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

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2026; 17(9); 368-375

Original Research Article

Retrospective Evaluation of Risk Factors and Clinical Outcomes Among Neonates with Sepsis

Pragati Agrawal[1], Nikhil Agrawal[2]

[1]MBBS, DNB Pediatrics, Department of Pediatrics, St. Stephen's Hospital, New Delhi, India
[2]MBBS, MD Medicine, Department of Medicine, VMMC and Safdarjung Hospital, New Delhi, India

Received: 12-07-2026 / Revised: 20-08-2026 / Accepted: 20-09-2026
Corresponding Author: Dr. Pragati Agrawal
Conflict of interest: Nil

Abstract:

Background: Neonatal sepsis is a major cause of neonatal morbidity and mortality, with outcomes influenced by maternal, perinatal, and neonatal risk factors. Early identification of high-risk neonates is essential for timely management.

Aim: To retrospectively evaluate risk factors, clinical and laboratory characteristics, and clinical outcomes among neonates with sepsis.

Methodology: A retrospective cohort study was conducted in the Department of Pediatrics, St. Stephen's Hospital, Delhi, India, involving 80 neonates with suspected or confirmed sepsis. Demographic, maternal, neonatal, clinical, laboratory, and outcome data were extracted from medical records and analyzed using SPSS version 27.0. Associations were assessed using appropriate statistical tests, with $p<0.05$ considered significant.

Results: Males constituted 56.3% of participants, while 38.8% were preterm and 42.5% had low birth weight. Lethargy (65.0%), poor feeding (58.8%), and respiratory distress (47.5%) were common manifestations. Elevated CRP occurred in 61.3% and blood culture positivity in 26.3%. Prematurity ($p=0.028$), low birth weight ($p=0.041$), elevated CRP ($p=0.019$), and positive blood culture ($p=0.036$) were significantly associated with adverse outcomes. Recovery occurred in 81.3%, complications in 33.8%, and mortality in 11.3%.

Conclusion: Prematurity, low birth weight, elevated CRP, and positive blood culture were significantly associated with adverse outcomes, emphasizing early recognition and close monitoring of high-risk neonates.

Keywords: Neonatal sepsis; Prematurity; Low birth weight; CRP; Blood culture; Clinical outcomes.

DOI: 10.25258/ijpqa.17.9.55

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0) and the Budapest Open Access Initiative (http://www.budapestopenaccessinitiative.org/read), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Neonatal sepsis is an infection with a disproportionate inflammatory response in early infancy which can be life threatening if left untreated [1]. It is still a major cause of morbidity and mortality in the newborn period, especially in low- and middle-income countries. Neonatal sepsis is usually divided into early onset sepsis (EOS), occurring in the first 72 hours after birth, usually linked to maternal and perinatal exposure to infection, and late onset sepsis (LOS) occurring after 72 hours of birth, which are typically associated with environmental, hospital acquired or community-acquired infections. Early recognition is challenging due to the nonspecific clinical signs and symptoms of neonatal sepsis, which include poor feeding, lethargy, respiratory difficulty, temperature instability, jaundice, apnea and cardiovascular instability.

The burden of neonatal sepsis is significantly different across different regions of the world, depending on country's healthcare system, maternal health services, infection control measures, and neonatal intensive care availability [2]. Newborns are at increased risk of developing a very bad infection due to their underdeveloped innate and adaptive immune system. Immature host defenses, invasive procedures, prolonged hospitalization and respiratory or nutritional support increase the risk of infection, which is further exacerbated by prematurity and low birth weight. The incidence of neonatal infection-related deaths has declined significantly in many settings due to developments in antenatal care, safe delivery practices, neonatal resuscitation and intensive care units; however, in developing countries, infection still plays a significant role in neonatal mortality.

Several maternal and perinatal factors influence the risk for neonatal sepsis in developing countries. Neonatal infections are more likely if the mother has fever during labour, if the membrane ruptures for longer than usual, if the mother has an infection in her urinary tract or genital tract, or if the mother feels she did not receive enough care during

pregnancy, if she received many vaginal inspections or if labour is longer than usual. Furthermore, pathogens can be transmitted to newborns during delivery when hygienic procedure is not observed or if it is, it is not properly done. Additionally, neonatal risk factors like low birth weight, invasive procedures, central venous access, and birth asphyxia are linked to greater risk of sepsis [3], and mechanical ventilation is also a risk factor. These factors should be identified as several are potentially modifiable with appropriate maternal and neonatal care.

