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Early Lactate Clearance and Mortality Risk in Neonatal Sepsis: A Systematic Review

[1]Putu Rika Anjani*, [2]Ida Bagus Antaratma Pradyumna
[1] Department of Pediatric Health Science, Maranatha Christian University, Bandung, West Java, Indonesia*; email: rikaanjani22@gmail.com
[2] General Practitioner, Warmadewa University, Denpasar, Bali, Indonesia; email: antaratma.pradyumna@gmail.com
*Correspondence

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Abstract
Introduction: *Neonatal sepsis remains an important cause of neonatal mortality, highlighting the need for accessible prognostic biomarkers. Early lactate clearance has been proposed as a potential indicator of adverse clinical outcomes.* ***Objective:*** *To evaluate the prognostic relevance of early lactate clearance for mortality in neonatal sepsis while considering complementary evidence from related lactate-based measurements.* ***Methods:*** *A systematic review was conducted using PubMed, Cochrane Library, and ScienceDirect. Five observational studies evaluating lactate clearance, serial lactate changes, or absolute lactate concentrations in neonatal populations were synthesized qualitatively. Risk of bias was assessed using the Newcastle–Ottawa Scale.* ***Result and Discussion:*** *Five observational studies involving 993 neonates found that reduced six-hour lactate clearance was associated with increased mortality in neonatal sepsis, but heterogeneity in populations and measurement approaches prevented pooling, suggesting lactate measurements may offer prognostic value despite limited strength due to observational designs and confounding.* ***Conclusion:*** *Early lactate clearance shows potential as a complementary prognostic marker in neonatal sepsis. Further prospective studies are needed to establish standardized measurement intervals, prognostic thresholds, and clinical applicability*

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Introduction

Neonatal sepsis remains a major cause of morbidity and mortality worldwide, particularly in low- and middle-income countries where early diagnosis and timely treatment remain challenging. Its clinical manifestations are frequently nonspecific, including temperature instability, feeding intolerance, lethargy, and respiratory distress, which may delay recognition and management. Conventional inflammatory biomarkers, such as C-reactive protein and procalcitonin, support clinical evaluation but may not adequately reflect circulatory dysfunction or the risk of deterioration. Consequently, accessible biomarkers that provide additional prognostic information are needed in neonatal intensive care settings (Celik et al., 2022); (Fleischmann et al., 2021); (Strunk et al., 2024).

Blood lactate has been investigated as a marker of metabolic stress and physiological instability in critically ill patients. Elevated lactate concentrations may result from impaired tissue perfusion, increased metabolic production, or reduced elimination, particularly during severe systemic illness. Although hyperlactatemia has been associated with adverse outcomes, an isolated lactate measurement may not adequately describe changes in physiological status over time. Lactate interpretation is particularly complex in neonates because metabolic maturity, gestational age, and underlying clinical conditions may influence circulating lactate concentrations (Deulkar et al., 2024); (Elataş et al., 2023); (Liu et al., 2024); (Matsushita et al., 2023); (Wasyluk & Zwolak, 2021).

Early lactate clearance, defined as the percentage reduction in lactate concentration between sequential measurements, has been proposed as a potential indicator of clinical prognosis. Previous investigations in adult and pediatric critical care have demonstrated associations between lactate-related measurements and adverse outcomes, suggesting that serial assessment may provide information beyond a single baseline measurement. However, prognostic association should be distinguished from evidence that targeting lactate clearance through treatment improves survival (Abdelaziz et al., 2024); (Çeleğen & Çeleğen, 2022); (Evans et al., 2021); (Rezar et al., 2023).

Evidence regarding lactate-based prognostic assessment in neonates remains limited and methodologically heterogeneous. Existing observational studies have evaluated different lactate-related variables, including six-hour percentage clearance, serial lactate changes, and absolute lactate concentrations. These measurements are related but not interchangeable, and their prognostic interpretation may vary according to patient characteristics, measurement timing, and clinical outcomes. Consequently, the specific prognostic value of early lactate clearance in neonatal sepsis remains incompletely established.

