International Journal of Medicine
pISSN 1468-3814 | eISSN 2667-7008
https://theinternationalmedicine.com/

Original Researcher Article *DOI: 10.61336/im/26-3-28*

CLINICAL PROFILE OF NEONATES WITH NEONATAL SEPSIS ADMITTED TO THE NICU OF A TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY

Dr. Anil Bajaj[1], Dr. Nilesh More[2], Dr. Sandeep Dankhade*[3]

[1,2,3]*Associate Professor, Department of Paediatrics, Dr. Rajendra Gode Medical College, Amravati.*

Correspondence:
Dr. Sandeep Dankhade
Associate Professor, Department of Paediatrics, Dr. Rajendra Gode Medical College, Amravati . ***ORCID ID:0009-0002-2669-4859***

Received: **February 04, 2026**
Revised: **February 25, 2026**
Accepted: **March 04, 2026**
Published: **March 16, 2026**

Abstract

Background: *Neonatal sepsis remains a major cause of neonatal morbidity and mortality worldwide, particularly in developing countries. Early identification of risk factors and clinical features is essential for prompt diagnosis and management.* ***Objectives:*** *To evaluate the clinical profile, maternal risk factors, microbiological pattern, management strategies, and outcomes of neonates with neonatal sepsis admitted to the neonatal intensive care unit (NICU) of a tertiary care hospital.* **Methods***: A hospital-based cross-sectional study was conducted in the NICU of the Department of Paediatrics over a period of 18 months from May 2024 to December 2025. A total of 180 neonates with clinically suspected or confirmed neonatal sepsis were included using convenience sampling. Data regarding maternal and neonatal risk factors, clinical manifestations, laboratory findings, and outcomes were collected using a structured case record proforma. Laboratory investigations included complete blood count, C-reactive protein, sepsis screening parameters, and blood culture. Data were analyzed using SPSS software, and associations between categorical variables were assessed using the Chi-square test with $p < 0.05$ considered statistically significant.* ***Results****: Among the 180 neonates studied, male neonates constituted 60.6% and preterm infants accounted for 66.7% of cases. Low birth weight was observed in 44.4% of neonates. The majority of deliveries were by lower segment cesarean section (71.7%). Early onset sepsis was the most common presentation (78%), while late onset sepsis occurred in 22% of neonates. Probable sepsis was the most frequent diagnostic category (44.4%), followed by culture-proven sepsis (31.1%) and clinical sepsis (24.4%). Respiratory distress (48.3%) was the most common clinical manifestation, followed by birth asphyxia (19.4%) and low birth weight (18.9%). Among maternal risk factors, pregnancy-induced hypertension (23.9%), need for neonatal resuscitation (19.4%), and gestational diabetes mellitus (10.6%) were most frequently observed. Mechanical ventilation was required in 58.9% of neonates and inotropic support in 32.2%. The overall survival rate was 85%, with a mortality rate of 15%. Culture-proven sepsis showed significantly higher mortality compared with clinical and probable sepsis ($\chi^2 = 35.79$, $p < 0.001$). Candida species (37%) were the most commonly isolated organisms, followed by Pseudomonas (17%) and Klebsiella (17%).* ***Conclusion****: Neonatal sepsis was more common among male neonates, preterm infants, and low birth weight babies. Early onset sepsis constituted the majority of cases. Respiratory distress was the most common presenting feature, and Candida species were the predominant organisms isolated. Culture-proven sepsis was associated with significantly higher mortality. Early identification of high-risk neonates and prompt management are essential to reduce morbidity and mortality associated with neonatal sepsis.*

Keywords: *Neonatal sepsis; Early onset sepsis; Late onset sepsis; Neonatal intensive care unit; Prematurity; Low birth weight; Maternal risk factors; Neonatal mortality.*

INTRODUCTION

Neonatal sepsis is a clinical syndrome characterized by systemic illness resulting from the invasion of pathogenic microorganisms during the neonatal period and is often manifested by nonspecific signs and symptoms [1,2]. When bacterial growth is detected in blood cultures or other normally sterile body fluids, the condition is considered culture-proven sepsis. However, the prevalence and clinical significance of culture-negative sepsis remain subjects of ongoing debate, particularly regarding whether antibiotic therapy should be continued in neonates with suggestive clinical features but negative culture results [3].

