Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 32s (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

Significance of CRP and Procalcitonin Level in the Early Diagnosis of Neonatal Sepsis in Erbil, Iraq

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Cite this paper as: Mahmood Mohammed Sadiq, Sasan Loqa Hanna, Media Abdullah Kakasur, (2025) Significance of CRP and Procalcitonin Level in the Early Diagnosis of Neonatal Sepsis in Erbil, Iraq *Journal of Neonatal Surgery*, 14, (32s) 9441-9448

ABSTRACT

Background and Objectives: Neonatal sepsis remains a leading cause of morbidity and mortality in developing countries, where timely diagnosis is challenging. This study aimed to evaluate the diagnostic performance of procalcitonin (PCT) compared with C-reactive protein (CRP) and white blood cell (WBC) count in the early detection of neonatal sepsis in Erbil, Iraq.

Methods: A hospital-based case-control study was conducted in the Raparin Teaching Hospital for Children between April 2023 and October 2024. A total of 80 neonates (40 with culture-confirmed sepsis and 40 controls) were enrolled. Laboratory investigations included complete blood counts, CRP, and PCT measurement. Diagnostic validity indices were calculated, and receiver operating characteristic (ROC) analysis was performed.

Results: PCT levels were significantly higher in septic neonates (773.00 ± 223.01 pg/mL) compared to controls (256.50 ± 137.70 pg/mL, $p<0.001$). CRP positivity was noted in 36 neonates with sepsis (90.0%) versus 9 controls (22.5%, $p=0.002$). Mean WBC count was elevated in cases (16.81 ± 2.29 $\times 10^9$/L) compared to controls (15.15 ± 0.82 $\times 10^9$/L, $p<0.001$). CRP demonstrated sensitivity of 90.0% (36/40) and specificity of 77.5% (31/40), while PCT displayed balanced accuracy with sensitivity of 87.5% (35/40) and specificity of 87.5% (35/40). ROC analysis showed the highest discriminatory power for PCT (AUC=0.975, 95% CI: 0.949–0.990), followed by CRP (AUC=0.838) and WBC count (AUC=0.735).

Conclusion: PCT outperformed traditional biomarkers in early diagnosis of neonatal sepsis, providing more balanced diagnostic accuracy. Combining PCT with CRP and clinical assessment may optimize prompt identification and management of sepsis in neonates.

Keywords: Biomarkers, Diagnostic accuracy, Procalcitonin, ROC curve

1. INTRODUCTION

Neonatal sepsis remains one of the most significant causes of morbidity and mortality among neonates worldwide, particularly in developing countries with limited healthcare access (1). Approximately 1.3 million neonatal sepsis cases are reported each year globally (2), with an estimated incidence of 2,824 cases per 100,000 live births (3). Mortality rates range from 10-29% in low- and middle-income countries, and deaths due to neonatal sepsis occur more frequently in preterm and low-birth-weight neonates (4).

The diagnosis of neonatal sepsis is contingent upon blood culture, which requires 24-48 hours and has a significant false negative rate. This leads to excessive antibiotic use and likely treatment of numerous newborns with clinically suspected bacterial sepsis. Therefore, the test is non-sensitive, non-specific and often, involves a significant time delay (5). Moreover, identification of early clinical signs in neonates is complicated by subtle and nonspecific clinical signs such as apnea, bradycardia, respiratory distress, feeding intolerance, and lethargy.

Identification of early clinical signs in neonates is complicated by subtle and nonspecific clinical signs such as apnea, bradycardia, respiratory distress, feeding intolerance, and lethargy (6). Traditional biomarkers, specifically C-reactive protein (CRP) and white blood cell (WBC) count, have been widely used for diagnosing sepsis; however, their limitations in early detection and specificity has led to a growing research interest for more reliable and usable alternatives. CRP is frequently used due to its low cost and easy-to-use nature; however, its early sensitivity is limited, and it is susceptible to non-infectious inflammatory etiologies (7).

