



## Procalcitonin and hs-CRP in Neonatal Sepsis: Diagnostic Accuracy and Clinical Implications

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### ABSTRACT:

Neonatal sepsis continues to cause substantial mortality and morbidity among newborns worldwide. Early and accurate diagnosis of sepsis is essential to improve treatment outcomes. This study examined 101 neonates who showed signs of sepsis while receiving care in the Neonatal Intensive Care Unit (NICU). Procalcitonin was measured using a fluorescence immunoassay, and high-sensitivity C-reactive protein (hs-CRP) was assessed using an immunoturbidimetric method. Statistical analysis was conducted using SPSS version 22. Procalcitonin (PCT) levels increased rapidly and significantly in neonates with suspected sepsis compared to high-sensitivity C-reactive protein high-sensitivity C-reactive protein levels. The diagnostic potential of Procalcitonin was supported by its superior sensitivity and specificity. Procalcitonin demonstrated better diagnostic performance than high-sensitivity C-reactive protein in the detection of neonatal sepsis. Incorporating procalcitonin and high-sensitivity C-reactive protein testing into clinical evaluation procedures may assist healthcare providers in the early identification and treatment of sepsis in neonates.

### Introduction

A systemic inflammatory reaction to infection in newborns up to 28 days of age is known as neonatal sepsis.<sup>1</sup> Nevertheless, it continues to rank among the leading causes of newborn morbidity and mortality around the world, especially in states with low and moderate incomes.<sup>2</sup> Approximately 1 to 3 million instances of neonatal sepsis are recorded each year, with fatality rates varying from 11% to 50% depending on the quality of healthcare infrastructure.<sup>3</sup> Many survivors experience significant morbidities like cerebral palsy, learning disabilities, and chronic lung disease.<sup>4</sup> The economic impact of neonatal sepsis becomes severe as it forces patients to spend longer hospital stays and need intensive care admission.<sup>5</sup> The advances in neonatal intensive care and survival statistics have not led to significant changes in neonatal sepsis rates during the last decade.<sup>6</sup> The ongoing threat demands solutions through prevention measures and swift detection methods, along with management strategies that prove the most effective. The worldwide improvement of newborn outcomes requires

complete comprehension of clinical features, together with causative organisms and diagnostic limitations.<sup>7</sup>

The division of neonatal sepsis based on symptom onset timing results in early-onset sepsis (EOS) and late-onset sepsis (LOS).<sup>8</sup> The onset of this illness occurs between delivery and the 7 postpartum day as of pathogen transmission from mother to baby during birth.<sup>9</sup> The main risk factors associated with early-onset sepsis include prematurity alongside low birth weight, and both protracted membrane rupture and maternal chorioamnionitis.<sup>10</sup> The infection develops 7 days after birth and usually affects infants who need extensive NICU stays following invasive medical procedures.<sup>11</sup> The medical condition Late-Onset Sepsis (LOS) presents a severe problem primarily affecting premature newborns along with infants who have existing medical conditions.<sup>12</sup> The differentiation between EOS and LOS matters when deciding about antibiotic use as a preventive measure. Nevertheless, group B streptococcus continues to be the most common pathogen in EOS, while coagulase-negative staphylococci are common in LOS.<sup>13</sup> Therefore, it is necessary to know the epidemiology and risk factors of



both forms of sepsis in detail to optimize neonatal care.<sup>14</sup> Pathogenesis of neonatal sepsis is via transplacental routes, ascending infections through the birth canal, or horizontal transmission in the hospital environment. Infectious process organisms in EOS are particularly *Group B Streptococcus*, *Escherichia coli*, *Listeria monocytogenes*, and *Haemophilus influenzae*. Usually, vertical transmission occurs during delivery when neonates are exposed to infected amniotic fluid or maternal genital tract flora.<sup>15</sup> LOS is characterized by hospital-acquired infections, and common isolates include coagulase-negative *staphylococci*, *Klebsiella spp.*, *Pseudomonas aeruginosa*, and *Candida spp.*

