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Original Research Article

Correlation Between TOLLINER Score and Blood Culture Positivity in Neonatal Sepsis: A Cross-Sectional Observational Study

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Abstract:

Background: Neonatal sepsis remains a leading cause of neonatal morbidity and mortality worldwide, particularly in low- and middle-income countries. Early diagnosis remains challenging because clinical manifestations are nonspecific and conventional diagnostic tools have important limitations.

Objective: To evaluate the correlation between the TOLLINER Score and blood culture positivity in neonates with suspected sepsis and to assess the diagnostic accuracy of the scoring system.

Methods: A hospital-based cross-sectional observational study was conducted in the Neonatal Intensive Care Unit (NICU) of C.U. Shah Medical College and Hospital, Surendranagar, Gujarat, from February to June 2025. Neonates with clinical suspicion of sepsis were enrolled consecutively. TOLLINER Scores were calculated using standardized clinical and laboratory parameters. Blood culture positivity was used as the reference standard. Statistical analysis included sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and receiver operating characteristic (ROC) curve analysis.

Results: A total of 105 neonates were included in the final analysis. Blood culture positivity was observed in 17.1% of neonates. Mean TOLLINER Scores were significantly higher among culture-positive neonates ($p < 0.05$). ROC curve analysis demonstrated excellent diagnostic discrimination with an area under the curve (AUC) of 0.99. The TOLLINER Score showed sensitivity of 89%, specificity of 97%, PPV of 84%, and NPV of 98%.

Conclusion: The TOLLINER Score demonstrated strong correlation with blood culture-confirmed neonatal sepsis and showed excellent diagnostic performance. The score may serve as a rapid and practical bedside screening tool for early identification of neonatal sepsis, especially in resource-limited settings.

Keywords: Neonatal Sepsis, TOLLINER Score, Blood Culture, Diagnostic Accuracy, NICU, Neonatal Infection.

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Introduction

Neonatal sepsis continues to be a major public health concern and contributes substantially to neonatal morbidity and mortality across the globe. The burden is particularly pronounced in developing countries where access to rapid diagnostic facilities and advanced neonatal care remains limited. Globally, neonatal sepsis accounts for nearly one-third of neonatal deaths annually.[1] Delayed diagnosis and treatment significantly worsen

outcomes, making early identification critically important.

Despite advances in neonatal intensive care, diagnosis of neonatal sepsis remains challenging because the presenting symptoms are often subtle and nonspecific. Clinical manifestations such as lethargy, respiratory distress, feeding intolerance, apnea, temperature instability, and poor perfusion frequently overlap with noninfectious neonatal conditions.[2] Blood culture remains the gold standard diagnostic method; however, its utility is restricted by prolonged turnaround time, low sensitivity due to inadequate blood sampling, and reduced positivity following prior antibiotic exposure.[3]

Biomarkers including C-reactive protein (CRP), procalcitonin, and interleukins have been evaluated as adjunctive diagnostic tools, but none have achieved sufficient sensitivity and specificity to independently establish the diagnosis of neonatal sepsis.[4] Consequently, composite scoring systems integrating clinical and laboratory variables have gained increasing attention. Such scoring systems may assist clinicians in identifying high-risk neonates and initiating timely treatment while minimizing unnecessary antibiotic exposure.[5]

The TOLLINER Score is a composite clinical scoring system developed to facilitate rapid bedside assessment of neonatal sepsis risk.[6] The score incorporates readily available clinical and laboratory parameters including temperature variation, oxygen saturation, blood lactate levels, and routine investigations. Preliminary evidence suggests promising diagnostic utility; however, data regarding its validation in real-world NICU settings remain limited.[7]

The present study was conducted to evaluate the relationship between the TOLLINER Score and blood culture positivity in neonates with suspected sepsis and to assess its diagnostic performance in a tertiary care NICU setting.

Objectives

1. To evaluate the correlation between the TOLLINER Score and blood culture positivity in neonates suspected of sepsis.
2. To assess the diagnostic performance of the TOLLINER Score using sensitivity, specificity, positive predictive value, negative predictive value, and ROC curve analysis.

Methodology

This hospital-based cross-sectional observational study was conducted over a period of five months from February to June 2025 in the Neonatal Intensive Care Unit (NICU) of C.U. Shah Medical College and Hospital, Surendranagar, Gujarat.

