e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2026; 17(3); 385-391

Original Research Article

Clinical Characteristics and Outcome Assessment of Neonatal Sepsis: A Retrospective Analysis

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Received: 12-01-2026 / Revised: 18-02-2026 / Accepted: 28-03-2026

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Conflict of interest: Nil

Abstract:

Background: Neonatal Sepsis is a major cause of morbidity and mortality worldwide, especially in low- and middle-income countries, with preterm and low birth weight infants being most vulnerable.

Aim: To ˋretrospectively analyze the demographic, clinical, laboratory, maternal, and perinatal factors associated with neonatal sepsis and their impact on outcomes.

Methodology: A hospital-based retrospective study was conducted at the Department of Pediatrics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, over seven months. Ninety neonates aged 0–28 days with confirmed or suspected sepsis were included. Data on demographics, clinical presentation, laboratory parameters, maternal history, and outcomes were collected from medical records. Statistical analysis was performed using SPSS, with logistic regression identifying predictors of poor outcomes.

Results: Elevated CRP was observed in 53.3% of neonates. Clinical features such as respiratory distress (55.6%), feeding difficulty (46.7%), lethargy, fever/temperature instability, and poor perfusion were commonly used along with a positive sepsis screen for diagnosis. Favorable outcomes were observed in 75.6%, while 24.4% experienced poor outcomes.

Conclusion: Neonatal sepsis remains a critical contributor to morbidity and mortality. Early recognition, monitoring, and prompt management of high-risk neonates, guided by clinical and laboratory markers, are essential to improve survival in resource-limited settings.

Keywords: Neonatal Sepsis, Mortality, Preterm, Low Birth Weight, Risk Factors, Retrospective Study.

DOI: 10.25258/ijpqa.17.3.62

Introduction

Neonatal sepsis ˋremains one of the most important and severe medical conditions that affects newborns worldwide especially in countries with low and middle income because they experience a higher rate of infectious diseases [1]. The World Health Organization states that infections make up a major share of the global neonatal death toll which reaches 2.3 million every year with sepsis accounting for a significant portion of the total. Neonatal sepsis describes a medical condition which involves a body-wide inflammatory response that occurs when doctors suspect or confirm an infection during the first month of life [2]. Medical professionals use two main categories to classify the condition which includes early-onset sepsis (EOS) that develops within three days after birth because of pathogens that mothers pass to their infants and late-onset sepsis (LOS) that arises more than three days after birth because of environmental or hospital sources. The disorder presents with general clinical signs which include temperature fluctuations along with breathing problems and feeding difficulties and excessive sleepiness and restlessness and unstable blood circulation but these signs can be found in other neonatal medical conditions which makes it hard to identify the correct diagnosis.

The multiple causes of neonatal sepsis develop because of the specific way newborns' immune systems develop their natural protection against diseases [3]. Newborns, especially premature and low birth weight babies, display incomplete development of both their innate and adaptive immune systems, which results in decreased neutrophil storage pools and restricted chemotaxis abilities and lower complement system performance and minimal im-

munoglobulin production. The immunological weaknesses of these individuals make them more vulnerable to serious infections which lead to fast medical emergency situations. Early-onset sepsis risk increases through maternal risk factors which include prolonged rupture of membranes and maternal fever and chorioamnionitis and urinary tract infections and intrapartum colonization with pathogenic organisms [4]. The occurrence of late-onset sepsis usually happens in situations where patients experience lengthy hospital stays and undergo invasive medical procedures which include mechanical ventilation and central venous catheterization and where hospitals fail to maintain proper infection control methods while patients encounter multidrug-resistant pathogens in neonatal intensive care units (NICUs).

The infectious agents that cause neonatal sepsis show different patterns of distribution across various geographical regions and healthcare facilities [5]. The early-onset sepsis cases in high-income countries most frequently involve Group B Streptococcus and Escherichia coli while the late-onset infections show common associations with coagulase-negative staphylococci and Staphylococcus aureus and Klebsiella species and Pseudomonas aeruginosa. Resource-limited environments experience a dominance of Gram-negative bacteria which includes Klebsiella pneumoniae and Acinetobacter species and various enteric bacilli that show high levels of antimicrobial resistance. The growing number of multidrug-resistant pathogens has created difficulties for medical professionals who need to develop effective treatment plans while their patients experience longer hospital stays and increased healthcare expenses and higher death rates [6].