The immune systems of premature neonates are underdeveloped, and neonates are often exposed to invasive devices such as catheters and ventilators, premature neonates are especially susceptible to LOS pathogens. Once bacteria enter the bloodstream, this massive systemic inflammatory activation is characterized by cytokine release, endothelial dysfunction, and even multiorgan failure if untreated.<sup>16</sup> Knowledge of the microbial aetiology and pathogenesis of neonatal sepsis is necessary for the development of targeted preventive or therapeutic strategies that will decrease the burden of neonatal sepsis. Though neonatal care has advanced, diagnosis of sepsis before its onset is still difficult.<sup>17</sup> The gold standard for sepsis diagnosis, i.e., blood culture, is associated with low sensitivity and prolonged turnaround times, thereby delaying definitive therapy.<sup>18</sup> This is compounded by prior antibiotic exposure and contamination that can affect blood culture results to be false negative.<sup>19</sup> As empirical antibiotic therapy is often necessary, the use of antibiotics also carries a risk of developing antimicrobial resistance, as well as other adverse drug effects.<sup>20</sup> The clinical indicators of newborn sepsis include lethargy, together with respiratory distress and poor feeding, although these signs are not specific enough for early detection. The diagnostic combination of PCT and hs-CRP stands as an additional tool to laboratory results and physician evaluation when seeking fast and precise sepsis diagnoses. Better survival of suspected septic newborns requires dependable, standardized diagnostic methods for early management.

This study aims to evaluate Procalcitonin (PCT) and high-sensitivity C-reactive protein (hs-CRP) for diagnosing neonatal sepsis. The study seeks to determine whether these biomarkers can predict sepsis early and how they

relate to clinical parameters, including gestational age, preterm status, and mode of delivery. The objectives also fit with the overall goal of determining how these factors affect biomarker expression and the diagnosis of sepsis in a neonatal care environment.

## Materials and Methods

### Study Design

The sample neonates received care in KLEs Dr Prabhakar Kore Hospital and Medical Research Centre NICU in Belagavi, Karnataka, with ages between 0 and 28 days. All newborns with suspected sepsis signs received blood cultures and biomarker analysis through blood tests before starting antibiotic treatment. The hospital-based cross-sectional study investigated biomarkers for newborn sepsis diagnosis. The evaluation of NICU-admitted neonates suspected of sepsis uses this study design to simultaneously study all subjects while determining blood culture results in relation to hs-CRP and procalcitonin (PCT).

### Study Period

The study period spanned from June 2022 until June 2023. The study period stretched long enough to recruit participants and perform sample collection, laboratory testing, and statistical analysis needed to achieve the study goals.

### Sample Size

A statistical procedure with a 95% confidence interval, along with 20% allowable error and 5% attribution, calculated the necessary sample size. The rounded-up 101 neonates in the sample met the analytical requirements of this study.

### Study Population

The signs and symptoms of newborn sepsis were evaluated among 101 NICU patients at KLE's Dr Prabhakar Kore Hospital. The study included participants who displayed clinical indications of newborn sepsis while being hospitalized in the NICU and being under 28 days old. The initial assessment of patients used clinical signs before testing their blood for cultures or biomarkers.



### Inclusion Criteria

The study included participants who were parents or guardians and also included infants who displayed signs of sepsis. The study included all newborns who displayed sepsis symptoms during the study duration.

### Exclusion Criteria

The study excluded newborns with congenital defects, together with those who received antibiotics before hospital admission. The set criteria helped avoid confusing results during biomarker assessment and sepsis diagnosis procedures.

### Specimen Collection of PCT

Healthcare staff collected aseptic blood samples through bedside syringe procedures. A 1 mL blood sample was moved to a plain vacutainer for hs-CRP biomarker examination and PCT testing, while 2 mL went into a BACTEC vial for culture analysis. All samples followed the established procedure for processing.