Neonatal sepsis is commonly categorized into early-onset and late-onset sepsis depending on the time of onset of symptoms. Early-onset sepsis generally develops within the first 72 hours of life and is usually associated with maternal or perinatal risk factors. In contrast, late-onset sepsis occurs after this period and is commonly associated with nosocomial or environmental

risk factors. Despite advances in neonatal intensive care and antimicrobial therapy, neonatal sepsis continues to remain a significant cause of neonatal morbidity and mortality worldwide [4]. Survivors of neonatal sepsis are also at increased risk of long-term neurodevelopmental complications such as cerebral palsy, hearing impairment, visual deficits, and cognitive impairment, even in cases where cultures are negative but empirical antibiotic therapy is administered [6].

The definitive diagnosis of neonatal sepsis traditionally relies on microbiological culture techniques, particularly blood culture. Although these methods are highly sensitive and capable of detecting low bacterial loads (1–4 CFU/mL), they are often time-consuming. Consequently, clinicians frequently encounter difficulties when managing critically ill neonates with negative blood culture results. The concept of "culture-negative" or "clinical" sepsis has therefore led to a substantial increase in empirical antibiotic use in neonates. Excessive antibiotic exposure in this population has been associated with several unintended adverse outcomes, including necrotizing enterocolitis, invasive fungal infections, bronchopulmonary dysplasia, and increased mortality [7].

Advances in rapid culture techniques, improved infection control measures, antibiotic stewardship programs, and bundled approaches for prevention of central line-associated bloodstream infections (CLABSI) have contributed to reductions in sepsis-related morbidity and mortality in neonatal intensive care units. Nevertheless, there remains a need for more rapid and reliable diagnostic strategies, including molecular diagnostic techniques and other non-culture-based methods, for early detection of neonatal sepsis [8].

Various biomarkers and hematological parameters are currently used as adjunctive tools in the diagnosis of neonatal sepsis in routine clinical practice. However, their interpretation is often challenging because of limited sensitivity and variability in normal reference ranges during the neonatal period. An ideal diagnostic marker should demonstrate high sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Despite extensive research, no single biomarker or combination of biomarkers has yet demonstrated sufficient diagnostic accuracy to be routinely used in clinical practice [9–10].

Therefore, the present study was conducted in a tertiary healthcare facility to evaluate the clinical profile of neonates with neonatal sepsis admitted to the neonatal intensive care unit (NICU), with particular emphasis on risk factors, etiological agents, clinical manifestations, laboratory findings, and management strategies.

MATERIALS AND METHODS

This hospital-based cross-sectional study was conducted in the Neonatal Intensive Care Unit (NICU) of the Department of Paediatrics at a tertiary care hospital. The study population comprised neonates admitted to the NICU who were clinically suspected or diagnosed with neonatal sepsis and fulfilled the predefined inclusion criteria. The study was carried out over a period of 18 months from May 2024 to December 2025.

The sample size was calculated based on the findings reported by Pradeep et al. (2015), who observed that the incidence of blood culture–positive neonatal sepsis was 45.2%. Using this prevalence, the sample size was determined using the formula $n = 4p(100-p)/L^2$, where p represents the estimated prevalence and L denotes the allowable error. With a prevalence of 45.2% and an absolute precision of 7% at a confidence level of 95%, the calculated minimum sample size was 180.

A convenience sampling technique was used, wherein all eligible neonates admitted to the NICU during the study period and meeting the inclusion criteria were included in the study. Neonates were enrolled if they were clinically suspected or diagnosed with neonatal sepsis based on clinical features and laboratory parameters. Clinical features considered suggestive of sepsis included hypothermia, fever, lethargy, poor cry, refusal to feed, convulsions, shock, poor perfusion, prolonged capillary refill time (>3 seconds), bradycardia or tachycardia, respiratory distress, apnea, gasping respiration, and abdominal distension. In addition to clinical findings, neonates with at least two abnormal sepsis screen parameters were considered for inclusion. These laboratory indicators included elevated C-reactive protein (CRP) >6 mg/dL, immature-to-total neutrophil ratio (I/T ratio) >0.2, abnormal absolute neutrophil count based on Monroe's chart for term neonates or Mouzinho's chart for very low birth weight infants, total leukocyte count <5000/mm³, and band cell count ≥20% or >1500 cells/mm³. Blood culture was also performed in suspected cases. Neonates with congenital anomalies identified on clinical examination or history were excluded from the study.