Therefore, this systematic review aimed to evaluate the relationship between early lactate clearance and mortality in neonatal sepsis while considering complementary evidence from related lactate-based measurements in neonatal populations. The review specifically sought to distinguish differences in lactate measurement approaches, summarize their reported prognostic associations, and identify limitations affecting their clinical applicability.

Method

This systematic review evaluated the prognostic value of early lactate clearance in neonatal sepsis following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A systematic literature search was conducted on March 7, 2026, using PubMed, Cochrane Library, and ScienceDirect. Search terms included combinations of "neonatal," "sepsis," "lactate clearance," and "mortality," using Boolean operators AND and OR. The search included English-language publications without publication-year restrictions.

Study eligibility was determined using the Population–Exposure–Comparator–Outcome (PECO) framework, focusing on neonates aged ≤28 days with suspected or confirmed sepsis, lactate clearance measurements, and mortality outcomes. Related studies examining serial lactate concentrations or critically ill neonates were considered complementary evidence. Non-original publications, non-neonatal studies, and articles lacking relevant prognostic data were excluded. Screening involved title, abstract, and full-text assessments following PRISMA procedures. Five observational studies met the eligibility criteria.

Data extraction included study characteristics, neonatal populations, lactate measurements, measurement intervals, and clinical outcomes. Methodological quality was evaluated using the Newcastle–Ottawa Scale (NOS), identifying two studies with low risk of bias and three with moderate risk. Findings were synthesized qualitatively because differences in study populations, lactate measurements, and outcome definitions prevented meaningful meta-analysis. Evidence directly examining early lactate clearance and mortality was distinguished from complementary prognostic findings.

Result and Discussions

1. Results

Study Selection

The systematic literature search identified 924 records from three electronic databases, including 100 from PubMed, 11 from Cochrane Library, and 813 from ScienceDirect. Following title and abstract screening, 917 records were excluded, leaving seven potentially eligible publications. One duplicate record was subsequently removed, and six full-text articles underwent eligibility assessment. One full-text article was excluded because its population or exposure characteristics did not meet the eligibility criteria.