### Detection and Measurement Procedure

The Cobas analyzer performed PCT level measurements through its Electrochemiluminescence immunoassay (ECLIA) testing method. The Siemens autoanalyzer performed hs-CRP measurements through the particle-enhanced turbidimetric immunoassay method while making optical density readings at 340 nm. The test utilized a sandwich immunodetection method for its detection mechanism.

### Statistical Analysis

Data entry took place in Microsoft Excel, while SPSS Version 22 handled the analysis procedures. The statistical analysis determined PCT and hsCRP sensitivity together with specificity, positive predictive value (PPV), and negative predictive value (NPV) values at a p-value less than 0.05.

### Ethical Consideration

The Institutional Ethics Committee authorized ethical clearance through Jawaharlal Nehru Medical College in Belagavi. The hospital authorities provided approval for the study, which followed all ethical research standards. All participating neonates received written consent from their parents or legal guardians for study participation. A document approved by the study described the study

methods together with its goals and potential risks before the study obtained consent.

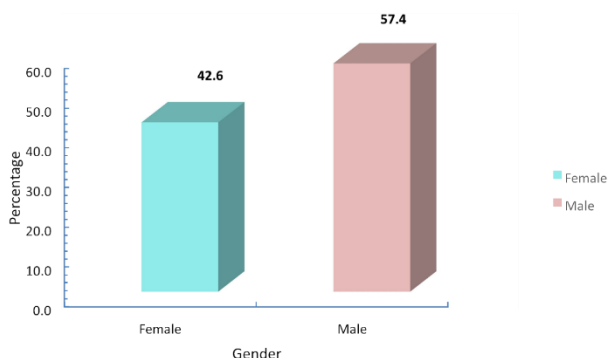
### Results

#### Demographic and Clinical Characteristics of Neonates with Sepsis

The study included 101 neonates among the 101 neonates 58 males made up 57.4% of the total, while females comprised 42.6%, at 43 individuals. The data showed that preterm birth occurred in 72 neonates (71.29%) while term birth happened in 29 neonates (28.71%), as shown in Table 1. The data showed that LSCS delivery occurred in 67 neonates (66.34%) while normal vaginal delivery resulted in 34 cases (33.66%). While 64 newborns (63.37%) had low birth weights, 13 neonates (12%) had normal birth weights. 2 (1.98%) and 22 (21.78%) were born with exceptionally low birth weights. The bacterial culture analysis showed *Klebsiella pneumoniae* at 64.36%, followed by *Streptococcus haemolyticus* at 25.74%, and other organisms.

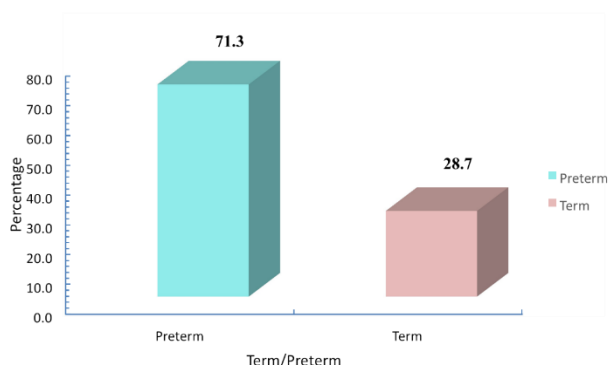
**Table 1: Frequency Distribution of Variables**

Variable	n (%)
<b>Gender</b>	
Female	43 (42.6%)
Male	58 (57.4%)
<b>Gestational Age</b>	
Preterm	72 (71.29%)
Term	29 (28.71%)
<b>Mode of Delivery</b>	
LSCS	67 (66.34%)
NVD	34 (33.66%)
<b>Birth Weight</b>	
NBW	13 (12.87%)
LBW	64 (63.37%)
VLBW	22 (21.78%)
ELBW	2 (1.98%)
<b>Culture Results</b>	
<i>Klebsiella pneumoniae</i>	65 (64.36%)
<i>S. haemolyticus</i>	26 (25.74%)
<i>A. baumannii</i>	5 (4.95%)
<i>S. pneumoniae</i>	5 (4.95%)