Neonatal sepsis is a difficult clinical diagnosis to make due to its overlap with other neonatal conditions. The clinical signs of infection may be subtle and a clinically deteriorating neonate may not have the classical signs of infection. Laboratory investigations (complete blood count, C-reactive protein, procalcitonin, and other inflammatory markers) may help with the diagnosis and should be used in conjunction with the clinical evaluation. Although blood culture is still a valuable tool for microbiological confirmation, low bacterial load, previous antibiotic use, inadequate blood samples and technical issues may all influence the yield of blood culture [5]. Therefore, practitioners are often faced with the challenge of starting empirical antimicrobial therapy based on clinical signs and risk factors, before the microbiological confirmation is available.

The growing antimicrobial resistance has further complicated management of neonatal sepsis. The organisms causing neonatal infections and their antimicrobial susceptibility varies from hospital to hospital and from region to region [6]. The most commonly reported bacterial pathogens are Escherichia coli, Klebsiella spp, Staphylococcus aureus, coagulase-negative staphylococci and other Gram-negative organisms, with variations depending on the type of sepsis and healthcare environment [7]. Exposure to inappropriate or extended courses of antibiotics can help with the emergence of antimicrobial resistance and delayed or insufficient treatment can lead to septic shock, organ dysfunction and death. It is therefore crucial to have local knowledge of risk factors and clinical patterns to help tailor appropriate empirical treatment and infection-control strategies.

There are important short- and long-term clinical effects of neonatal sepsis. Severe infection can lead to septic shock, disseminated intravascular coagulation, respiratory failure, metabolic abnormalities, multi-organ dysfunction and death [8]. Survivors, especially those who are pre-term and very-low-birth weight, can have long hospital stays and problems due to infection and intensive care. Neurological complications, such as neurological impairment, and developmental delay have also been linked to severe infection in newborns. In addition, longer hospital stays result in higher healthcare costs and further healthcare associated infections and complications to neonates.

Although neonatal sepsis survival has improved, there are significant gaps in knowledge regarding risk and outcomes of neonatal sepsis at the institutional and regional level. Data from routinely collected maternal, neonatal, clinical, laboratory, treatment and outcome data, when evaluated post facto, can be helpful in understanding the features of affected newborns and the factors associated with poor outcomes. This information could be used to help identify high risk neonates, enhance early recognition, reinforce infection control measures, inform empirical antimicrobial therapy choices, and optimize care of the neonates.

This is why the present study, "Retrospective Evaluation of Risk Factors and Clinical Outcomes Among Neonates with Sepsis" is conducted to assess the burden and clinical characteristics of neonatal sepsis in the study population. Maternal, neonatal, and environmental risk factors for sepsis will be studied, clinical and laboratory characteristics of affected neonates will be described, and short-term clinical results (complications and mortality) will be studied. The results can help to better identify neonates with a higher risk, and inform the creation of timely and effective strategies to decrease sepsis associated morbidity and mortality."

Methodology

Study Design: This study was conducted as a retrospective cohort study to evaluate the risk factors and clinical outcomes among neonates with sepsis. The study utilized previously recorded clinical and laboratory information available in hospital medical records. The retrospective design enabled the assessment of maternal, neonatal, clinical, and laboratory factors associated with neonatal sepsis and its subsequent outcomes. Relevant records of eligible neonates admitted during the defined study period were reviewed systematically, and the collected information was analyzed to identify factors associated with disease severity, complications, duration of hospitalization, recovery, and mortality.

Study Area: The study was conducted in the Department of Pediatrics, St. Stephen's Hospital, Delhi, India. The department provided specialized neonatal and pediatric care and maintained clinical, laboratory, and microbiological records required for retrospective evaluation. Data were obtained from the available medical records of neonates who had been admitted and managed for suspected or confirmed neonatal sepsis.

Study Duration: The study was conducted over a period of one year.