Neonates admitted with clinical suspicion of sepsis were included in the study. Clinical suspicion was based on established neonatal sepsis guidelines and included signs such as respiratory distress, poor feeding, lethargy, apnea, temperature instability, and abnormal laboratory findings suggestive of infection. Neonates who had received antibiotics prior to blood culture sampling, as well as those with major congenital anomalies or known metabolic disorders, were excluded.

Consecutive sampling was employed, and a total of 118 neonates were enrolled during the study period. However, complete analyzable data were available for 105 neonates. Demographic variables including sex, birth weight, and gestational age were recorded.

The TOLLINER Score was calculated for each participant using standardized clinical and laboratory criteria. Blood cultures were collected under strict aseptic precautions and processed according to standard microbiological protocols. The personnel calculating TOLLINER Scores were blinded to blood culture results to minimize observer bias.

Data were analyzed using SPSS version 31. Descriptive statistics were expressed as mean ± standard deviation and percentages. Categorical variables were analyzed using Chi-square or Fisher's exact test. Diagnostic performance of the TOLLINER Score was evaluated using sensitivity, specificity, PPV, NPV, and ROC curve analysis. A p-value <0.05 was considered statistically significant.

Ethical approval was obtained from the Institutional Ethics Sub-Committee of C.U. Shah Medical College. Patient confidentiality and data privacy were maintained throughout the study.

Results

A total of 105 neonates were included in the final analysis. The blood culture positivity rate was 17.1%, indicating confirmed sepsis in approximately one-sixth of the study population.