**Figure 1: Gender-wise distribution of newborns in sepsis (%)**

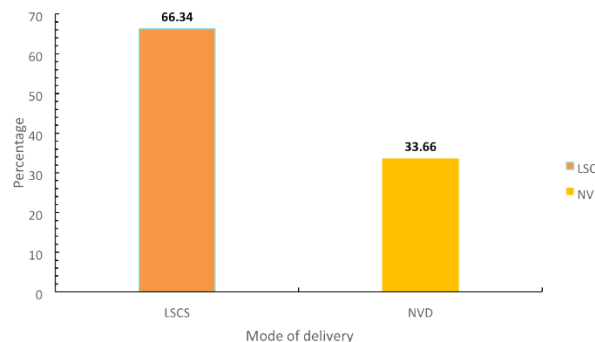
The findings demonstrated that sepsis affected male neonates more often than female neonates in the study population. The statistics revealed that out of 101 sepsis cases, 57.4% involved male infants while 42.6% involved female infants, according to Figure 1. The gender-wise distribution showed that male newborns faced greater sepsis risks than their female counterparts. The graphical analysis verified the increased sepsis occurrence among males, which supports previous studies demonstrating biological risks for males. The study results demonstrated that gender served as a significant factor in determining the incidence of neonatal sepsis among the investigated population.



**Figure 2: Distribution of newborns in sepsis by gestational age (%)**

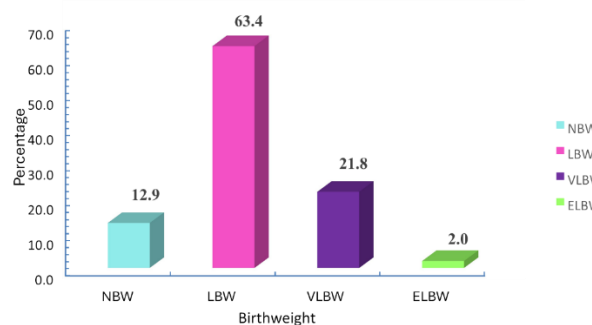
Sepsis proved to be more prevalent among preterm neonates than among term neonates, according to Figure 2. The 101 newborns included 71.29% preterm cases and 28.71% term births. Prematurity proved to be a major risk factor for developing neonatal sepsis based on the observed data patterns. Underdeveloped immune systems of preterm infants increased their vulnerability to

infections, according to the data. The visual presentation demonstrated how gestational age acted as the main determinant for sepsis outcomes in NICU neonates.



**Figure 3: Distribution by mode of delivery in neonatal sepsis (%)**

The study showed that Lower Segment Caesarean Section (LSCS) accounted for most sepsis cases among neonates. A total of 66.34% of newborns underwent LSCS delivery, whereas NVD resulted in 33.66% of births, according to Figure 3. The analysis showed that surgical delivery methods might elevate the risk of infections for newborns as hospital stays are longer, and they encounter nosocomial pathogens. The graphical presentation showed that the delivery method established a direct connection between sepsis development in newborns.

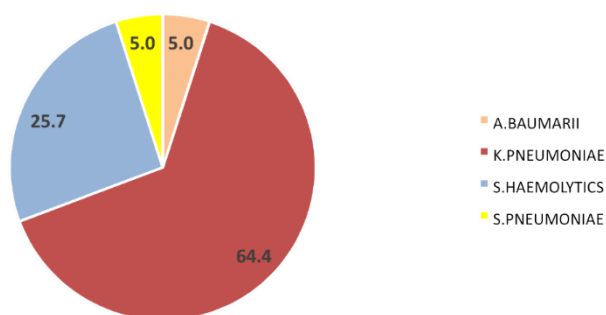


**Figure 4: Distribution of neonates in sepsis by birthweight (%)**

Most neonates with sepsis weighed less than average at birth according to the birth weight analysis. A total of 63.37% of newborns had LBW, and VLBW affected 21.78% of the infants, while ELBW was present in 1.98% of the subjects, as shown in Figure 4. The total number of



neonates who received a Normal Birth Weight (NBW) diagnosis amounted to 12.87%. The study data through the figure demonstrated that sepsis risk increased significantly with reduced birth weight, thus confirming the relationship between fetal growth problems and newborn infection chances in this population.