Study Participants

Inclusion Criteria

- Neonates aged ≤28 days at the time of admission.

- Neonates with suspected or confirmed neonatal sepsis based on documented clinical and/or laboratory findings.
- Neonates who had been admitted and managed in the Department of Pediatrics during the study period.
- Neonates with sufficiently complete medical records containing relevant demographic, maternal, clinical, laboratory, and outcome data.

Exclusion Criteria

- Neonates with major congenital anomalies that could have significantly influenced clinical presentation or outcomes.
- Neonates with incomplete or missing medical records that prevented reliable data extraction.
- Neonates transferred from other hospitals with inadequate or incomplete clinical documentation.
- Neonates whose records lacked essential information required for assessment of sepsis-related risk factors or outcomes.

Sample Size: A total of 80 neonates were included in the study. The sample consisted of eligible neonates identified through a retrospective review of hospital records according to the predefined inclusion and exclusion criteria.

Procedure: The study was conducted by retrospectively reviewing the medical records, admission notes, laboratory reports, treatment charts, discharge summaries, and other relevant clinical documents of the selected neonates. Demographic characteristics including age, sex, gestational age, birth weight, and mode of delivery were recorded. Maternal and perinatal risk factors such as prolonged rupture of membranes (≥18 hours), maternal urinary tract infection, chorioamnionitis, and other documented maternal illnesses were assessed. Neonatal risk factors including prematurity (<37 weeks), low birth weight (<2500 g), and Apgar scores were recorded. Clinical manifestations of sepsis, including lethargy, poor feeding, temperature instability, respiratory distress, and other documented signs, were evaluated. Laboratory parameters including total leukocyte count (TLC), platelet count, C-reactive protein (CRP), and blood culture results were reviewed. Information regarding treatment and clinical course was also recorded. Clinical outcomes, including duration of hospital stay, time to recovery, complications, and mortality, were documented. The collected data were entered into a structured data collection format and subsequently analyzed to determine the relationship between potential risk factors and clinical outcomes among neonates with sepsis.

Statistical Analysis: The collected data were entered, coded, and analyzed using Statistical Package for the Social Sciences (SPSS) version 27.0. Continuous variables were expressed as mean ± standard deviation or median with interquartile range, as appropriate, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square test or Fisher's exact test, as appropriate. For comparison of continuous variables between groups, the independent samples t-test or Mann–Whitney U test was applied according to the distribution of the data. Appropriate regression analysis was performed, where applicable, to identify factors associated with adverse clinical outcomes. A p-value <0.05 was considered statistically significant."

Result

Table 1 presents the demographic and baseline characteristics of the 80 study participants. Males constituted the majority of the study population, accounting for 45 (56.3%) participants, while females comprised 35 (43.8%). Regarding gestational age, 49 (61.3%) participants were born at term (≥37 weeks), whereas 31 (38.8%) were preterm (<37 weeks). In terms of birth weight, 46 (57.5%) neonates had a birth weight of ≥2500 g, while 34 (42.5%) had a birth weight of <2500 g. Regarding the mode of delivery, vaginal delivery was slightly more common, accounting for 43 (53.8%) births, compared with 37 (46.3%) delivered by caesarean section. Assessment of the Apgar score at 5 minutes showed that the majority of neonates, 62 (77.5%), had a score of ≥7, whereas 18 (22.5%) had a score <7. Overall, the study population predominantly comprised term neonates with birth weight ≥2500 g and favourable 5-minute Apgar scores.

Table 1: Demographic and Baseline Characteristics of the Study Participants (N=80)

Variable	Category	n	%
Sex	Male	45	56.3
	Female	35	43.8
Gestational age	Term (≥37 weeks)	49	61.3
	Preterm (<37 weeks)	31	38.8
Birth weight	<2500 g	34	42.5
	≥2500 g	46	57.5
Mode of delivery	Vaginal delivery	43	53.8
	Caesarean section	37	46.3
Apgar score at 5 min	<7	18	22.5
	≥7	62	77.5

