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MACHINE LEARNING MODELS FOR EARLY PREDICTION OF NEONATAL SEPSIS: PERFORMANCE ANALYSIS AND CLINICAL UTILITY ASSESSMENT

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ABSTRACT

Background: Neonatal sepsis remains a leading cause of neonatal mortality, with early recognition critically impacting survival outcomes. Objective: To evaluate the diagnostic and predictive performance of machine learning (ML) models for early neonatal sepsis identification compared to conventional clinical screening tools. Methods: A prospective observational study was conducted in a tertiary neonatal intensive care unit (NICU) over 24 months. ML models including Random Forest, XGBoost, and Long Short-Term Memory (LSTM) networks were trained on electronic health record data. Results: Among 2,847 neonates, 412 (14.5%) developed confirmed sepsis. The LSTM model achieved the highest predictive performance (AUC-ROC 0.94, sensitivity 88.3%, specificity 93.7%), outperforming conventional sepsis screening scores (AUC-ROC 0.71). Time to diagnosis was reduced by a mean of 6.2 hours. Conclusion: ML-based early warning systems demonstrate superior performance to conventional screening tools for neonatal sepsis prediction, with clinically significant reductions in time to diagnosis.

Keywords: neonatal sepsis, machine learning, LSTM, early warning system, NICU, predictive modeling, electronic health records

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INTRODUCTION

Neonatal sepsis, defined as a clinical syndrome of systemic infection occurring within the first 28 days of life, contributes to an estimated 3 million neonatal deaths annually worldwide, representing approximately 26% of all neonatal mortality (Liu et al., 2023). Early-onset sepsis (EOS), occurring within 72 hours of birth, and late-onset sepsis (LOS) present distinct epidemiological and microbiological profiles requiring differentiated clinical approaches (Puopolo et al., 2024).

Conventional sepsis screening tools, including the Kaiser Permanente Neonatal Early-Onset Sepsis Calculator and C-reactive protein monitoring, demonstrate moderate sensitivity but significant false-positive rates, contributing to unnecessary antibiotic exposure and prolonged NICU stays (Kuzniewicz et al., 2023). The integration of continuous physiological monitoring data, laboratory results, and clinical observations into ML models offers the potential for earlier and more accurate sepsis identification.

Recent advances in time-series analysis using recurrent neural networks have enabled processing of longitudinal physiological signals with temporal dependencies, capturing deterioration patterns hours before clinical manifestation (Brown et al., 2024). This prospective study evaluates the comparative performance of multiple ML architectures for neonatal sepsis prediction in a real-world NICU setting.

METHODS

Study Setting and Population: A prospective observational study was conducted at a level-III NICU from January 2022 to December 2023. All neonates admitted within 72 hours of birth were eligible. Exclusion criteria included major

congenital malformations, inborn errors of metabolism, and incomplete EHR data (>20% missing values).

Data Collection: Features extracted from the EHR included: vital signs (heart rate, respiratory rate, temperature, oxygen saturation) sampled hourly; laboratory values (complete blood count, C-reactive protein, procalcitonin, blood glucose); clinical observations (feeding tolerance, activity level, skin color); and maternal risk factors (chorioamnionitis, GBS status, prolonged rupture of membranes).

ML Model Development: Three model architectures were developed and compared: (1) Random Forest using ensemble decision trees with 500 estimators; (2) XGBoost with gradient boosting optimization; (3) LSTM network processing 24-hour sequential physiological windows with 128 hidden units and dropout regularization (rate = 0.3). Models were trained on 70% of the dataset with 15% validation and 15% holdout test sets, with stratified splitting to maintain class balance.

Outcome Definition: Primary outcome was confirmed sepsis, defined as positive blood culture with clinical deterioration requiring antibiotic initiation lasting ≥5 days. Secondary outcomes included time to diagnosis and antibiotic-related complications.

Statistical Analysis: Model performance was evaluated using AUC-ROC, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Calibration was assessed using the Brier Score and calibration plots. Clinical decision curve analysis evaluated net benefit across threshold probabilities.

RESULTS

Patient Characteristics: Of 3,124 eligible neonates, 2,847 met inclusion criteria. Mean gestational age was 33.2 ± 4.7 weeks; mean birth weight 1,847 ± 712 g.

Confirmed sepsis was identified in 412 neonates (14.5%). Gram-negative organisms predominated in LOS (62.3%), while Streptococcus agalactiae accounted for 71.4% of EOS cases.

Model Performance: The LSTM model achieved superior performance across all metrics: AUC-ROC 0.94 (95% CI: 0.92–0.96), sensitivity 88.3%, specificity 93.7%, PPV 79.2%, NPV 96.8%. XGBoost demonstrated AUC-ROC of 0.89, and Random Forest achieved 0.86. Conventional sepsis screening scores (EOS Calculator) achieved AUC-ROC of 0.71 in the same population.

Time to Diagnosis: ML-based early warning triggered alerts a mean of 6.2 hours (95% CI: 5.1–7.3 h) before conventional clinical recognition. This early detection window was associated with a 31.4% reduction in sepsis-related complications ($p<0.001$).

Antibiotic Stewardship Impact: ML-guided antibiotic initiation reduced unnecessary antibiotic courses by 22.7% compared to the pre-implementation period ($p=0.003$), with no increase in culture-confirmed sepsis mortality.

DISCUSSION

The LSTM model's superior performance reflects the temporal nature of neonatal deterioration, where sequential physiological changes over hours carry greater predictive value than single time-point assessments (Park et al., 2024). The 6.2-hour early detection advantage represents a clinically meaningful window during which targeted interventions can prevent hemodynamic compromise and multi-organ dysfunction.

The reduction in unnecessary antibiotic exposure is particularly significant in the context of emerging antimicrobial resistance and evidence linking early-life antibiotic use to long-term alterations in gut microbiome composition and immune development (Gasparrini et al., 2024). ML-guided antibiotic stewardship

therefore addresses both immediate clinical and long-term developmental outcomes.

Model calibration demonstrated excellent agreement between predicted probabilities and observed outcomes (Brier Score 0.09), supporting the clinical utility of probability-based decision thresholds. Decision curve analysis confirmed net benefit of ML-guided management over treat-all and treat-none strategies across threshold probabilities of 15–40%.

Limitations include the single-center design and potential for overfitting to institution-specific EHR structures, practice patterns, and pathogen profiles. External validation across diverse NICUs, including resource-limited settings with limited monitoring infrastructure, is essential before generalized deployment.

CONCLUSION

Machine learning models, particularly LSTM networks processing sequential physiological data, demonstrate substantially superior performance for early neonatal sepsis prediction compared to conventional screening tools. The 6.2-hour early detection advantage and 22.7% reduction in unnecessary antibiotic exposure support the clinical and public health value of ML integration in NICU workflows. Prospective multicenter validation and implementation studies are needed to establish generalizability and define optimal alert thresholds for diverse clinical settings.

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