There is increased evidence in the literature that used procalcitonin (PCT) as an early and more promising biomarker as it has been shown to increase earlier than CRP and to be correlated to the severity of bacterial colonization (8, 9). The PCT is a peptide emerged in response to pro-inflammatory stimulants, especially those of bacterial origin. The exact biological function of PCT is still mostly unknown; however, recent experimental work suggests that PCT may be pathogenetic in sepsis (10). PCT has the greatest diagnostic accuracy since its levels increase quickly (within 6–12 hours) after an infectious cause that has systemic effects. Besides being a diagnostic aid in sepsis, PCT is an effective indicator of the progress and severity of the systemic inflammatory response (5).

Recent studies show that PCT has a greater diagnostic accuracy than CRP for detecting neonatal sepsis. The research by Shaukat et al. (2025) showed that PCT had greater diagnostic accuracy than CRP with sensitivity and specificity of 74.3% and 43.4% for PCT versus 56.6% and 19.3% for CRP (11). Likewise, a study by Habibet al. (2021) demonstrated sensitivity and specificity of PCT of 92.0% and 83.3% respectively, with a negative predictive value of 93.8% and area under the ROC curve of 0.927 (9).

The present study addresses the critical need for improved diagnostic accuracy in neonatal sepsis detection within the specific healthcare context of Erbil, Iraq, where regional epidemiological patterns and resource constraints may differ from global settings. The necessity for this research stems from the urgent requirement to reduce diagnostic delays, minimize unnecessary antibiotic exposure, and improve clinical outcomes for newborns at risk of sepsis. This case-control study aimed to evaluate the diagnostic efficacy of PCT for the early identification of newborn sepsis and to compare it with CRP and WBC count.

2. METHODS AND MATERIALS

Study design and setting

The present study was structured as a case-control investigation to evaluate the prognostic value of the biomarkers PCT, CRP, and WBC count in diagnosing sepsis in a neonatal population. The study was undertaken in the Raparin Teaching Hospital for Children in Erbil city, Iraq. Data collection spanned a total period of 18 months, covering the timeframe from April 1, 2023 to October 31, 2024.

Participants

The study population included neonates admitted to the NCU during the study period either with clinical suspicion of sepsis or for non-infective conditions such as neonatal jaundice. A purposive convenient sampling technique was utilized. The final sample comprised 80 neonates, split evenly between case and control groups. The sample size was determined by reviewing results from comparable previously published studies assessing PCT and CRP as biomarkers of neonatal sepsis, where diagnostic validity was assessed with similar group sizes (5). An 80-participant sample was deemed sufficient to ensure statistical reliability and power.

All neonates aged 0-28 days, admitted to the NCU during the data collection period, and whose parent or guardian consented to participate were eligible for inclusion. For the sepsis cohort, clinical features consistent with neonatal sepsis were present, and there was laboratory confirmation of diagnosis via positive blood culture. The control cohort included healthy neonates who required admission with no evidence of sepsis who had self-limited conditions such as jaundice. Neonates were excluded from the study if they had a history of perinatal asphyxia, suspected or confirmed congenital malformations, chromosomal anomalies, or any dysmorphic features that might interfere with clinical or laboratory interpretation. Additionally, neonates who were treated with antibiotics prior to sample collection were excluded from the study to avoid confounding results.

Data Collection

Data collection occurred in a systematic manner at admission by a senior pediatric resident while being supervised by the neonatologist on call. After obtaining informed parental consent, infant demographics as well as information about the maternal background, birth details, and clinical characteristics were recorded using a structured data collection form. Each newborn also underwent a detailed physical examination.

Blood samples were collected aseptically prior to commencing antibiotic therapy. Approximately 2 mL of venous blood was obtained with sterile precautions. One mL was inoculated into blood culture vials containing brain–heart infusion broth (Oxoid, UK) and incubated in a controlled environment at 37 °C for 3–5 days. Growth was sub-cultured onto blood agar and MacConkey agar, and samples subjected to identification procedures, following standard bacteriological methods.

The residual blood samples underwent hematological and biochemical analysis. CBC and differential leukocyte counts were performed utilizing an automated hematology analyzer (Sysmex XN-1000, Sysmex Corporation, Japan). Serum CRP concentrations were assessed via an automated latex agglutination turbidimetric immunoassay (Beckman Coulter AU480, USA). Serum PCT levels were determined using a commercially available immunoluminometric ELISA kit (ELISA M6, USA). PCT values above 0.5 ng/mL (500 pg/mL) were determined to be abnormal based on international laboratory standards. Cerebrospinal fluid (CSF) samples were obtained and sent for cell counts, glucose, protein, and bacterial culture analysis on select neonates as part of the sepsis workup.