Table 2 presents the maternal and neonatal risk factors associated with neonatal sepsis among the 80 study participants. Prolonged rupture of membranes (≥18 hours) was reported in 22 (27.5%) neonates, while 58 (72.5%) had no prolonged rupture of membranes. Maternal urinary tract infection was present in 14 (17.5%) cases and absent in 66 (82.5%). Chorioamnionitis was identified in 8 (10.0%) participants, whereas 72 (90.0%) had no documented chorioamnionitis. Prematurity was observed in 31 (38.8%) neonates, while 49 (61.3%) were not premature. Low birth weight (<2500 g) was present in 34 (42.5%) neonates compared with 46 (57.5%) with birth weight ≥2500 g. An Apgar score <7 at 5 minutes was recorded in 18 (22.5%) neonates, whereas 62 (77.5%) had an Apgar score ≥7. Overall, prematurity and low birth weight were relatively common characteristics, while chorioamnionitis and maternal urinary tract infection were less frequently reported.

Table 2: Maternal and Neonatal Risk Factors Associated with Neonatal Sepsis (N=80)

Risk factor	Category	n	%
Prolonged rupture of membranes	Yes (≥18 hours)	22	27.5
	No (<18 hours)	58	72.5
Maternal urinary tract infection	Present	14	17.5
	Absent	66	82.5
Chorioamnionitis	Present	8	10
	Absent	72	90
Prematurity	Yes	31	38.8
	No	49	61.3
Low birth weight	Yes (<2500 g)	34	42.5
	No (≥2500 g)	46	57.5
Apgar score <7 at 5 min	Yes	18	22.5
	No	62	77.5

Table 3 presents the clinical and laboratory characteristics of the 80 neonates with sepsis. Lethargy was the most frequently reported clinical feature, being present in 52 (65.0%) neonates, followed by poor feeding in 47 (58.8%). Respiratory distress was observed in 38 (47.5%) neonates, while temperature instability was present in 29 (36.3%). Among the laboratory abnormalities, elevated C-reactive protein (CRP) was the most common finding, occurring in 49 (61.3%) neonates. Abnormal total leukocyte count (TLC) was observed in 35 (43.8%) cases, whereas thrombocytopenia was present in 24 (30.0%). Blood culture was positive in 21 (26.3%) neonates, while 59 (73.8%) had negative culture results. Overall, the findings demonstrate that lethargy, poor feeding, and respiratory distress were prominent clinical manifestations, while elevated CRP and abnormal TLC were frequently observed laboratory abnormalities. Although only about one-fourth of neonates had positive blood cultures, the clinical and laboratory findings supported the presence of sepsis in the study population."

Table 3: Clinical and Laboratory Characteristics of Neonates with Sepsis (N=80)

Clinical/Laboratory parameter	Category	n	%
Lethargy	Present	52	65
	Absent	28	35
Poor feeding	Present	47	58.8
	Absent	33	41.3
Temperature instability	Present	29	36.3
	Absent	51	63.8
Respiratory distress	Present	38	47.5
	Absent	42	52.5
Thrombocytopenia	Present	24	30
	Absent	56	70
Abnormal TLC	Present	35	43.8
	Absent	45	56.3
Elevated CRP	Present	49	61.3
	Absent	31	38.8
Blood culture	Positive	21	26.3
	Negative	59	73.8

"Table 4 presents the clinical outcomes among the 80 neonates with sepsis. The majority of neonates, 65 (81.3%), recovered, whereas 15 (18.8%) did not recover. Complications were observed in 27

(33.8%) neonates, while 53 (66.3%) had no documented complications. Regarding duration of hospitalization, 36 (45.0%) neonates required a prolonged hospital stay of >7 days, whereas 44 (55.0%) were hospitalized for ≤7 days. Mortality was recorded in 9 (11.3%) neonates, while 71 (88.8%) survived. Overall, the findings indicate that most neonates with sepsis recovered and survived, although a considerable proportion developed complications or required prolonged hospitalization. The mortality rate was 11.3%, highlighting the clinical severity associated with neonatal sepsis in the study population. These findings demonstrate that, despite a generally favourable recovery proportion, neonatal sepsis was associated with substantial morbidity, including complications and extended hospital stay in a notable number of cases.