**Figure 5: Distribution of culture of bacteria in newborn sepsis (%)**

*Klebsiella pneumoniae* emerged as the main pathogen in sepsis cases since it was identified in 64.36% of tested patients. *Staphylococcus haemolyticus* was detected in 25.74% of cases, while *Streptococcus pneumoniae* was present in 4.95% of samples. *Klebsiella* species along with other Gram-negative pathogens proved to be the most dangerous bacteria affecting neonates in the NICU based on the data presented in Figure 5. The microbial distribution revealed by culture results showed which bacteria primarily caused sepsis so healthcare providers must implement specific infection control strategies.

#### Descriptive Statistics of Neonatal, Maternal Parameters along with PCT and hs-CRP

The study's maternal participants ranged in age from 18 to 38, with a median age of 25. According to Table 2, neonates' birth weights ranged from 1.0 kg to 3.4 kg, with a median of 2.3 kg. At 1 minute, neonates' median APGAR scores were 6, and at 5 minutes, they were eight. The study's PCT measurements revealed a median result of 1 ng/mL and a value range of 0.00 to 3.90 ng/mL. The interquartile range for the high-sensitivity C-reactive protein (hs-CRP) measurement was 54 mg/L, the median was 78 mg/L, and the measurement ranged from 11.00 to 168.00 mg/L.

**Table 2: Descriptive Statistics of Maternal and Neonatal Parameters with PCT and hs-CRP Levels**

Parameter	Media n	IQ R	Minimu m	Maximu m
Mother's Age	25.00	5	18.00	38.00
Birth Weight (kg)	2.3	1	1.00	3.40
1-min APGAR	6.0	2	3.00	8.00
5-min APGAR	8.0	2	2.00	9.00
Procalcitonin (PCT)	1.0	1	0.00	3.90
hs-CRP (mg/dL)	78.0	54	11.00	168.00

#### Gender-wise Distribution by Mode of Delivery

The data in Table 3 shows that 32 female infants (47.76%) and 35 male infants (52.24%) received delivery through Lower Segment Caesarean Section (LSCS) among the total 67 newborns. The normal vaginal delivery (NVD) mode consisted of 11 females (32.35%) while 23 males (67.64%) made up the total of 34 neonates.

**Table 3: Gender-wise distribution by mode of delivery in neonatal sepsis**

Delivery Mode	Female (n%)	Male (n%)	Total (n)
LSCS	32 (47.76%)	35 (52.24%)	67
NVD	11 (32.35%)	23 (67.64%)	34

#### Discussion

A cross-sectional study examined the diagnostic value of Procalcitonin (PCT) and high-sensitivity C-reactive protein (hs-CRP) for detecting neonatal sepsis. A substantial number of the 101 enrolled neonates displayed elevated PCT and hs-CRP levels, which pointed toward systemic inflammation related to sepsis. The data in Table 1 showed that clinically suspected cases had elevated PCT levels above 2 ng/mL in 67% of the cases, thus demonstrating PCT's early detection capability in infection. The hs-CRP levels of 61% of the neonates exceeded the threshold of >6 mg/L according to Table 2. The analysis in Table 3 demonstrated *Klebsiella*



*pneumoniae* and *Escherichia coli* as the primary organisms isolated from blood cultures, and these organisms were present in 32% of cases. The visual data presented in Figures 1–5 demonstrated that PCT and hs-CRP levels increased with PCT and hs-CRP levels increased with clinical suspicion/severity of sepsis, not with culture positivity.