Ethical Considerations

The protocol received approval from the research ethics committee of ministry of health. Written informed consent was obtained from parents or guardians prior to undertaking the research in accordance with regulatory and ethical standards. Participation was voluntary and participants were free to withdraw at any time without compromising care. Confidentiality was maintained through coded identifiers and data access was restricted. The study adhered to the Declaration of Helsinki (2013) and applicable local regulations.

Statistical Analysis

All gathered data were inputted and encoded into the Statistical Package for the Social Sciences (SPSS) software version 27.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were reported as frequencies and percentages for categorical variables, and as means with standard deviations for continuous variables. Group comparisons were evaluated using the Chi-square test or Fisher's exact test for categorical data, and the independent sample t-test for continuous data. Diagnostic validity indices, such as sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for CRP and PCT, were computed in relation to the reference standard of blood culture. Receiver operating characteristic (ROC) curve analysis were performed to assess the discriminatory capabilities of various biomarkers. The area under the curve (AUC) with 95% confidence intervals (CIs) was documented, and p-values below 0.05 were deemed statistically significant.

3. RESULTS

This study compared 40 neonates with sepsis to 40 healthy controls. In terms of sex distribution, males predominated in both groups, 31 (77.5%) in the sepsis group and 32 (80.0%) in the control group (p=0.075). The mean age was significantly higher among septic neonates (13.50 ± 7.39 days) than controls (4.55 ± 2.42 days, p <0.001). Cesarean delivery was more frequent in controls (31, 77.5%) compared to septic neonates (14, 35.0%), while vaginal delivery was more frequent in sepsis cases (26, 65.0%; p <0.001). Clinical features were strikingly more common among neonates with sepsis: lethargy (37, 92.5%), irritability (19, 47.5%), poor feeding (40, 100.0%), fever/cold manifestations (40, 100.0%), convulsions (12, 30.0%), bulging fontanelle (20, 50.0%), poor reflexes (18, 45.0%), dyspnea (29, 72.5%), and cyanosis (12, 30.0%), all highly significant compared to the control group (all p<0.001). In contrast, pallor (19, 47.5% vs. 16, 60.0%, p=0.499), jaundice (4, 10.0% vs. 8, 20.0%, p=0.210), and skin rash (5, 7.5% vs. 1, 2.5%, p=0.090) did not show significant differences. Mortality occurred in 5 (12.5%) of septic neonates, while none occurred among controls (p=0.021).

Table 1. Demographic attributes and clinical characteristics of the examined cohorts.

Variables		Sepsis, N=40 N(percent)	Control, N=40 N(percent)	P-value
Sex	Male	31 (77.5%)	32 (80.0%)	0.075
	Female	9 (22.5%)	8 (20.0%)	
Age	Mean ± SD	13.50 ± 7.39	4.55 ± 2.42	<0.001
Delivery type	CS	14 (35.0%)	31 (77.5%)	<0.001
	NVD	26 (65.0%)	9 (22.5%	
Lethargy	No	3 (7.5%)	39 (77.5%)	<0.001
	Yes	37 (92.5%)	9 (22.5%)	
Irritability	No	21 (52.5%)	40 (100.0%)	<0.001