Table 4: Clinical Outcomes Among Neonates with Sepsis (N=80)

Clinical outcome	Category	n	%
Recovery	Recovered	65	81.3
	Not recovered	15	18.8
Complications	Present	27	33.8
	Absent	53	66.3
Prolonged hospital stay	>7 days	36	45
	≤7 days	44	55
Mortality	Yes	9	11.3
	No	71	88.8

Table 5 presents the association of selected risk factors with adverse clinical outcomes among the 80 neonates with sepsis. Adverse outcomes were observed more frequently among premature neonates, occurring in 15 (48.4%) compared with 12 (24.5%) among non-premature neonates, with a statistically significant association (p=0.028). Similarly, low birth weight was associated with a higher frequency of adverse outcomes, observed in 15 (44.1%) neonates compared with 12 (26.1%) neonates without low birth weight (p=0.041). Prolonged rupture of membranes was associated with adverse outcomes in 10 (45.5%) cases compared with 17 (29.3%) among those without prolonged rupture, although the difference was not statistically significant (p=0.087). Elevated CRP was significantly associated with adverse outcomes, occurring in 21 (42.9%) neonates compared with 6 (19.4%) without elevated CRP (p=0.019). Positive blood culture was also significantly associated with adverse outcomes, reported in 10 (47.6%) compared with 17 (28.8%) among culture-negative neonates (p=0.036).

Table 5: Association of Selected Risk Factors with Adverse Clinical Outcome (N=80)

Risk factor	Adverse outcome Present n (%)	Adverse outcome Absent n (%)	Total	p-value
Prematurity				
Yes (n=31)	15 (48.4)	16 (51.6)	31	**0.028**
No (n=49)	12 (24.5)	37 (75.5)	49	
Low birth weight				
Yes (n=34)	15 (44.1)	19 (55.9)	34	**0.041**
No (n=46)	12 (26.1)	34 (73.9)	46	
Prolonged rupture of membranes				
Yes (n=22)	10 (45.5)	12 (54.5)	22	**0.087**
No (n=58)	17 (29.3)	41 (70.7)	58	
Elevated CRP				
Yes (n=49)	21 (42.9)	28 (57.1)	49	**0.019**
No (n=31)	6 (19.4)	25 (80.6)	31	
Positive blood culture				
Yes (n=21)	10 (47.6)	11 (52.4)	21	**0.036**
No (n=59)	17 (28.8)	42 (71.2)	59	

Discussion

This is a retrospective study to assess the demographic parameters, maternal and neonatal risk factors, clinical and laboratory characteristics and outcome of 80 neonates with sepsis. The results show that there were maternal infection risk factors, non-specific clinical characteristics, inflammatory and haematological abnormalities, in addition to neonatal vulnerability, that all contributed to the presence of neonatal sepsis. Despite the majority of neonates being recovered, complications did occur, length of hospital stay was long, and deaths were recorded, suggesting that neonatal sepsis still causes a

significant mortality and morbidity. All these observations are in line with previous studies conducted in low and middle-income countries including India, in which prematurity, low birth weight, maternal infections, prolonged rupture of membranes, and abnormal inflammatory markers have been found to be important factors associated with neonatal sepsis and its outcomes [9,10]."

"The male to female ratio among the study population was 56.3:43.8 with a slight male predominance in the present study. Male predominance has also been observed in a number of studies of neonatal sepsis, with differences in the degree of excess varying between populations. Rafi et al., 2020 [11] reported a more or less equal sex ratio of neonates, and also found that male sex was a factor that was associated with late onset neonatal sepsis. Also, there have been many reports of higher male sex ratio in septic neonates in neonatal intensive care units. The gender difference shown in the present study, thus, is similar to what has been reported in literature, though the small difference between the genders indicates that neonatal sepsis impacted both male and female neonates significantly (Nyma et al., 2020) [12]. It is important to note that sex alone should not be used as a significant risk factor for present findings as the primary adverse-outcome associations were with prematurity, low birth weight, CRP elevation and blood-culture positivity.