For the purpose of the study, several operational definitions were used. A neonate was defined as an infant aged between birth and 28 days of life. Neonatal sepsis was defined as a clinical syndrome characterized by signs and symptoms of infection with or without bacteremia during the first month of life. Early-onset sepsis (EOS) was defined as sepsis presenting within the first 72 hours of life, whereas late-onset sepsis (LOS) referred to sepsis occurring after 72 hours of life. Probable sepsis was defined as cases with sterile culture but positive sepsis screen and clinical features suggestive of sepsis. Clinical sepsis referred to cases with clinical features suggestive of infection but negative culture and sepsis screen. Culture-proven sepsis was defined as cases in which pathogenic organisms were isolated from blood

culture irrespective of sepsis screen results. Respiratory distress was defined as the presence of abnormal respiratory patterns such as tachypnea, nasal flaring, chest wall retractions, grunting, wheezing, stridor, or dyspnea.

Maternal and neonatal risk factors associated with neonatal sepsis were also recorded. These included low birth weight (<2500 g), prematurity, maternal fever, chorioamnionitis indicated by foul-smelling amniotic fluid, prolonged rupture of membranes (>24 hours), prolonged labor, perinatal asphyxia (Apgar score <4 at 1 minute), and pathological evidence of funisitis or presence of polymorphs in gastric aspirate. Additional clinical indicators such as capillary refill time, cyanosis, tachycardia, bradycardia, and temperature instability were also assessed. Hypothermia was defined as a core body temperature below 36.5°C, whereas hyperthermia was defined as a temperature above 37.5°C.

Data collection was performed using a standardized semi-structured and pre-validated case record proforma. Detailed clinical history, maternal risk factors, neonatal characteristics, and findings of general and systemic examination were recorded for each participant. Laboratory investigations included complete blood count (CBC), absolute neutrophil count, immature-to-total neutrophil ratio, C-reactive protein levels, and blood culture.

For hematological investigations, approximately 1–2 mL of venous blood was collected under strict aseptic precautions using a sterile syringe and transferred into an EDTA vial. The samples were processed in the central pathology laboratory using an automated hematology analyzer (ADVIA Hematology 2120, Siemens). This analyzer operates based on flow cytometry principles, where cells pass individually through a laser beam for identification and counting. Band cells were determined using microscopic examination, and the immature-to-total neutrophil ratio was calculated by dividing the number of immature neutrophils by the total neutrophil count. Absolute neutrophil count was derived by multiplying the total leukocyte count with the proportion of segmented neutrophils and band forms.

C-reactive protein estimation was performed using serum samples collected under aseptic conditions. Approximately 2 mL of blood was drawn into a plain vial, and serum was separated after centrifugation. CRP levels were measured using a fully automated analyzer (Dimension RXL Max, USA) based on particle-enhanced turbidometric immunoassay (PETIA) technology. A CRP value greater than 6 mg/dL was considered suggestive of sepsis.

Blood cultures were obtained prior to initiation of antibiotic therapy. The venipuncture site was disinfected thoroughly using povidone-iodine and alcohol applied in concentric circles and allowed to dry before sample collection. Approximately 1 mL of blood was inoculated into blood culture bottles and processed using the automated Bact/ALERT 3D system (bioMérieux). The system continuously monitored microbial growth, and bottles were incubated for up to seven days. Positive cultures were subcultured on appropriate media including blood agar and MacConkey agar for identification of the causative organisms.

All collected data were entered into Microsoft Excel and subsequently analyzed using statistical software (SPSS version 22 and STATA version 10.1). Quantitative variables were summarized using mean and standard deviation, whereas categorical variables were expressed as frequencies and percentages. Inferential statistics were performed using the Chi-square test to assess associations between categorical variables. A p-value of less than 0.05 was considered statistically significant. Confidentiality of patient information was strictly maintained, and ethical approval for the study was obtained from the Institutional Ethics Committee prior to initiation of the research.