	Yes	19 (47.5%)	0 (0.0%)	
Poor feeding	No	0 (0.0%)	37 (92.5%)	<0.001
	Yes	40 (100.0%)	3 (7.5%)	
Fever cold	No	0 (0.0%)	35 (87.5%)	<0.001
	Yes	40 (100.0%)	5 (12.5%)	
Convulsion	No	28 (70.0%)	40 (100.0%)	<0.001
	Yes	12 (30.0%)	0 (0.0%)	
Bulging fontanelle	No	20 (50.0%)	40 (100.0%)	<0.001
	Yes	20 (50.0%)	0 (0.0%)	
Poor reflexes	No	22 (55.0%)	40 (100.0%)	<0.001
	Yes	18 (45.0%)	0 (0.0%)	
Pallor	No	21 (52.5%)	24 (60.0%)	0.499*
	Yes	19 (47.5%)	16 (60.0%)	
Jaundice	No	36 (90.0%)	32 (80.0%)	0.210
	Yes	4 (10.0%)	8 (20.0%)	
Dyspnea	No	11 (27.5%)	39 (97.5%)	<0.001
	Yes	29 (72.5%)	1 (2.5%)	
Cyanosis	No	28 (70.0%)	40 (100.0%)	<0.001
	Yes	12 (30.0%)	0 (0.0%)	
Skin rash	No	35 (87.5%)	39 (97.5%)	0.090
	Yes	5 (7.5%)	1 (2.5%)	
Death	No	35 (87.5%)	40 (100.0%)	0.021
	Yes	5 (12.5%)	0 (0.0%)	

Laboratory investigations showed significant differences between neonates with sepsis and controls. PCT was markedly elevated in the sepsis group (773.00 ± 223.01 pg/mL) compared to controls (256.50 ± 137.70 pg/mL, p<0.001). The mean WBC count was significantly higher among septic neonates (16.81 ± 2.29 $\times 10^9$/L) relative to controls (15.15 ± 0.82 $\times 10^9$/L, p<0.001). Interestingly, neutrophil percentages were lower in the sepsis group (55.33 ± 6.03%) compared to controls (60.50 ± 2.90%, p<0.001), whereas lymphocyte levels showed no significant difference (29.58 ± 4.68% vs. 30.30 ± 2.07%, p=0.133). C-reactive protein (CRP) positivity was strongly associated with sepsis, being detected in 36 (90.0%) septic neonates versus only 9 (22.5%) controls (p=0.002).

Table 2. Hematology and Blood Test Results of Neonates with Sepsis Compared to Controls.

Variables	Sepsis, N=40 Mean ± SD	Control, N=40 Mean ± SD	P-value
PCT (pg/ml)	773.00 ± 223.01	256.50 ± 137.70	<0.001
WBC (count$\times 10^9$/L)	16.81 ± 2.29	15.15 ± 0.82	<0.001
Neutrophils (percent)	55.33 ± 6.03	60.50 ± 2.90	<0.001
Lymphocytes (percent)	29.58 ± 4.68	30.30 ± 2.07	0.133

CRP Positive, N(percent)	36 (90.0%)	9 (22.5%)	0.002

The analysis of diagnostic performance revealed that both CRP and PCT are strong predictors of neonatal sepsis, though PCT demonstrated slightly superior overall validity. CRP showed a sensitivity of 90.0% and specificity of 77.5%, with a PPV of 80.0% and a NPV of 88.6%. PCT, using a threshold of 500 pg/mL (equivalent to 0.5 ng/mL), demonstrated balanced and robust diagnostic accuracy with sensitivity of 87.5% and specificity of 87.5%, both PPV and NPV also at 87.5%.

Table 3. Diagnostic Validity of CRP and PCT in Detecting Neonatal Sepsis.

Validity test	CRP	PCT
Sensitivity	90.0%	87.5%
Specificity	77.5%	87.5%
PPV	80.0%	87.5%
NPV	88.6%	87.5%

The ROC analysis demonstrated that PCT had the highest diagnostic accuracy for neonatal sepsis, with an AUC of 0.975 (SE 0.013, 95% CI: 0.949–0.990, p<0.001), indicating excellent discriminatory power. CRP also showed strong diagnostic performance with an AUC of 0.838 (SE 0.048, 95% CI: 0.744–0.931, p<0.001). WBC count had moderate accuracy with an AUC of 0.735 (SE 0.061, 95% CI: 0.615–0.855, p<0.001). In contrast, neutrophil percentage performed poorly, showing an inverse relationship (AUC 0.239, SE 0.055, 95% CI: 0.131–0.346, p<0.001), suggesting that lower neutrophil percentages were associated with sepsis. Lymphocyte percentage was not a significant discriminator, with an AUC of 0.403 (SE 0.067, 95% CI: 0.271–0.535, p=0.135) (Table 4 and Figure 1).

Table 4. ROC Analysis for Diagnostic Markers in Neonatal Sepsis.