This is especially significant for the finding on gestational age and birth weight in the present study. There were 80 neonates, with 38.8% being preterm and 61.3% term. Similarly, 42.5% had a birth weight below 2500 g and 57.5% had a birth weight of ≥2500 g. The proportion of neonates born at an early gestational age (preterm) or with LBW is relatively high and this has been associated with increased susceptibility to infections. In another study, Rafi et al (2020) reported that 46% of neonates with sepsis were premature, which was independently associated with neonatal sepsis, compared to 18.7% of controls. Similarly, a study by Nyma et al. in 2020 found that neonates weighing ≤2500 g were at higher risk of developing sepsis (OR: 3.82 (95% CI: 1.59–9.19)). The findings of the present study are consistent with studies that found adverse outcomes to be common, as well as the fact that low birth weight and premature birth are common. The rates of adverse outcomes were 48.4% for premature neonates and 24.5% for non-premature neonates, and 44.1% for neonates with a birth weight < 2500 g compared with 26.1% for neonates ≥ 2500 g. This is also consistent with the systematic review and meta-analysis undertaken by Bech et al., 2022, who also found that neonatal vulnerability and prematurity were also an important factor that was associated with neonatal sepsis in sub–Saharan African populations. This uniformity within geographic areas implies that immaturity of immune function, suboptimal physiological reserve and increased requirement for invasive interventions may predispose premature and low-birth weight neonates to increased vulnerability.

Maternal and perinatal factors too were associated to the risk profile seen in the current study. 27.5% of neonates had prolonged rupture of membranes, 17.5% had UTI and 10.0% had chorioamnionitis recorded. The results are comparable to previous studies showing a correlation between maternal infections, prolonged ruptured membranes and neonatal infections. Rafi et al. (2020) found that 27.5% of the neonatal sepsis cases had PROM, while only 15.5% of the controls had PROM; they also determined that maternal urinary tract infection was an important risk factor. In a similar study carried out in a hospital setting, Adatara et al. (2019) [13] also reported PROM as a significant risk factor for neonatal sepsis. The high level of similarity between the present study and the study of Rafi et al. (2020) (27.5% of PROM in both studies) supports this finding. In the present study, PROM was correlated with adverse outcomes in 45.5% of those exposed to PROM and 29.3% of those not exposed to PROM, although this difference was not statistically significant. This contrast may be due to the relatively small number of women in the present study, length of rupture of membranes, provision of antibiotics during labour and differences in neonatal management between the study sites.

The clinical picture of neonatal sepsis, seen in the present study, further emphasizes the unspecificity of neonatal sepsis. Lethargy was the most common symptom, seen in 65.0% of neonates, with poor feeding seen in 58.8%, respiratory distress in 47.5% and temperature instability in 36.3%. The results of the current study were similar to that of the previous studies on neonatal sepsis, which revealed that feeding difficulty, altered activity, respiratory abnormalities and temperature instability are commonly observed clinical patterns. Similarly, Rafi et al., (2020) highlighted that neonatal sepsis can present with relatively non-specific clinical features, which can pose difficulties in early clinical recognition. In their study on urinary tract infection in neonatal sepsis, Kamel et al. 2022 [14] showed that feeding abnormalities were clinically significant among neonates with UTI. The predominant lethargy and poor feeding seen in the present study, therefore, is clinically relevant in that they may precede more overt signs of systemic infection. Early detection of such signs is very crucial because clinical decompensation may be rapid in premature and low-birth-weight neonates.

Systemic inflammatory and hematological involvement was further confirmed by laboratory results in the present study. High levels of CRP were noted in 61.3% of the neonates, abnormal TLC in 43.8% and thrombocytopenia in 30.0%. The high levels of CRP

is seen consistently, and this is why it is commonly used as an inflammatory marker when evaluating patients for possible neonatal sepsis. The present results, however, also showed that none of the laboratory measurements were abnormal in 100% of the neonates. Only 26.3% of blood culture were positive while 73.8% were culture negative. This is a comparatively low culture positivity which is akin to the known challenges of obtaining microbiological confirmation in neonatal sepsis. There are considerable differences in reported estimates of neonatal sepsis, due to the variety of definitions and methods used to arrive at these estimates, as noted by Fleischmann et al. 2021 [15]. The cause of culture-negative sepsis can be due to previous antibiotic exposure, insufficient blood-volume collection, low levels of bacteria in the bloodstream or limitations of traditional microbiological methods. Therefore, if clinically suspected sepsis is accompanied by laboratory findings, a negative blood culture should not rule out the diagnosis.

