 6 hours showed good sensitivity and specificity. Thus, in addition to the initial lactate level, using a single lactate value at 6 hours could be a simpler and more practical option for prediction, particularly in a busy critical care setting, compared to calculating lactate clearance, which can be time-consuming.

Sepsis-associated hyperlactatemia (SAHL) has been a subject of extensive research and some recent evidence indicates that it is an adaptive response to increase efficiency of energy utilization.⁵ It is a strong predictor of mortality in

patients presenting with sepsis and mortality rises linearly with increasing serum lactate levels.²⁷ In our study AUC of 0.847 on ROC curve for lactate level at 6 hours proved to be superior to other lactate values 0, 6 and 24hrs.

Markers of severity, such as high APACHE II scores, high q-SOFA scores, CRP/Albumin ratio, and the need for mechanical ventilation or inotropic support, have been identified as independent predictors of mortality in sepsis patients.^{28,29} However, in our study, we did not compare the predictive value of these variables with lactate levels or lactate clearance.

While our study provides valuable insights, it is important to note that it is a single-center study with a relatively small sample size of 64 patients. Additionally, the exclusion of co-morbidities, which may have influenced the final outcome, is a factor that should be considered.

5. Conclusion

Arterial lactate is a key predictor of mortality in sepsis, with higher levels linked to an increased risk of death. Lactate measurements at the 6-hour mark provide greater prognostic accuracy than those taken at 0 and 24 hours. Focusing on lactate levels in sepsis at the 6-hour time point demonstrate strong predictive capabilities for mortality, suggesting that early lactate monitoring and clearance assessment can guide risk stratification and improve patient outcomes in critical care setting.

6. Source of Funding

None.

7. Conflict of Interest

None.

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