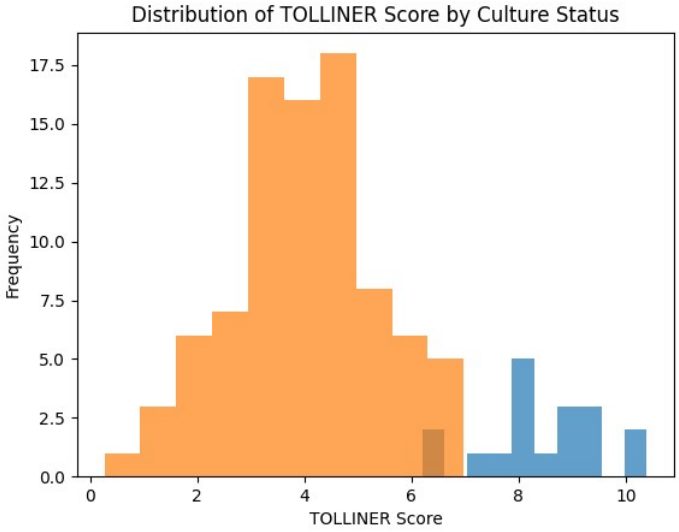

Figure 1: Distribution of TOLLINER Scores

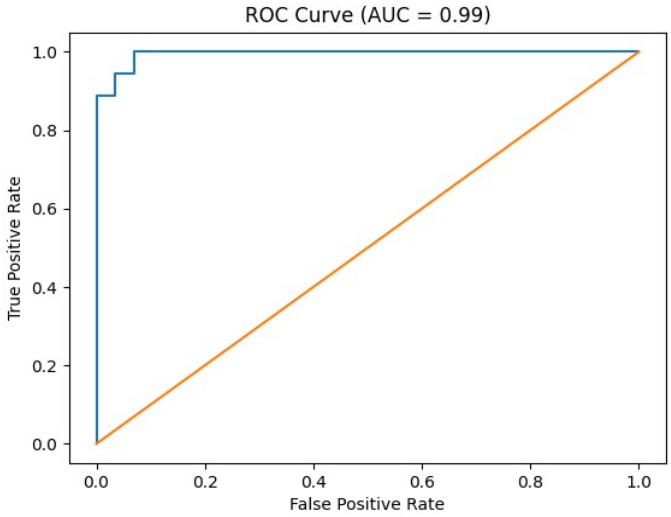

Figure 2: ROC Curve Analysis

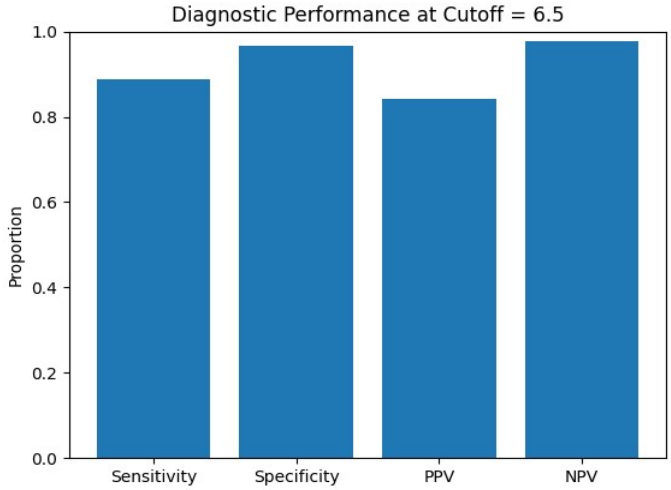

Figure 3: Diagnostic Performance Metrics

Mean TOLLINER Scores were significantly higher among neonates with culture-positive sepsis compared to culture-negative neonates ($p < 0.05$), suggesting a strong association between elevated scores and confirmed infection.

Receiver operating characteristic (ROC) analysis demonstrated excellent diagnostic accuracy of the TOLLINER Score, with an area under the curve (AUC) of 0.99. Diagnostic performance parameters were as follows:

- Sensitivity: 89%
- Specificity: 97%
- Positive Predictive Value (PPV): 84%
- Negative Predictive Value (NPV): 98%

These findings indicate that the TOLLINER Score possesses excellent discriminatory capacity and may be particularly valuable as a screening tool to rule out neonatal sepsis in low-risk neonates.

Discussion

The present study demonstrated a strong and statistically significant correlation between the TOLLINER Score and blood culture-confirmed neonatal sepsis. Neonates with positive blood cultures exhibited significantly higher mean TOLLINER Scores, indicating that the scoring system effectively reflects the severity of systemic inflammatory response in neonatal infection.

The blood culture positivity rate of 17.1% observed in this study is consistent with previously published NICU-based studies reporting positivity rates ranging from 10% to 30%. Although blood culture remains the reference standard for diagnosis, its limitations—including delayed reporting and reduced sensitivity—restrict its effectiveness in urgent clinical decision-making. Consequently, bedside scoring systems capable of identifying high-risk neonates assume considerable clinical importance. [8,9]

The diagnostic performance of the TOLLINER Score in our study was excellent, with high sensitivity and specificity. Particularly noteworthy was the very high negative predictive value (98%), suggesting that the score may reliably identify neonates at low risk of sepsis. This has important implications for antimicrobial stewardship because unnecessary empirical antibiotic use in NICUs contributes to antimicrobial resistance, altered neonatal microbiota, prolonged hospitalization, and increased healthcare costs. [10,11]

The AUC value of 0.99 observed in ROC analysis further supports the strong discriminatory ability of the TOLLINER Score. Similar findings have been reported in studies evaluating composite neonatal sepsis prediction scores, where integration of clinical and laboratory parameters improved diagnostic accuracy compared with isolated biomarkers. [12,13]

An important strength of the present study is the blinded assessment methodology, which minimized observer bias. Consecutive sampling and inclusion of both early- and late-onset sepsis improved the practical applicability of findings within tertiary care NICU settings.

Nevertheless, several limitations should be acknowledged. The study was conducted at a single tertiary care center with a moderate sample size, potentially limiting generalizability. Serial TOLLINER Score measurements were not assessed, and direct comparisons with biomarkers such as CRP or procalcitonin were not performed. Additionally, long-term neonatal outcomes including mortality, duration of antibiotic therapy, and neurodevelopmental sequelae were beyond the scope of the study.

Future multicenter prospective studies with larger sample sizes are necessary to validate these findings and determine optimal clinical cut-off values for broader implementation.

Conclusion

The TOLLINER Score demonstrated a significant association with blood culture-confirmed neonatal sepsis and exhibited excellent diagnostic performance in this study. High sensitivity, specificity, and negative predictive value indicate that the score may serve as a reliable bedside screening tool for early identification of neonatal sepsis.

The scoring system may assist clinicians in initiating timely treatment while simultaneously reducing unnecessary antibiotic exposure in low-risk neonates. Given its simplicity and rapid applicability, the TOLLINER Score appears particularly useful in resource-constrained settings where advanced diagnostic facilities may not be readily available.

Further multicenter validation studies are recommended before widespread clinical adoption. Additional research comparing the TOLLINER Score with established biomarkers and evaluating its impact on neonatal outcomes will further clarify its clinical utility.

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