Of particular interest in the current study was the correlation between laboratory abnormalities and outcomes. Neonates with elevated CRP had more adverse outcomes (42.9%) than those with CRP non-elevated (19.4%) and this association was statistically significant. This discovery implies that an increased inflammatory response could be correlated with severity of disease and an adverse clinical course. Likewise, a positive blood culture was also significantly related to adverse outcome: culture positive neonates had 47.6% compared with 28.8% of culture negative neonates. This increased association of culture positive neonates may be explained by the presence of microbiologically confirmed infection and therefore possibly more infectious burden in the systemic circulation. The results confirm the importance of using a combination of clinical findings, laboratory and microbiological findings, and not just one of these parameters.

The overall outcome profile revealed that 81.3% of neonates recovered while 18.8% of neonates failed to recover. Even though the recovery rate is relatively high, 33.8% had complications and 45.0% were hospitalized for over a week. Eleven percent (11.3%) of cases died. The results in this study indicate that despite successful treatment for neonatal sepsis, there can be significant morbidity and ongoing health care utilization. We conducted a global systematic review and meta-analysis to estimate the mortality due to neonatal sepsis, which found an approximate mortality of 17.6%, with significant heterogeneity among studies and healthcare settings (Fleischmann et al., 2021). The mortality rate for the present study is within the range reported in previous studies but caution must be exercised when comparing as there are differences in severity of disease, referral patterns, case definition and availability of neonatal intensive care.

There is overall support for the multifactorial nature of neonatal sepsis and outcome from the present study. Important features of the clinical profile were the presence of maternal infectious risk factors, elevated inflammatory markers, microbiological confirmation and prematurity/low birth weight. A total of five factors were assessed; the factors that showed significant association with poor outcomes were: positive blood culture, elevated CRP, low birth weight, and prematurity. These findings align with other studies from developing countries like India and other regions, which have previously shown that neonatal immaturity and maternal and perinatal risk factors are significant risk factors for neonatal sepsis (Manandhar et al., 2021; Bech et al., 2022) [16]. The results highlight the need for early identification of neonates at risk, regular clinical surveillance, lab evaluation in a timely fashion, and early treatment of suspected infection. The associations observed should also be interpreted taking into account the retrospective design and the relatively small number of neonates (80) included in the study. However, the findings of the study are clinically relevant to the risk factors and outcome of neonatal sepsis in the analyzed population of patients in the studied hospital.

Conclusion

The present retrospective study demonstrated that neonatal sepsis remains associated with substantial morbidity and mortality despite a favourable overall recovery rate. Among the 80 neonates evaluated, prematurity and low birth weight were common and were significantly associated with adverse clinical outcomes. Lethargy, poor feeding, and respiratory distress were the predominant clinical manifestations, while elevated CRP and abnormal TLC were frequent laboratory abnormalities. Although blood culture positivity was observed in only 26.3% of neonates, culture positivity was significantly associated with adverse outcomes. Overall, 81.3% of neonates recovered, while 33.8% developed complications, 45.0% required hospitalization beyond seven days, and mortality occurred in 11.3%. These findings emphasize the importance of early identification of high-risk neonates, prompt clinical assessment, appropriate laboratory evaluation, timely treatment, and vigilant monitoring to reduce sepsis-related complications and mortality.

References

1. Klingenberg C, Kornelisse RF, Buonocore G, Maier RF, Stocker M. Culture-negative early-onset neonatal sepsis—at the crossroad between efficient sepsis care and antimicrobial stewardship. Frontiers in pediatrics. 2018 Oct 9;6:285.
2. Enweronu-Laryea C, Dickson KE, Moxon SG, Simen-Kapeu A, Nyange C, Niermeyer S, Bégin F, Sobel HL, Lee AC, von Xylander SR, Lawn JE. Basic newborn care and neonatal resuscitation: a multi-country analysis of health