RESULTS

A total of 180 neonates admitted to the neonatal intensive care unit (NICU) with clinically suspected or confirmed neonatal sepsis were included in the study. The demographic and neonatal characteristics of the study population are presented in Table 1. Among the neonates, 109 (60.6%) were males and 71 (39.4%) were females, showing a male predominance among sepsis cases. With regard to gestational age, 120 (66.7%) neonates were preterm, 54 (30%) were term, and 6 (3.3%) were post-term. Analysis of birth weight distribution revealed that 80 (44.4%) neonates had low birth weight (1500–2500 g), 36 (20%) had very low birth weight (1000–1499 g), and 6 (3.3%) had extremely low birth weight (<1000 g), whereas 58 (32.2%) neonates had normal birth weight (>2500 g). Regarding the mode of delivery, the majority of neonates were delivered by lower segment cesarean section (129, 71.7%), while 51 (28.3%) were delivered through normal vaginal delivery

The type of sepsis and diagnostic classification among the study participants are summarized in Table 2. Early onset sepsis was the most common presentation, observed in 140 (78%) neonates, whereas 40 (22%) neonates presented with late onset sepsis. Based on diagnostic criteria, probable sepsis was the most frequently diagnosed category, accounting for 80 (44.4%) cases, followed by culture proven sepsis in 56 (31.1%) cases, and clinical sepsis in 44 (24.4%) cases

Table 1: Demographic and neonatal characteristics of study subjects

Variable	Category	Number (n)	Percentage
Gender	**Male**	109	60.60%
	Female	71	39.40%
Gestational age	**Preterm**	120	66.70%
	Term	54	30.00%
	Post-term	6	3.30%
Birth weight	**ELBW (<1000 g)**	6	3.30%
	VLBW (1000–1499 g)	36	20.00%
	LBW (1500–2500 g)	80	44.40%
	Normal (>2500 g)	58	32.20%
Mode of delivery	**Normal vaginal delivery**	51	28.30%
	LSCS	129	71.70%

Table 2: Type of sepsis and diagnostic classification

Variable	Category	Number (n)	Percentage
Type of sepsis	**Early onset sepsis**	140	78%
	Late onset sepsis	40	22%
Diagnosis	**Clinical sepsis**	44	24.40%
	Probable sepsis	80	44.40%
	Culture proven sepsis	56	31.10%

The clinical features observed among neonates with sepsis are shown in Figure 1. The most common presenting symptom was respiratory distress, observed in 87 (48.3%) neonates. Other frequently noted clinical manifestations included birth asphyxia in 35 (19.4%) neonates, low birth weight or very low birth weight in 34 (18.9%) neonates, and lethargy in 23 (12.8%) neonates. Additional symptoms such as vomiting (7.8%), jaundice (6.7%), refusal to feed (5%), abdominal distension (4.4%), and convulsions (2.8%) were also documented. Meconium stained liquor was noted in a small proportion of cases, while sclerema was not observed in the study population.

The maternal risk factors associated with neonatal sepsis are presented in Table 3. Among these, pregnancy induced hypertension or pre-eclampsia was the most commonly observed maternal risk factor, present in 43 (23.9%) cases, followed by need for neonatal resuscitation at birth in 35 (19.4%) cases. Other risk factors included gestational diabetes mellitus in 19 (10.6%) neonates, prolonged rupture of membranes (>24 hours) in 14 (7.8%) cases, and maternal fever in 5 (2.8%) cases. Intrapartum fever was documented in only 1 (0.6%) case.