Area Under the Curve					
Variables	Area	Std. Error	p value	95% Confidence Interval	
				Lower Bound	Upper Bound
PCT	0.975	0.013	<0.001	0.949	0.990
CRP	0.838	0.048	<0.001	0.744	0.931
WBC count	0.735	0.061	<0.001	0.615	0.855
Neutrophils (percent)	0.239	0.055	<0.001	0.131	0.346
Lymphocytes (percent)	0.403	0.067	0.135	0.271	0.535

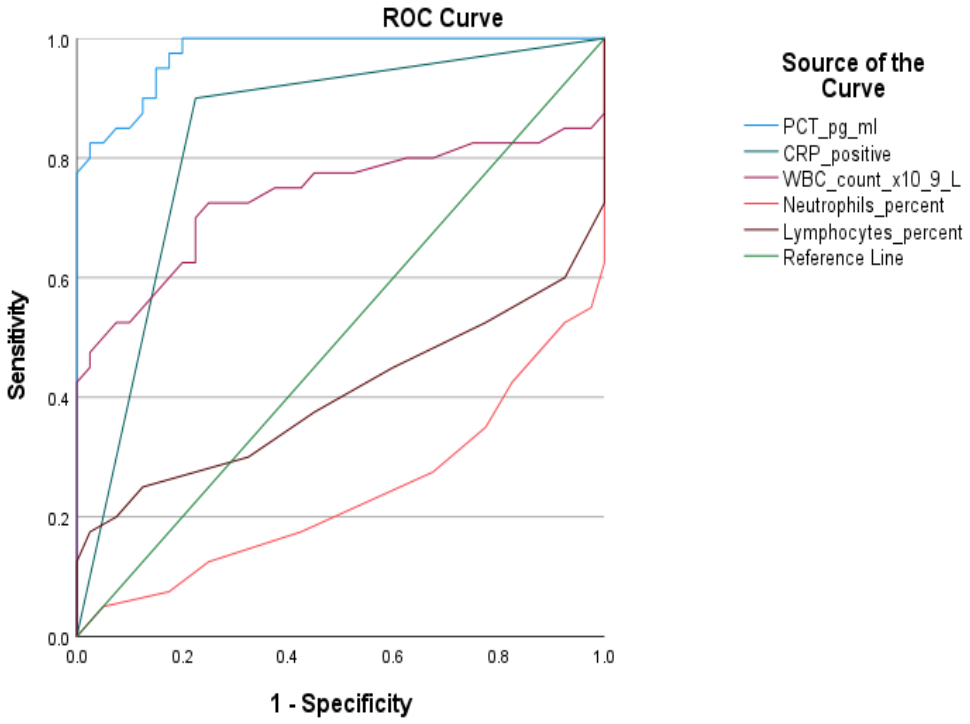

Figure 1. ROC curve and AUC for the laboratory parameters of the sepsis group.

4. DISCUSSION

Neonatal sepsis continues to represent one of the paramount challenges in neonatal intensive care, with global rates ranging from 1-10 per 1,000 live births, and much higher rates in preterm neonates (12). Diagnosis relies heavily on clinical presentation and laboratory biomarkers, as blood culture, traditionally regarded as the gold standard, has low sensitivity, delayed turnaround time, with low positive yields (5). This study examined the diagnostic capability of PCT compared to CRP and WBC for the early diagnosis of neonatal sepsis. The study found that infants with sepsis had significantly higher values of PCT, had notable distinctions in clinical presentations, and that PCT demonstrated superior diagnostic accuracy compared to traditional biomarkers.

The current study revealed that PCT levels were markedly elevated in septic neonates compared to controls, with an AUC of 0.975, demonstrating excellent discriminatory power. These findings are consistent with recent meta-analyses that have established PCT as one of the most reliable biomarkers for neonatal sepsis diagnosis. A comprehensive meta-analysis by Rati et al. involving 1,245 newborns found PCT to have the highest pooled sensitivity (0.85) and specificity (0.82) among biomarkers evaluated for neonatal sepsis diagnosis (13). Similarly, a study by Ahmad et al. (2024), demonstrated PCT's superior diagnostic accuracy with sensitivity of 87.76% and specificity of 90.48%, which closely aligns with the current study's findings of 87.5% sensitivity and specificity (14). The consistent performance across multiple studies reinforces PCT's value as a primary diagnostic tool in neonatal sepsis evaluation.