system bottlenecks and potential solutions. BMC pregnancy and childbirth. 2015 Sep 11;15(Suppl 2):S4.
3. G/eyesus T, Moges F, Eshetie S, Yeshitela B, Abate E. Bacterial etiologic agents causing neonatal sepsis and associated risk factors in Gondar, Northwest Ethiopia. BMC pediatrics. 2017 Jun 6;17(1):137.
4. Malik A, Hui CP, Pennie RA, Kirpalani H. Beyond the complete blood cell count and C-reactive protein: a systematic review of modern diagnostic tests for neonatal sepsis. Archives of pediatrics & adolescent medicine. 2003 Jun 1;157(6):511-6.
5. Lamy B, Dargère S, Arendrup MC, Parienti JJ, Tattevin P. How to optimize the use of blood cultures for the diagnosis of bloodstream infections? A state-of-the art. Frontiers in microbiology. 2016 May 12;7:697.
6. Sharma CM, Agrawal RP, Sharan H, Kumar B, Sharma D, Bhatia SS. "Neonatal sepsis": bacteria & their susceptibility pattern towards antibiotics in neonatal intensive care unit. Journal of clinical and diagnostic research: JCDR. 2013 Sep 30;7(11):2511.
7. Upreti N, Rayamajhee B, Sherchan SP, Choudhari MK, Banjara MR. Prevalence of methicillin resistant Staphylococcus aureus, multidrug resistant and extended spectrum β-lactamase producing gram negative bacilli causing wound infections at a tertiary care hospital of Nepal. Antimicrobial Resistance & Infection Control. 2018 Oct 8;7(1):121.
8. Sharma CM, Agrawal RP, Sharan H, Kumar B, Sharma D, Bhatia SS. "Neonatal sepsis": bacteria & their susceptibility pattern towards antibiotics in neonatal intensive care unit. Journal of clinical and diagnostic research: JCDR. 2013 Sep 30;7(11):2511.
9. Murthy S, Godinho MA, Guddattu V, Lewis LE, Nair NS. Risk factors of neonatal sepsis in India: A systematic review and meta-analysis. PloS one. 2019 Apr 25;14(4):e0215683.
10. Bech CM, Stensgaard CN, Lund S, Holm-Hansen C, Brok JS, Nygaard U, Poulsen A. Risk factors for neonatal sepsis in Sub-Saharan Africa: a systematic review with meta-analysis. BMJ open. 2022 Sep;12(9):e054491.
11. Rafi MA, Miah MM, Wadood MA, Hossain MG. Risk factors and etiology of neonatal sepsis after hospital delivery: A case-control study in a tertiary care hospital of Rajshahi, Bangladesh. PloS one. 2020 Nov 13;15(11):e0242275.
12. Nyma Z, Rahman M, Hasan SM, Roby NU, Khanam F, Alam ME, Ali M. Prevalence and associated risk factors of sepsis among neonates admitted into neonatal intensive care units of public hospitals in Dhaka. Cureus. 2020 Mar 29;12(3).
13. Adatara P, Afaya A, Salia SM, Afaya RA, Konlan KD, Agyabeng-Fandoh E, Agbinku E, Ayandayo EA, Boahene IG. Risk factors associated with neonatal sepsis: a case study at a specialist hospital in Ghana. The Scientific World Journal. 2019;2019(1):9369051.
14. Kamel AS, Abd El Moktader AM, Abd El Reheem F, Sayed MA. Incidence and risk factors of urinary tract infection in neonatal sepsis. Beni-Suef University Journal of Basic and Applied Sciences. 2022 Jun 27;11(1):87.
15. Fleischmann C, Reichert F, Cassini A, Horner R, Harder T, Markwart R, Tröndle M, Savova Y, Kissoon N, Schlattmann P, Reinhart K. Global incidence and mortality of neonatal sepsis: a systematic review and meta-analysis. Archives of disease in childhood. 2021 Aug;106(8):745-52.
16. Manandhar S, Amatya P, Ansari I, Joshi N, Maharjan N, Dongol S, Basnyat B, Dixit SM, Baker S, Karkey A. Risk factors for the development of neonatal sepsis in a neonatal intensive care unit of a tertiary care hospital of Nepal. BMC infectious diseases. 2021 Jun 9;21(1):546.