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Evaluation Of Platelet Indices as A Diagnostic Tool for Early Diagnosis of Neonatal Sepsis

Dr Eahsanul Haque[1]*, Prof. (Dr.) Rajesh Kumar Singh[2], Dr. Shruti[3]

[1*]Junior Resident, Department of Pediatrics Institution - Integral Institute of Medical Science & Research, Lucknow,
Email ID: **dreahsanulhaque@gmail.com,**
[2]Professor, Department of Pediatrics Institution - Integral Institute of Medical Science & Research, Lucknow-
Email ID: rrarri@yahoo.co.in
[3]Associate Professor, Department of Pediatrics Institution - Integral Institute of Medical Science & Research, Lucknow,
Email ID : **shrutipaeds@gmail.com**
[*]**Corresponding author:**
Email ID **: dreahsanulhaque@gmail.com**

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ABSTRACT

Neonatal sepsis remains a leading cause of morbidity and mortality, particularly in low- and middle-income countries. Early and accurate diagnosis is essential to initiate prompt treatment. Platelet indices have emerged as accessible and cost-effective markers for the early detection of sepsis in neonates. To evaluate the diagnostic utility of platelet count (PC), mean platelet volume (MPV), and platelet distribution width (PDW) in the early identification of neonatal sepsis. This randomized prospective study was conducted over 18 months (2023–2025) in the Neonatal Division of the Department of Paediatrics and the Department of Haematology at the Integral Institute of Medical Sciences and Research, Lucknow. A total of 200 neonates were enrolled, including 100 with suspected or confirmed sepsis (cases) and 100 age-matched healthy neonates (controls). All participants underwent clinical examination and laboratory investigations, including complete blood count, C-reactive protein (CRP), platelet indices (PC, MPV, PDW), and blood culture. Statistical analysis was performed using SPSS version 20.0. Septic neonates exhibited significantly higher rates of fever (94% vs. 44%), respiratory distress (89% vs. 58%), and feeding intolerance (88% vs. 48%) compared to controls ($p < 0.0001$). Thrombocytopenia (1.5 lakh/µL) was observed in 86% of cases and 24% of controls. Elevated MPV (>10.8 fL) and PDW (>19.1) were significantly associated with sepsis ($p < 0.0001$). Platelet count alone showed 86% sensitivity and 76% specificity. When PC, MPV, and PDW were combined, specificity improved to 83.9%, with an overall diagnostic accuracy of 81.3%. Platelet indices, particularly when assessed together, offer valuable support in the early diagnosis of neonatal sepsis. Their routine availability and affordability make them suitable for integration into standard sepsis screening protocols

Keywords: *Neonatal sepsis, Platelet count, Mean platelet volume, Platelet distribution width, Diagnostic markers*

1. INTRODUCTION

Neonatal sepsis is a major global health concern and one of the leading causes of morbidity and mortality in newborns, accounting for a substantial proportion of hospital admissions in this vulnerable population.[1] Nearly one million neonatal deaths are attributed to sepsis each year, with the majority occurring in low- and middle-income countries (LMICs).[2] According to the Global Burden of Disease (GBD) Study 2016–17, an estimated 1.3 million incident cases of neonatal sepsis are reported annually, resulting in approximately 203,000 sepsis-related deaths worldwide.[3] Given their immature immune systems and heightened susceptibility to rapid clinical deterioration, neonates require early diagnosis and prompt treatment to improve clinical outcomes.

Blood culture remains the gold standard for diagnosing neonatal sepsis.[4] However, its utility is limited by a low positivity rate approximately 20% in early-onset and 30% in late-onset cases.[5] Additionally, culture results typically require 48 hours to 7 days, which may delay critical treatment decisions.[9–11] In India, the case fatality rate for neonatal sepsis ranges from 25% to 65%, underscoring the urgent need for faster and more reliable diagnostic tools.[6] Clinically, neonatal sepsis presents with non-specific signs such as lethargy, poor feeding, respiratory distress, hypotension, and seizures. Laboratory findings may include elevated C-reactive protein (CRP), neutropenia, a left shift in neutrophils, and thrombocytopenia.[7] However, these findings are not specific to sepsis and may also be seen in other neonatal conditions—commonly referred to as "sepsis mimickers"—making accurate diagnosis challenging. This highlights the need for simple, accessible, and cost-effective diagnostic markers, particularly in primary care and resource-limited settings where early detection is critical.[8].