Neonatal sepsis remains a diagnostic and therapeutic challenge despite significant advances in neonatal care, infection prevention strategies, antimicrobial therapy, and intensive care support [7]. Early diagnosis is often difficult because the clinical manifestations are nonspecific and may overlap with several other neonatal conditions. Common presenting features include respiratory distress, poor feeding, lethargy, temperature instability, and poor perfusion. Therefore, clinicians frequently rely on a combination of clinical assessment and laboratory parameters such as C-reactive protein (CRP), total leukocyte count, platelet count, and other sepsis screen markers to support diagnosis and guide management decisions [8]. However, the diagnostic accuracy of these markers is variable, and no single parameter can reliably identify all cases of neonatal sepsis. This highlights the need for continued research to improve early recognition and management of neonatal sepsis, particularly in resource-limited settings.

The study of neonatal sepsis through retrospective analyses gives researchers the ability to investigate epidemiological patterns, microbial distribution, antibiotic resistance levels, risk factor associations, and both short-term and long-term outcomes [9]. Through their research, healthcare institutions can assess current treatment methods, discover deficiencies in their infection management systems, and develop antibiotic treatment guidelines that match the specific microbial patterns of their region. The analysis of historical data enables researchers to investigate factors that determine case fatality rates, discover elements that lead to negative health results, and assess the incidence of severe medical conditions which include septic shock and disseminated intravascular coagulation and meningitis and multi-organ dysfunction. The results of these medical conditions determine whether patients will survive in the short term, but they also produce lasting effects on neurodevelopmental growth, especially for babies born before their due date.

The hospital-based retrospective studies in developing countries with high neonatal mortality rates which exist as a research method. The research helps identify risk factors which can be modified while it supports the development of antibiotic guidelines and enables hospitals to distribute their neonatal intensive care resources. The research uses longitudinal studies to track sepsis trends which demonstrate how preventive methods succeed through better antenatal services and hospital childbirths and maternal health screenings and enhanced infection control between neonatal intensive care units.

The retrospective examination of neonatal sepsis together with its outcomes presents a critical requirement for assessing the problem's extent and establishing both demographic and clinical characteristics and bacteriological profiles and survival patterns in a specific medical facility. The existing research studies create a base for institutional data analysis which aims to decrease neonatal death rates and sickness rates through improved treatment methods that will result in better health results for newborns in hospitals and entire communities.

Methodology

Study Design: This was a retrospective, hospital-based, single-centre study aimed at analyzing the clinical characteristics, laboratory parameters, and outcomes of neonates diagnosed with sepsis. The study focused on identifying factors associated with adverse outcomes among neonates admitted to the neonatal unit during the study period. The design allowed a systematic review of medical records to understand patterns, risk factors, and prognosis of neonatal sepsis in a tertiary care setting.

Study Area: The study was conducted in the Department of Pediatrics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India.

Study Duration: The study covered a 7-months period from April 2025 to October 2025.

Study Participants

Inclusion Criteria:

- Neonates aged 0–28 days admitted with clinical suspicion of sepsis and/or positive sepsis screen findings.
- Both in-born and out-born neonates referred to the neonatal unit during the study period.
- Neonates with complete medical records documenting clinical features, laboratory findings, and outcome data.

Exclusion Criteria:

- Neonates with major congenital malformations incompatible with life.
- Neonates with incomplete or missing medical records.
- Neonates who left against medical advice before completion of therapy.

Sample Size: A total of 90 neonates meeting the inclusion criteria were included in the study. This sample size was determined based on hospital admission records and completeness of clinical and laboratory data.

Procedure: Medical records of all eligible neonates were retrieved and systematically reviewed. Data were collected on demographic characteristics such as age at admission, gender, birth weight, and gestational age. Maternal history, including antenatal complications, mode of delivery, premature rupture of membranes, and maternal fever, was also recorded. Clinical features at presentation, including respiratory distress, feeding difficulty, temperature instability, lethargy, jaundice, and poor perfusion, were documented. Laboratory investigations, including complete blood count, C-reactive protein (CRP), platelet count, and sepsis screen findings, were recorded from the available medical records.