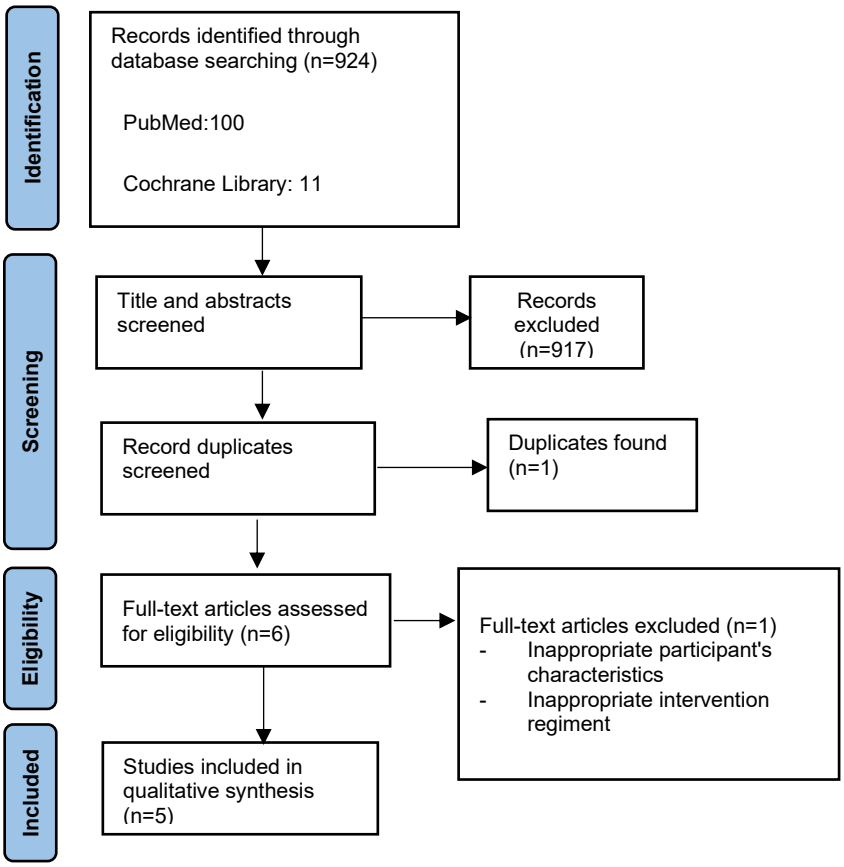


Figure 1. Diagram flow of literature search strategy for this systematic review

Ultimately, five observational studies were retained for qualitative synthesis (Figure 1). These studies investigated different aspects of lactate-based prognostic assessment in neonatal populations, including early lactate clearance, serial lactate variation, and absolute lactate concentrations. Differences in study applicability and outcome definitions were considered during the interpretation of findings.

Characteristics of Included Studies

Five observational studies published between 2016 and 2025 were included in the qualitative synthesis, comprising 993 neonates. The studies were conducted in Indonesia, Pakistan, Turkey, India, and China and included investigations by Trisnadi (2016), Chaudhry (2022), Kışlal (2023), Kulkarni (2024), and Lun (2025). Sample sizes varied across studies, ranging from 40 neonates in Trisnadi et al. to 596 very-low-birth-weight infants in Lun et al. The included studies differed in their population characteristics, lactate measurement protocols, and reported outcomes. Trisnadi et al. (2016) and Chaudhry et al. (2022) directly investigated early lactate clearance in neonatal sepsis, including measurements obtained within six hours. Kışlal et al. (2023) examined serial lactate measurements and their relationships with physiological variables among neonates with sepsis. Lun et al. (2025) investigated absolute lactate concentrations and mortality among very-low-birth-weight infants with late-onset sepsis. Kulkarni et al. (2024)

evaluated lactate-related prognostic outcomes in critically ill preterm neonates, representing a broader clinical population not restricted to sepsis.

Accordingly, the evidence was interpreted according to the measurement approach and clinical population of each study. The distinction between direct neonatal sepsis evidence and complementary neonatal critical care evidence was maintained throughout the narrative synthesis. These methodological differences were considered important when evaluating the applicability and consistency of reported prognostic associations. Regarding study design, the included investigations consisted primarily of cohort studies, including both prospective and retrospective observational approaches. Prospective designs, such as that used by Trisnadi et al., allowed for real-time monitoring of lactate changes following diagnosis and treatment initiation. In contrast, retrospective studies relied on medical record data and laboratory results obtained during routine clinical care. Although retrospective designs may introduce certain biases related to data completeness and confounding variables, they also provide valuable insights from larger patient populations over extended periods.

The timing and methodology of lactate measurement varied among the studies but generally focused on early assessment following diagnosis or admission. Some studies specifically evaluated lactate clearance within the first six hours, calculated as the percentage reduction between initial lactate levels and subsequent measurements. Others analyzed serial lactate measurements during the first several days of hospitalization, examining dynamic changes in lactate levels as indicators of treatment response and disease progression. Overall, the included studies consistently examined the relationship between lactate metabolism and clinical outcomes, particularly mortality, disease severity, and indicators of tissue perfusion. These characteristics collectively provided a framework for evaluating whether early lactate clearance could serve as a reliable prognostic biomarker in neonatal sepsis.