Although sepsis screening panels are widely used, their diagnostic accuracy varies considerably, with inconsistent sensitivity and specificity across different clinical settings.[5] The limitations of current diagnostic approaches particularly the low yield and delayed results of blood cultures highlight the need for effective adjunctive biomarkers. Thrombocytopenia is frequently observed in neonates admitted to neonatal intensive care units (NICUs), and recent studies suggest that platelet indices may undergo significant alterations in the presence of sepsis.

The complete blood count (CBC) is a routinely performed, rapid, and cost-effective investigation in neonatal care. Among its parameters, platelet indices particularly mean platelet volume (MPV)—have garnered increasing attention due to their association with systemic inflammation and infection. MPV, which reflects platelet size and activation, can be easily measured using automated hematology analyzers. Emerging evidence supports the diagnostic and prognostic value of MPV and related platelet parameters in neonatal and perinatal infections [12,13] A recent study by Go H, et al.,[14] demonstrated a significant association between elevated MPV and mortality in preterm neonates born before 32 weeks of gestation.

Therefore, the present study aims to evaluate the diagnostic utility of platelet indices specifically total platelet count (TPC), mean platelet volume (MPV), and the MPV/TPC ratio as potential early biomarkers for neonatal sepsis.

2. MATERIALS AND METHODS

Study Design and Setting

This randomized prospective study was conducted over a period of 18 months (2023–2025) in the Neonatal Division of the Department of Paediatrics and the Department of Haematology at the Integral Institute of Medical Sciences and Research, Integral University, Lucknow. The primary aim was to evaluate and compare platelet indices as diagnostic markers in neonates with suspected sepsis. The study duration included 12 months for data collection and clinical evaluation, followed by 6 months for data analysis and interpretation.

Ethical Consideration

Prior to initiation, ethical clearance was obtained from the Institutional Ethics Committee (Approval No. IEC/IIMSR/2023/53). Written informed consent was obtained from the parents or legal guardians of all participating neonates.

Study Population

The study enrolled neonates either delivered at or referred to the institute who presented with clinical features suggestive of sepsis, based on National Neonatology Forum (NNF) criteria. These features included poor feeding, irritability, lethargy, temperature instability, respiratory distress, neurological signs, and/or circulatory compromise.

A total of 200 neonates were included in the study:

100 neonates with suspected or confirmed sepsis (case group)

100 healthy neonates with no clinical signs of sepsis (control group)

Inclusion Criteria

Term neonates exhibiting clinical suspicion of sepsis as per NNF guidelines.

Exclusion Criteria

Neonates born to mothers with pregnancy-induced hypertension or diabetes mellitus

Neonates with a history of birth asphyxia

Neonates with congenital anomalies

Preterm neonates

Randomization and Grouping

Participants were randomly allocated into case and control groups using computer-generated random numbers to minimize selection bias. Grouping was based on clinical presentation and CDC criteria, as follows:

Culture-confirmed sepsis: Clinical signs of sepsis with a positive blood culture

Clinical sepsis: Clinical signs of sepsis with negative culture results

Controls: No clinical or microbiological evidence of sepsis

Methodology and Data Collection

All neonates underwent detailed clinical examination. Blood samples (1 ml) were collected under aseptic precautions for the following investigations:

Complete Blood Count (CBC)

C-Reactive Protein (CRP)

Total Leukocyte Count (TLC)

Absolute Neutrophil Count (ANC)

Immature-to-Total Neutrophil Ratio (I/T ratio)

Platelet indices: Platelet Count, Mean Platelet Volume (MPV), and Platelet Distribution Width (PDW)

Microbiological Analysis

For neonates in the suspected sepsis group, 1 ml of blood was inoculated into heart infusion broth and incubated at 37°C. Cultures were observed daily for up to 7 days. Growth-positive samples were further processed using standard microbiological techniques for bacterial identification.

Laboratory Evaluation of Platelet Indices

CBC and platelet indices (platelet count, MPV, PDW) were measured for all participants using EDTA blood samples. Analyses were performed using automated hematology analyzers, following standardized laboratory protocols.

Data Variables Collected

Demographic data: Age in days, sex, and gestational age

Clinical features: As per NNF criteria

Laboratory findings: CBC parameters, sepsis screen components, platelet indices

Blood culture results

Statistical Analysis

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 20.0. Diagnostic accuracy was assessed through sensitivity, specificity, PPV, and NPV calculations for each platelet parameter. Receiver Operating Characteristic (ROC) curves were plotted to evaluate diagnostic performance. The Chi-square test was used for categorical variables, and Student's t-test was applied to compare continuous variables. A p-value < 0.05 was considered statistically significant.

3.OBSERVATION & RESULTS

Table 1: Comparison of Demographic and Clinical Variables Between Neonatal Sepsis Cases and Controls.