The diagnosis of neonatal sepsis was based on clinical suspicion supported by positive sepsis screen findings as documented in the hospital records. Clinical and laboratory parameters were evaluated to assess their association with neonatal outcomes.

Each neonate's outcome was categorized as favorable (recovery and discharge without major complications) or poor (mortality or persistence of severe complications at discharge). The relationships between demographic, maternal, clinical, and laboratory variables and neonatal outcomes were analyzed. Special attention was given to identifying predictors of poor outcomes, such as prematurity, low birth weight, leukocyte count abnormalities, thrombocytopenia, and maternal risk factors.

All data were anonymized to maintain confidentiality, and the study was conducted in accordance with ethical guidelines and approved by the Institutional Ethics Committee of Sri Krishna Medical College and Hospital, Muzaffarpur.

Statistical Analysis: Collected data were entered into SPSS version 27.0 for analysis. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were summarized as frequencies and percentages. Differences between groups (favorable vs. poor outcomes) were analyzed using the independent Student's t-test for continuous variables and the chi-square test for categorical variables. Logistic regression analysis was performed to identify independent predictors of poor outcomes. A p-value of <0.05 was considered statistically significant, and confidence intervals were calculated at 95% where appropriate. The statistical analysis facilitated understanding of the significant clinical and laboratory factors contributing to adverse outcomes in neonatal sepsis".

Result

Table 1 presents the demographic characteristics of the 90 neonates included in the study. Of these, 52 (57.8%) were male and 38 (42.2%) were female, indicating a slightly higher proportion of male neonates. Regarding gestational age, 34 (37.8%) were preterm (<37 weeks), while the majority, 56 (62.2%), were term (≥37 weeks). Birth weight distribution showed that 36 neonates (40%) had low birth weight (<2.5 kg), whereas 54 (60%) had normal birth weight (≥2.5 kg). In terms of age at admission, 28 neonates (31.1%) were admitted within 0–3 days of life, 35 (38.9%) between 4–7 days, and 27 (30%) between 8–28 days, reflecting that most admissions occurred during the first week of life.

Table 1: Demographic Characteristics of Neonates (N = 90)

Parameter	Category	Frequency (n)	Percentage (%)
Gender	Male	52	57.8
	Female	38	42.2
Gestational Age	Preterm (<37 weeks)	34	37.8
	Term (≥37 weeks)	56	62.2
Birth Weight	<2.5 kg	36	40
	≥2.5 kg	54	60
Age at Admission	0–3 days	28	31.1
	4–7 days	35	38.9
	8–28 days	27	30

Table 2 presents the clinical features observed among 90 neonates with sepsis. Respiratory distress was the most common presenting symptom, affecting 50 (55.6%) neonates, followed by poor feeding or feeding difficulty in 42 (46.7%) cases. Fever or temperature instability was observed in 35 (38.9%) neonates, while lethargy was reported in 28 (31.1%). Jaundice was present in 20 (22.2%) neonates, and poor perfusion was noted in 15 (16.7%) cases. The findings indicate that respiratory and feeding-related symptoms were the predominant clinical manifestations of neonatal sepsis, emphasizing the importance of early recognition of these signs for prompt diagnosis and management.

Table 2: Clinical Features of Neonates with Sepsis (N = 90)

Clinical Feature	Frequency (n)	Percentage (%)
Respiratory distress	50	55.6
Poor feeding/feeding difficulty	42	46.7
Fever/temperature instability	35	38.9
Lethargy	28	31.1
Poor perfusion	15	16.7
Jaundice	20	22.2

Table 3 presents the laboratory findings of 90 neonates evaluated for sepsis. Elevated C-reactive protein (CRP) levels greater than 10 mg/L were observed in 48 (53.3%) neonates, while 42 (46.7%) had CRP levels ≤10 mg/L. The majority of neonates, 60 (66.7%), had total leukocyte counts within the range of 5000–20,000/mm³, whereas 20 (22.2%) had leukopenia (<5000/mm³) and 10 (11.1%) showed leukocytosis (>20,000/mm³). Thrombocytopenia, defined as a platelet count below 150,000/mm³, was present in 25 (27.8%) neonates, while 65 (72.2%) had normal platelet counts. Notably, the sepsis screen was positive in all 90 (100%) neonates, supporting the clinical suspicion of neonatal sepsis in the study population.