In this study, the diagnostic performance of our CRP metric exhibited commendable sensitivity, at 90.0%. However, specificity was lower compared to PCT, at 77.5%. These findings have been mirrored in several studies. A recent study from Kenya, (2025), revealed CRP performance metrics similar to those by this study (15), and a systematic review done by Anugu and Khan (2021) determined that CRP, despite extensive and widespread utilization, possesses variable diagnostic sensitivity and specificity related to neonatal populations (16). The specificity of CRP will be lower because it can be non-specifically elevated in a number of inflammatory states outside of bacterial infection, including viral infection and non-infectious inflammatory processes. This can be particularly problematic in neonates, since there are so many potential problems leading to inflammatory states that may mimic sepsis.

Interestingly, the current study found that WBC count had moderate diagnostic accuracy (AUC 0.735), while neutrophil percentage showed an inverse relationship with sepsis (AUC 0.239). This finding is supported by recent research emphasizing the limitations of traditional hematological parameters in neonatal sepsis diagnosis. A 2025 meta-analysis by Hyde et al. examining complete blood count parameters in neonatal sepsis found that functional parameters like immature-to-total neutrophil ratio (ITR) showed better diagnostic utility than absolute WBC counts, with ITR demonstrating 66.3% sensitivity and 85.4% specificity (17). The paradoxical finding of lower neutrophil percentages in septic neonates can be

explained by the phenomenon of neutrophil consumption and sequestration that occurs during severe bacterial infections, particularly in preterm neonates whose immune systems are immature (18, 19).

Recent progress in neonatal sepsis biomarker research has identified several potential emerging candidates to complement traditional biomarkers. For example, a 2024 study from India evaluated interleukin-27 (IL-27) as a novel biomarker and reported promising results, with a sensitivity of 78.05% and specificity of 61.54%. Despite these results, PCT remains more accurate than other emerging biomarkers in the vast majority of comparative studies (20). Combining biomarkers has also garnered attention as a unique approach to diagnosing neonatal sepsis. Ruan et al. (2018), demonstrated that when using a combination of PCT and CRP, the sensitivity was 0.91, and the specificity was between 0.84-0.95, when compared to other individual markers (21). Perhaps the future of neonatal sepsis diagnosis will rely on utilizing a combination of biomarkers, instead of recommending one biomarker as an alternative to others.

These results have an important clinical relevance, especially in the context of antibiotic stewardship in the neonate population. Current practice guidelines highlight the value of biomarker-based antibiotic decisions to help mitigate unnecessary antibiotic exposure. PCT's superior diagnostic accuracy, in addition to his ability to tailor antibiotic treatment duration, positions it as an invaluable tool in the NICU setting. Contrary to common assumption about antibiotics and steroids, a research conducted in 2023 by Sturrock et al., indicated that it was safe to consider a PCT-guided antibiotic stewardship protocol; thereby decreasing the overall treatment duration without complications. Despite the clinical relevance, challenges exist when implementing a management protocol, particularly in settings with limited resources for blood testing like PCT (22, 23).

5. CONCLUSIONS

In conclusion, this study establishes that PCT is a more robust diagnostic biomarker of neonatal sepsis than historical biomarkers, such as CRP and WBC count. The well-balanced diagnostic performance of PCT makes it a valuable tool for initiation of sepsis evaluation and decision-making around early antibiotic therapy. However, the best approach is likely to be a combination of PCT with other biomarkers and clinical assessment to enhance accuracy as a diagnostic tool. As the field advances, the incorporation of new biomarkers, molecular diagnostics, and artificial Intelligence may continue to enhance the diagnosis and management of neonatal sepsis.

6. ACKNOWLEDGMENTS:

We express our sincere gratitude to everybody who devoted their time, effort, and expertise to assure the success of this study.

Conflict of interest: All authors declare the absence of any conflict of interest.

Data availability: The study data may be acquired from the relevant author upon a reasonable request.

Authors' contributions: Each author made an equal contribution to this research work.

Funding: Not applicable

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