Parameter	Category	Cases (n)	Controls (n)	p-value
Onset of Illness (Age)	**<72 hours**	42	44	0.774
	>72 hours	58	56	
Sex	**Male**	54	62	0.252
	Female	46	38	
Mode of Delivery	**Caesarean Section**	48	40	0.254
	Normal	52	60	
Birth Weight (Q)	**<2500 gms**	60	42	0.011
	>2500 gms	40	58	
Gestational Age	**Pre-term**	56	44	0.090
	Term	44	**56**	

Table 1 compares key demographic and clinical variables between neonates with sepsis (cases) and without sepsis (controls). Both groups included 100 subjects each. The timing of illness onset (<72 hours vs. >72 hours) showed no significant difference between cases and controls (p = 0.774), indicating that early or late onset was similarly distributed in both groups.

Sex distribution was also comparable, with 54 males and 46 females among cases, and 62 males and 38 females among

controls (p = 0.252). Mode of delivery (caesarean vs. normal) did not show a significant association with neonatal sepsis either (p = 0.254), with 48 caesarean and 52 normal deliveries among cases, compared to 40 and 60 respectively among controls.

Birth weight, however, showed a significant association. A greater number of cases (60%) had low birth weight (<2500 gms) compared to controls (42%) (p = 0.011), indicating that low birth weight may be a risk factor for sepsis. Although preterm births were more common among cases (56%) than controls (44%), this difference was not statistically significant (p = 0.090).

Table 2: Showing distribution of Patients by Gestational age in Case and Control Groups

VARIABLE	CASES	CONTROLS	P-VALUE
Respiratory Distress	89	58	<0.0001
Diarrhoea	76	42	<0.0001
Feed Intolerance	88	48	<0.0001
Fever	94	44	<0.0001
Heart Rate>160	58	32	<0.001

Table 2 presents the distribution of clinical features among neonatal sepsis cases and controls. Respiratory distress was observed in a significantly higher number of cases (89%) compared to controls (58%), with a p-value of <0.0001, indicating a strong association with sepsis. Similarly, diarrhoea was reported in 76% of cases versus 42% of controls (p < 0.0001), and feed intolerance was present in 88% of cases compared to 48% of controls (p < 0.0001). Fever was the most commonly reported symptom among cases (94%) compared to 44% of controls (p < 0.0001), making it a key indicator. Additionally, elevated heart rate (>160 bpm) was seen in 58% of cases versus 32% of controls, with a statistically significant p-value of <0.001. These findings suggest that symptoms such as fever, respiratory distress, feed intolerance, diarrhoea, and tachycardia are significantly more common in neonates with sepsis and can serve as important clinical indicators for early diagnosis.

Table 3: Comparison of Hematological Parameters Between Cases and Control

Parameter	Category	Cases (n)	Controls (n)	p-value
CRP (mg/ml)	<10	12	84	<0.0001
	≥10	88	16	
TLC	<16000	44	64	0.005
	≥16000	56	36	
Platelet Count (lakh/µL)	<1.5	86	24	<0.0001
	≥1.5	14	76	
MPV (fL)	>10.8	69	23	<0.0001
	≤10.8	31	77	
PDW	>19.1	70	18	<0.0001
	≤19.1	30	82	
Mean Platelet Count	-	1.16 ± 0.29	1.60 ± 0.30	<0.0001
Mean MPV	-	11.05 ± 5.9	9.13 ± 1.9	0.002
Mean PDW	-	18.17 ± 2.5	15.59 ± 2.8	<0.0001

The hematological profile showed significant differences between neonatal sepsis cases and controls. Elevated C-reactive protein (CRP ≥10 mg/ml) was observed in 88% of cases compared to only 16% of controls ($p < 0.0001$), indicating strong inflammatory response in sepsis. Total leukocyte count (TLC ≥16000) was significantly higher in cases (56%) than in controls (36%) with a p-value of 0.005. Thrombocytopenia (platelet count <1.5 lakh/µL) was found in 86% of cases versus 24% of controls ($p < 0.0001$). Mean platelet volume (MPV >10.8 fL) and platelet distribution width (PDW >19.1) were both significantly elevated in cases (69% and 70%, respectively) compared to controls (23% and 18%) with p-values <0.0001. Additionally, mean platelet count was lower in cases (1.16 ± 0.29) compared to controls (1.60 ± 0.30), while mean MPV (11.05 ± 5.9) and mean PDW (18.17 ± 2.5) were significantly higher in sepsis cases ($p < 0.0001$ and $p = 0.002$, respectively). These hematological markers serve as important diagnostic indicators of neonatal sepsis.