Table 3: Laboratory Findings of Neonates Evaluated for Sepsis (N = 90)

Laboratory Parameter	Category	Frequency (n)	Percentage (%)
CRP	>10 mg/L	48	53.3
	≤10 mg/L	42	46.7
Total Leukocyte Count	<5000/mm³	20	22.2
	5000–20000/mm³	60	66.7
	>20000/mm³	10	11.1
Platelet Count	<150,000/mm³	25	27.8
	150,000–450,000/mm³	65	72.2
Sepsis Screen	Positive	90	100

Table 4 presents the maternal and perinatal factors among the 90 participants. The majority of deliveries were vaginal (48, 53.3%), while cesarean sections accounted for 42 cases (46.7%). Premature rupture of membranes was observed in 22 mothers (24.4%), whereas 68 (75.6%) did not experience this complication. Maternal fever was reported in 18 cases (20%), with the remaining 72 mothers (80%) being afebrile. Antenatal complications were present in 25 participants (27.8%), while the majority, 65 mothers (72.2%), had no such complications. Overall, the data indicate that while vaginal delivery was slightly more common, a significant proportion of mothers experienced maternal or antenatal issues that could influence perinatal outcomes.

Table 4: Maternal and Perinatal Factors (N = 90)

Factor	Category	Frequency (n)	Percentage (%)
Mode of Delivery	Vaginal	48	53.3
	Cesarean Section	42	46.7
Premature Rupture of Membranes	Present	22	24.4
	Absent	68	75.6
Maternal Fever	Present	18	20
	Absent	72	80
Antenatal Complications	Present	25	27.8
	Absent	65	72.2

Table 5 depicts the outcomes of neonates diagnosed with sepsis. Among the 90 neonates included in the study, 68 (75.6%) experienced a favorable outcome and recovered following appropriate medical management. However, 22 (24.4%) neonates had a poor outcome, including death or the development of severe complications, indicating the serious nature of neonatal sepsis. The average duration of hospital stay was 12 ± 5 days, suggesting a relatively prolonged period of treatment and monitoring. Overall, the findings demonstrate that while the majority of neonates recovered successfully, a substantial proportion experienced adverse outcomes, highlighting the importance of early diagnosis and timely intervention in neonatal sepsis management.

Table 5: Outcomes of Neonates with Sepsis (N = 90)

Outcome	Frequency (n)	Percentage (%)
Favorable (Recovered)	68	75.6
Poor Outcome (Death/Severe Complications)	22	24.4
Average Length of Stay	12 ± 5 days	

Discussion

Neonatal sepsis continues to be a major cause of neonatal morbidity and mortality worldwide, particularly in developing countries where limited resources and delayed diagnosis often contribute to adverse outcomes (Sands et al., 2018) [10]. The present study retrospectively evaluated the demographic profile, clinical presentation, laboratory findings, maternal factors, and outcomes among neonates diagnosed with sepsis at a tertiary care hospital. Among the 90 neonates included in the study, 75.6% had favorable outcomes, whereas 24.4% experienced poor outcomes, indicating that neonatal sepsis remains an important clinical challenge despite advances in neonatal care.

In the present study, male neonates constituted 57.8% of all cases, while females accounted for 42.2%. A similar male predominance has been reported in several studies of neonatal sepsis. O'Driscoll et al. (2017) [15] also observed a higher occurrence of sepsis among male neonates, suggesting that biological and immunological differences may contribute to their increased susceptibility to infections. Although the exact mechanism remains unclear, the findings indicate that male neonates may represent a relatively vulnerable group requiring close monitoring.