The study showed PCT provided better sensitivity than hs-CRP for prompt diagnosis. Early detection of infection appears possible through PCT measurements since the biomarker becomes elevated before clinical deterioration occurs. The data in Figure 1 showed PCT values reached their maximum point before hs-CRP values started to increase, as shown in Figure 2. PCT and hs-CRP levels both increased in neonates with clinical signs of sepsis, indicating their potential as early biomarkers for infection, according to Figure 3. The data presented in Figure 4 showed that early-onset sepsis patients displayed higher PCT values than those with late-onset sepsis, which supports the theory that bacterial invasion happens more rapidly in EOS cases. The data in Figure 5 demonstrated a robust positive relationship between PCT and hs-CRP measurement results. The combined use of PCT with hs-CRP provides enhanced diagnostic accuracy through better sensitivity and reduced false negative results, which proves essential for diagnosing sepsis in nonspecific clinical neonatal cases.

The study data support previous conclusions that PCT functions better than other markers for detecting early neonatal sepsis. The conducted documented PCT elevation starting from 2–4 hours after infection initiation, which the study cohort displayed similarly.<sup>21</sup> A cross-sectional study established PCT as a more accurate diagnostic tool than CRP by showing an 80% diagnostic capacity, which supports the study findings.<sup>22</sup> The study highlighted how dynamic hs-CRP interpretation adds value as a supplementary test rather than an independent marker that matches the dual-marker method.<sup>23</sup> The culture positivity rate of 32% in this investigation exceeded the results reported, which obtained a 25% positivity in neonatal patients. The study procedures, alongside patient demographics and antibiotic treatment duration, probably led to this measurement discrepancy.<sup>24</sup> Biomarker testing has gained increasing support for use in early neonatal care pathways according to recent clinical literature.<sup>25</sup>

Future studies need to conduct extended time frame research using larger patient populations to establish the

predictive capabilities of PCT and hs-CRP. Neonatal patient care will undergo a transformative change through the development of quick bedside testing methods that provide instantaneous results at the point of care. Both PCT and hs-CRP monitoring systems, when incorporated into antimicrobial stewardship programs, enable better antibiotic usage that decreases microbial resistance development. The study must conduct comparative analyses to determine whether biomarker-based antibiotic therapy guidance costs less than starting antibiotics based on standard clinical protocols. The neonatal biomarkers must be developed according to regional specifications since differing healthcare methods and microbial variations are present between different geographic regions.

This study had several advantages, and it faced various limitations. The study conducted at a single tertiary care centre prevents the findings from applying to wider populations. The small study participant number of 101 individuals reduces the ability to detect uncommon infections and minor statistical patterns. While blood culture represents the established diagnostic measure, the technique has limitations that might lead to sub-optimal detection of infections. The study lacked serial PCT and hs-CRP measurement protocols, which limited the study from observing changes that occurred over time. Future studies must utilize repetitive biomarker assessments along with involvement from multiple institutions and superior molecular diagnostic methods to enhance the evidence foundation for the early detection of neonatal sepsis.

## Conclusion

The biomarker Procalcitonin (PCT) demonstrated exceptional efficiency as an early sepsis diagnostic tool in newborns since it standardises diagnostic techniques such as blood culture testing. The supportive diagnostic marker high-sensitivity C-reactive protein (hs-CRP) demonstrated usefulness in neonatal sepsis diagnosis but had slightly lower diagnostic sensitivity than PCT. Elevated PCT and hs-CRP levels serve as important diagnostic tools for the early detection of neonatal sepsis, enabling timely clinical intervention. The study demonstrates that neonatal intensive care units require rapid biomarkers as early detection followed by prompt treatment to reduce both patient mortality and morbidity rates. The study indicates that clinical protocols would become more accurate and therapeutic actions could start earlier with the



implementation of PCT and hs-CRP screening. Multi-centre research involving large neonatal populations should be conducted to validate and optimize biomarkers for early sepsis diagnosis across different global neonatal populations.

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