Table 4: Comparison of Onset and Gestational Age Between Neonatal Sepsis Cases and Controls

Parameter	Category	Cases (n)	Controls (n)	p-value
Onset of Illness	<72 hours (n=86)	28	58	0.062
	>72 hours (n=114)	52	62	
Gestational Age	Pre-term (100)	70	30	<0.0001
	Term (n=100)	40	60	

The comparison of onset of illness and gestational age between neonatal sepsis cases and controls reveals notable patterns. Among neonates with an onset of illness within 72 hours, a higher proportion belonged to the control group (58) compared to the case group (28), though this difference did not reach statistical significance ($p = 0.062$). Conversely, for those with illness onset beyond 72 hours, more were observed in the case group (52) than in the controls (62).

Gestational age showed a significant association with neonatal sepsis. A markedly higher number of preterm neonates were found among the cases (70) as compared to controls (30), with a statistically significant p-value of <0.0001. This indicates that preterm birth is strongly associated with an increased risk of neonatal sepsis. In contrast, among term neonates, more were observed in the control group (60) than in the case group (40).

Table 5: Relationship between Blood culture reports and Platelet count in diagnosis of neonatal sepsis.

BLOOD CULTURE	PC<1.5	PC ≥1.5	P value
Positive(N=100)	86	14	<0.001
Negative(N=100)	24	76	
Total	100	100	

Among the 100 neonates with a positive blood culture, 86 had a platelet count less than 1.5 lakh/µL (PC<1.5), suggesting thrombocytopenia, while only 14 had a normal or higher platelet count (PC≥1.5 lakh/µL). In contrast, among the 100-blood culture-negative neonates, 24 had thrombocytopenia and 76 had normal or elevated platelet counts.

This distribution indicates a strong association between low platelet count and positive blood culture results. A statistical analysis using the chi-square test reveals a P value < 0.001, indicating that the association is highly statistically significant.

Table 6: Showing Performance Variables of Platelet Indices for Diagnosis of Neonatal Sepsis with Blood Culture Being Gold Standard

	SENSITIVITY	SPECIFICITY	PPV	NPV	ACCURACY
PLATLET COUNT	**86**	**76**	**78.18**	**84.44**	**81**

PLATELET COUNT +MPV	**77.6**	**78.5**	**69.2**	**84.9**	**78.1**
PLATELET COUNT +MPV+PDW	**77.2**	**83.9**	**75.9**	**84.9**	**81.3**

The diagnostic performance of various platelet indices for neonatal sepsis was evaluated using blood culture as the gold standard. Individually, platelet count demonstrated a sensitivity of 86% and specificity of 76%, with a positive predictive value (PPV) of 78.18%, negative predictive value (NPV) of 84.44%, and an overall diagnostic accuracy of 81%.

When platelet count was combined with mean platelet volume (MPV), the sensitivity slightly decreased to 77.6% and specificity to 78.5%, while the PPV was 69.2% and NPV improved to 84.9%, resulting in an overall accuracy of 78.1%.

Further addition of platelet distribution width (PDW) to this combination enhanced specificity to 83.9% and maintained a similar NPV (84.9%), with sensitivity at 77.2% and PPV at 75.9%. This combination yielded the highest overall accuracy of 81.3%.

3. DISCUSSION

Neonatal sepsis remains a major contributor to morbidity and mortality in newborns, particularly in low- and middle-income countries. The condition poses a diagnostic challenge due to its nonspecific clinical presentation and the delayed turnaround time of confirmatory blood cultures, which remain the gold standard. In this context, readily accessible hematological markers—especially platelet indices such as thrombocytopenia, mean platelet volume (MPV), and PDW—are gaining attention as potential tools for early detection. The present study was designed to evaluate the diagnostic utility of these platelet indices in identifying neonatal sepsis promptly and accurately.

A total of 200 neonates were studied, equally divided into confirmed sepsis cases and healthy controls. The results reinforce that thrombocytopenia, elevated MPV, and increased PDW are significantly associated with neonatal sepsis and hold considerable diagnostic potential.