Association Between Lactate Clearance and Mortality

The most directly applicable findings regarding early lactate clearance and mortality in neonatal sepsis were reported by Trisnadi et al. (2016) and Chaudhry et al. (2022). These studies assessed changes in lactate concentration during the early treatment period and examined their associations with survival outcomes. Trisnadi et al. (2016) evaluated six-hour lactate clearance in 40 neonates with sepsis. Mortality occurred in 48% of neonates with low lactate clearance compared with 7% of those with higher clearance. Multivariate analysis identified six-hour lactate clearance as an independent predictor of mortality within the study population, suggesting that impaired early lactate reduction was associated with unfavorable survival outcomes

Similarly, Chaudhry et al. (2022) reported that elevated initial lactate concentrations and reduced six-hour lactate clearance were significantly associated with mortality among neonates with sepsis. Nonsurvivors demonstrated higher initial lactate concentrations and lower clearance than survivors, supporting the potential prognostic relevance of early lactate changes. Kulkarni et al. (2024) reported an association between early lactate clearance below 10% and increased seven-day mortality among critically ill preterm neonates. The reported sensitivity and specificity were 83% and 64%, respectively. However, because the study population was not restricted to neonatal sepsis, its findings were interpreted as complementary rather than direct sepsis-specific evidence. Lun et al. (2025) evaluated absolute lactate concentrations in very-low-birth-weight infants with late-onset sepsis and reported an association between higher lactate levels and mortality

risk. Unlike studies measuring percentage clearance, this investigation focused on lactate concentration thresholds and therefore contributed evidence regarding a different prognostic exposure.

Kışlal et al. (2023) investigated serial lactate measurements in neonatal sepsis and reported correlations with physiological indicators of perfusion and oxygenation. Although these findings supported the clinical relevance of longitudinal lactate monitoring, they did not provide a directly comparable assessment of six-hour lactate clearance as a mortality predictor. Overall, the findings indicated that reduced early lactate clearance was associated with increased mortality in studies directly addressing neonatal sepsis. Complementary investigations also supported the clinical relevance of lactate-related measurements, although their different populations, exposures, and outcomes limited direct comparisons.

Diagnostic and Prognostic Performance of Lactate Measurements

The prognostic performance of lactate-based measurements varied according to the type of exposure, measurement interval, and study population. Trisnadi et al. (2016) reported an area under the receiver operating characteristic curve (AUC) of 0.73 for six-hour lactate clearance, indicating moderate discrimination between survivors and nonsurvivors. This finding suggested potential prognostic utility, although it did not establish sufficient performance for standalone mortality prediction. Chaudhry et al. (2022) identified a significant association between reduced six-hour lactate clearance and mortality, supporting the prognostic relevance of early changes in lactate concentrations. Kulkarni et al. (2024) reported a sensitivity of 83% and specificity of 64% for early lactate clearance in critically ill preterm neonates, although these findings were not specific to neonatal sepsis.

Other studies evaluated different prognostic approaches. Lun et al. (2025) investigated absolute lactate thresholds in very-low-birth-weight infants with late-onset sepsis, whereas Kışlal et al. (2023) assessed serial lactate changes and their associations with physiological parameters. These measurements differed from six-hour percentage clearance and therefore could not be directly compared as equivalent prognostic indicators. Differences in lactate measurement intervals, reported thresholds, and clinical populations prevented the identification of a single optimal lactate clearance cut-off or measurement time. Consequently, the available prognostic findings were interpreted descriptively rather than combined into a pooled estimate.

Risk of Bias Assessment

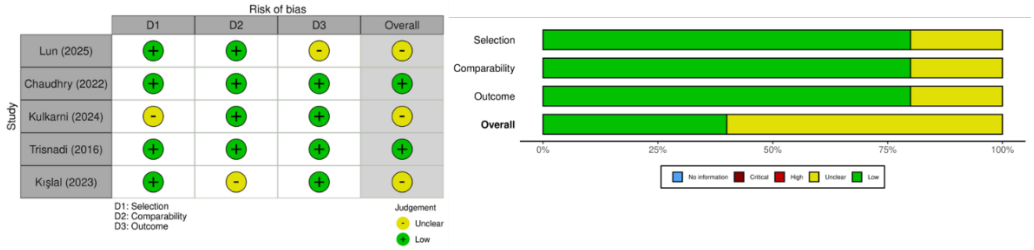


Figure 2. Risk of bias assessment result for the included studies using Newcastle Ottawa Scale (NOS)