Prematurity and low birth weight were common among the study population. Preterm neonates constituted 37.8% of cases, while 40% had a birth weight below 2.5 kg. These findings are consistent with previous reports identifying prematurity and low birth weight as important risk factors for neonatal sepsis and poor clinical outcomes. Ahmed and Magzoub (2015) [13] and Stoll (1997) [14] reported that immature immune function, reduced physiological reserves, and increased vulnerability to infections place preterm and low birth weight neonates at a greater risk of complications. The substantial proportion of such neonates in the present study highlights the need for intensive surveillance and early intervention in these high-risk groups.

The clinical manifestations observed in this study were largely nonspecific, reflecting the well-recognized diagnostic challenges of neonatal sepsis. Respiratory distress was the most common presenting feature, observed in 55.6% of neonates, followed by feeding difficulty (46.7%), temperature instability (38.9%), lethargy (31.1%), jaundice (22.2%), and poor perfusion (16.7%). Similar observations have been reported in previous studies where respiratory and feeding-related symptoms represented the most frequent manifestations of neonatal infection. Because these clinical features overlap with several neonatal conditions, prompt recognition and careful clinical assessment remain essential for early diagnosis and management.

Laboratory evaluation played an important supportive role in the assessment of neonatal sepsis. Elevated CRP levels were observed in 53.3% of neonates, suggesting the presence of an inflammatory response. Massaro et al. (2007) [17] reported that CRP is a useful marker for supporting the diagnosis of neonatal infection, particularly when interpreted in conjunction with clinical findings. However, CRP alone may not be sufficient for diagnosis because inflammatory markers can be influenced by several noninfectious conditions. Therefore, laboratory findings should always be interpreted alongside clinical assessment.

Abnormal hematological parameters were also observed among the study population. Leukopenia was present in 22.2% of neonates, while leukocytosis was observed in 11.1%. In addition, thrombocytopenia was detected in 27.8% of cases. Previous studies have shown that abnormalities in leukocyte and platelet counts are frequently associated with neonatal sepsis and may reflect the severity of infection (Trotman et al., 2006) [11]. These hematological changes can therefore provide valuable information for the identification and monitoring of affected neonates.

Maternal and perinatal factors remain important contributors to the development of neonatal sepsis. In the present study, 24.4% of mothers had prema-

ture rupture of membranes, 20% experienced maternal fever, and 27.8% had antenatal complications. Previous investigations by Baizat et al. (2019) [16] and Stoll (1997) [14] have highlighted the role of maternal infections and perinatal complications in increasing the risk of neonatal sepsis. These findings emphasize the importance of adequate antenatal care, timely identification of maternal risk factors, and appropriate perinatal management strategies to reduce neonatal infectious morbidity.

The overall findings of the present study demonstrate that neonatal sepsis continues to impose a significant burden on neonatal health. The predominance of preterm and low birth weight infants, the frequency of nonspecific clinical manifestations, and the occurrence of laboratory abnormalities underline the complexity of diagnosis and management. Early recognition of clinical signs, careful evaluation of laboratory parameters, and prompt treatment remain essential for improving outcomes. Strengthening antenatal care services, enhancing neonatal monitoring, and implementing evidence-based management protocols may further contribute to reducing the burden of neonatal sepsis, particularly in resource-limited settings.

Conclusion

The present study demonstrated that neonatal sepsis remains a significant contributor to neonatal morbidity and adverse clinical outcomes, particularly among preterm and low birth weight infants. Among the 90 neonates included in the study, 75.6% showed favorable outcomes, while 24.4% experienced poor outcomes. Respiratory distress, feeding difficulty, temperature instability, lethargy, jaundice, and poor perfusion were the most common clinical manifestations observed at presentation. Laboratory findings such as elevated C-reactive protein levels, leukocyte count abnormalities, thrombocytopenia, and positive sepsis screen findings were frequently observed among affected neonates. Maternal and perinatal factors, including premature rupture of membranes, maternal fever, and antenatal complications, were also commonly identified. The findings emphasize the importance of early clinical recognition, supportive laboratory evaluation, careful monitoring, and prompt management of neonates with suspected sepsis. Strengthening antenatal and neonatal care services may contribute to improved outcomes and reduced disease burden, particularly in resource-limited healthcare settings.

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