Low birth weight (<2500 g) was significantly more prevalent among neonates with sepsis (60%) compared to controls (42%) ($p = 0.011$), highlighting its role as a key risk factor. This is consistent with previous research suggesting that low birth weight infants are immunologically immature and hence more vulnerable to infections. While the proportion of preterm neonates was higher in the sepsis group (56%) compared to controls (44%), the difference was not statistically significant ($p = 0.090$), suggesting that prematurity may contribute to risk but is not an independent predictor—supporting findings from earlier studies. [15,16]

Clinical symptoms such as fever, respiratory distress, feed intolerance, and diarrhea were significantly more common among sepsis cases. Fever emerged as the most prominent feature, seen in 94% of cases ($p < 0.0001$), followed by feed intolerance (88%) and respiratory distress (89%). These signs reflect systemic inflammatory responses and impaired neonatal adaptation and are consistent with earlier literature identifying them as reliable early indicators of neonatal sepsis. [17,18]

From a hematological standpoint, thrombocytopenia (platelet count $<150 \times 10^9$/L) was the most notable finding, present in 86% of sepsis cases compared to 24% of controls ($p < 0.0001$). The mean platelet counts in the sepsis group ($1.16 \pm 0.29 \times 10^9$/L) was significantly lower than in controls ($1.60 \pm 0.30 \times 10^9$/L). These findings are in agreement with those reported by Majumdar et al. [19], who demonstrated thrombocytopenia as the most sensitive platelet index (87.91%) for detecting neonatal sepsis, followed by MPV (84.9%) and PDW (79.12%). Similar observations have been reported by lal Meena I. et al., Bhat et al., and Mittal et al. [20–22]

MPV was elevated in 69% of sepsis cases compared to 23% of controls ($p < 0.0001$). The mean MPV in sepsis cases was 11.05 ± 5.9 fL, significantly higher than the 9.13 ± 1.9 fL observed in controls. These results align with findings by Mittal et al. [22] and Choudhary et al. [23], who reported elevated MPV in 70.7% and 70.9% of sepsis cases, respectively. An MPV cut-off >10.8 fL yielded a sensitivity of 77.6% and a negative predictive value (NPV) of 84.9%, suggesting moderate sensitivity for early detection of sepsis. However, MPV may lack specificity due to its elevation in other inflammatory conditions.

PDW was elevated in 70% of sepsis cases versus 18% of controls ($p < 0.0001$), with a mean value of 18.17 ± 2.5 fL in sepsis cases compared to 15.59 ± 2.8 fL in controls. These findings support those of Guclu et al. [24] and Patrick & Lazarchick [25], who demonstrated that elevated PDW and MPV reflect increased platelet activation and variability in size—hallmarks of systemic inflammation.

Blood culture, while considered the definitive diagnostic method, is limited by time constraints and availability in many

settings. In this study, blood culture was positive in all sepsis cases. Thrombocytopenia was present in 86% of these culture-positive cases, confirming a significant association with proven sepsis ($p < 0.001$), consistent with findings by Panda SK et al. [8]

In terms of diagnostic performance, platelet count alone demonstrated the highest sensitivity (86%) and overall accuracy (81%). However, combining thrombocytopenia with MPV and PDW improved specificity to 83.9% while maintaining a high NPV (84.9%). The diagnostic accuracy of this three-marker combination was 81.3%, slightly surpassing platelet count alone and indicating a more comprehensive diagnostic profile.

This study confirms the diagnostic value of platelet indices—particularly thrombocytopenia, elevated MPV, and increased PDW—as effective early markers for neonatal sepsis. Given their availability, cost-effectiveness, and rapid turnaround, integrating these indices into routine neonatal screening protocols may enable earlier diagnosis and timely intervention, particularly in resource-limited settings where sepsis remains a significant threat.

4. CONCLUSION

Neonatal sepsis remains a major clinical concern, requiring early and accurate diagnosis to reduce morbidity and mortality. This study identified low birth weight and preterm gestation as significant risk factors, while demographic variables such as sex, mode of delivery, and illness onset were not significantly associated with sepsis. Clinical features—fever, respiratory distress, feed intolerance, diarrhoea, and tachycardia—were more prevalent among septic neonates, highlighting their diagnostic value. Hematological parameters such as elevated CRP, leukocytosis, thrombocytopenia, increased mean platelet volume (MPV), and PDW were significantly associated with sepsis, with thrombocytopenia (platelet count <1.5 lakh/µL) strongly correlating with positive blood cultures. Platelet count alone demonstrated high sensitivity (86%) and diagnostic accuracy (81%), while combining MPV and PDW slightly improved specificity (83.9%). These findings support the use of platelet indices as cost-effective, readily available tools that, when used with clinical assessment and CRP, enhance early diagnosis and management of neonatal sepsis, especially in settings where culture results are delayed.

Strengths and Limitations

A notable strength of this study is its direct comparison of platelet indices with the gold standard blood culture, using rigorous diagnostic criteria and a well-defined study cohort. However, as a single-center study, its generalizability is limited. Although efforts were made to control for potential confounders—such as maternal health, birth complications, and neonatal comorbidities—their residual effects on platelet indices cannot be entirely excluded. Larger multicentric studies are recommended to validate these findings and establish standardized cut-off values.

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