The Newcastle–Ottawa Scale assessment classified two studies as having low risk of bias and three studies as having moderate risk of bias (Figure 2). The identified methodological concerns primarily involved participant selection, comparability between study groups, and potential confounding associated with differences in neonatal clinical characteristics. Several studies employed retrospective observational designs, which may be susceptible to incomplete documentation and residual confounding. Gestational age, birth weight, respiratory compromise, and illness severity were considered particularly relevant because these factors may influence both lactate concentrations and clinical outcomes. Differences in study setting and patient characteristics also limited the generalizability of the findings.

Although no study was classified as having high risk of bias in the retained assessment, the observational nature of the available evidence warranted cautious interpretation. The risk-of-bias findings were therefore considered when assessing the reliability of reported prognostic associations and the applicability of findings across different neonatal populations.

2. Discussion

Interpretation of the Main Findings

This systematic review evaluated the prognostic relevance of early lactate clearance and related lactate-based measurements in neonatal populations. The findings from five observational studies involving 993 neonates suggested that lactate measurements may provide clinically relevant prognostic information. However, the degree of applicability to neonatal sepsis varied according to study population, exposure definition, and reported outcomes. The most direct evidence was provided by Trisnadi et al. (2016) and Chaudhry et al. (2022), which reported associations between reduced six-hour lactate clearance and increased mortality in neonatal sepsis. These findings support the potential prognostic value of early lactate changes, consistent with broader critical care literature suggesting that lactate dynamics may reflect changes in physiological status (Evans et al., 2021); (Rezar et al., 2023); (Trisnadi et al., 2016).

Nevertheless, the remaining studies investigated related but distinct lactate-based measurements. Kışlal et al. (2023) evaluated serial lactate variation and physiological parameters, Lun et al. (2025) examined absolute lactate thresholds in late-onset sepsis, and Kulkarni et al. (2024) investigated lactate-related prognostic outcomes in critically ill preterm neonates. These differences indicate that the findings should not be interpreted as equivalent evidence for six-hour lactate clearance in neonatal sepsis.

Prognostic Performance, Timing, and Lactate Thresholds

The available evidence suggests that the prognostic value of lactate measurements depends partly on their timing and definition. Trisnadi et al. (2016) reported an AUC of 0.73 for six-hour lactate clearance, suggesting moderate discrimination between survivors and nonsurvivors. Chaudhry et al. (2022) also identified an association between reduced six-hour clearance and mortality, whereas Kulkarni et al. (2024) reported sensitivity and specificity estimates in a broader population of critically ill preterm neonates. Absolute lactate concentrations and serial lactate changes may provide additional information but should be distinguished from percentage clearance. This distinction is important because differences in baseline lactate concentrations, sampling intervals, and physiological conditions may affect the interpretation of prognostic performance. Previous pediatric critical care investigations have similarly demonstrated the relevance of lactate

measurements while highlighting differences in clinical populations and outcome definitions (Abdelaziz et al., 2024); (Çeleğen & Çeleğen, 2022); (Zhu et al., 2024). Although some studies evaluated clearance during the first six hours, others assessed lactate concentrations over longer periods or investigated absolute thresholds. Consequently, the available evidence does not establish a universally applicable lactate clearance threshold or optimal measurement interval for neonatal sepsis.

Confounding Factors and Interpretation of Prognostic Associations

Several clinical factors may influence lactate measurements and mortality risk in neonatal populations. Gestational age, birth weight, respiratory compromise, circulatory dysfunction, and underlying illness severity may affect lactate production and elimination. Neonatal metabolic maturity may also contribute to variability in baseline lactate concentrations, particularly among preterm infants (Elataş et al., 2023); (Matsushita et al., 2023). These factors may introduce confounding into observational prognostic studies. Differences in neonatal characteristics and clinical management may partly explain variations in reported associations between lactate-related measurements and mortality. Accordingly, the existing findings should be interpreted as prognostic associations rather than evidence of causation.

Furthermore, prognostic association should be distinguished from the effectiveness of therapeutic strategies targeting lactate clearance. Although lactate changes may accompany physiological improvement, observational studies cannot establish that interventions designed to achieve a particular lactate clearance threshold reduce mortality. This distinction is consistent with the broader sepsis literature, which recognizes the complexity of lactate metabolism and its interpretation during critical illness (Evans et al., 2021); (Liu et al., 2024); (Wasyluk & Zwolak, 2021).

Clinical Implications

Lactate measurements may serve as complementary indicators during the clinical assessment of neonates with suspected or confirmed sepsis. Serial measurements may provide information regarding changes in metabolic status, particularly when interpreted alongside hemodynamic findings, respiratory parameters, and conventional laboratory investigations. However, the evidence remains insufficient to recommend a single lactate clearance threshold as an independent determinant of prognosis or treatment decisions.

Importantly, elevated lactate concentrations are not specific to infection and may also occur in other neonatal or pediatric critical conditions. This limitation emphasizes the need to interpret lactate measurements within the broader clinical context rather than using them as standalone diagnostic or prognostic markers (Bowers et al., 2024); (Song et al., 2024). Therefore, early lactate clearance may support risk stratification in neonatal sepsis, but its clinical application should remain complementary to comprehensive assessment until further prospective evidence becomes available.

Limitations and Future Research

Several limitations should be acknowledged. First, only five observational studies were retained, and the number directly evaluating six-hour lactate clearance and mortality in neonatal sepsis was smaller than the total evidence base. Second, differences in patient populations, measurement protocols, lactate thresholds, and outcome definitions limited direct comparisons across studies. The inclusion of complementary evidence from broader critically ill neonatal populations also reduced the sepsis-specific applicability of

the overall synthesis. Third, observational study designs were susceptible to residual confounding, particularly from gestational maturity, underlying comorbidities, and severity of illness. Fourth, the lack of standardized measurement intervals and consistent reporting of prognostic performance prevented quantitative synthesis and identification of an optimal threshold. Finally, the review relied on English-language studies identified from three electronic databases, which may have limited the comprehensiveness of evidence retrieval. Future prospective multicenter studies should apply standardized neonatal sepsis definitions, consistent lactate measurement intervals, and clearly defined mortality outcomes. Additional research should evaluate prognostic discrimination, clinically meaningful clearance thresholds, and the incremental value of lactate monitoring alongside established clinical indicators. Interventional studies would also be necessary to determine whether lactate-guided treatment strategies improve neonatal outcomes.

Conclusion

This systematic review suggests that reduced early lactate clearance is associated with increased mortality risk in neonatal sepsis, particularly in studies directly evaluating six-hour lactate changes. Complementary evidence from serial lactate measurements, absolute lactate concentrations, and critically ill preterm neonates further supports the clinical relevance of lactate-based assessment, although these measurements are not directly interchangeable. The findings should be interpreted cautiously because of differences in study populations, measurement intervals, lactate thresholds, and potential confounding in observational studies. Early lactate clearance may serve as a complementary prognostic marker rather than a standalone predictor or established therapeutic target. Further prospective studies using standardized measurement protocols are needed to clarify its prognostic performance, optimal assessment timing, and clinical applicability in neonatal sepsis.

Declaration of AI Assistance

The authors declare that no generative AI or AI-assisted technologies were used in the preparation of this manuscript. All authors reviewed and verified the final content and take full responsibility for its accuracy and scientific integrity

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