Figure 1: Neonatal clinical features associated with sepsis

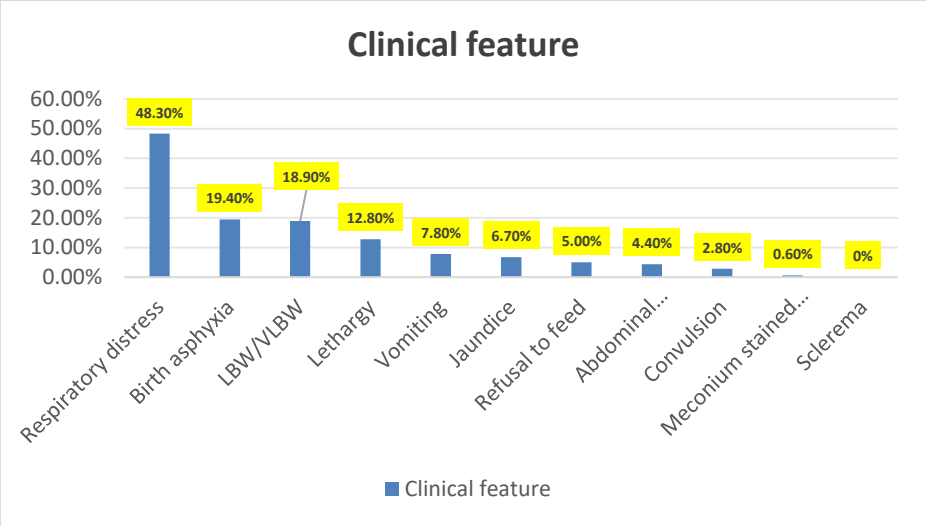

Table 3: Maternal risk factors associated with neonatal sepsis

Maternal risk factor	Number (n)	Percentage
Pregnancy induced hypertension / pre-eclampsia	**43**	23.90%
Need for neonatal resuscitation	**35**	19.40%
Gestational diabetes mellitus	**19**	10.60%
PROM (>24 hours)	**14**	7.80%
Maternal fever	**5**	2.80%
Intrapartum fever	**1**	0.60%

The management strategies, outcomes, and organisms isolated among the study participants are summarized in Table 4. Mechanical ventilation was required in 106 (58.9%) neonates, while 58 (32.2%) neonates required inotropic support. Combined use of inotropes and mechanical ventilation was observed in 60 (33.3%) neonates, indicating severe clinical illness requiring advanced supportive care. Regarding outcomes, the majority of neonates 153 (85%) were discharged successfully, whereas 27 (15%) neonates died during the hospital stay.

Microbiological analysis revealed that Candida species were the most commonly isolated organisms, accounting for 37% of culture positive cases, followed by Pseudomonas species and Klebsiella species (17% each). Other organisms identified included Burkholderia cepacia (11.1%), coagulase negative Staphylococcus (5.5%), Escherichia coli (3.7%), non-fermenting gram-negative bacilli (3.7%), Micrococci species (1.8%), and methicillin resistant Staphylococcus aureus (MRSA) (1.8%).

The association between type of neonatal sepsis and outcome is presented in Table 5. Among the 180 neonates included in the study, survival was highest among neonates with clinical sepsis (95.6%) and probable sepsis (94.9%), whereas a considerably lower survival rate was observed among neonates with culture-proven sepsis (60.7%). Correspondingly, mortality was markedly higher in the culture-proven sepsis group (39.3%) compared to clinical sepsis (4.4%) and probable sepsis (5.1%). Statistical analysis using the Chi-square test demonstrated a highly significant association between type of sepsis and outcome ($\chi^2 = 35.79$, $p < 0.001$), indicating that neonates with culture-proven sepsis had a substantially higher risk of mortality compared to those with clinical or probable sepsis

Table 4: Management, outcome, and organisms isolated

Variable	Category	Number	Percentage
Management	**Inotropes**	58	32.20%
	Mechanical ventilation	106	58.90%
	Inotropes + ventilation	60	33.30%
Outcome	**Discharged**	153	85%
	Death	27	15%
Organisms isolated	**Candida**	21	37%
	Pseudomonas	9	17%
	Klebsiella	9	17%
	Burkholderia cepacia	6	11.10%
	Coagulase negative Staphylococcus	3	5.50%
	Escherichia coli	2	3.70%
	Non-fermenter	2	3.70%
	Micrococci	1	1.80%
	MRSA	1	1.80%

Table 5: Association between type of sepsis and outcome

Outcome	Clinical Sepsis (n=45)	Probable Sepsis (n=79)	Proven Sepsis (n=56)	Total	p value
Survival	43 (95.6%)	75 (94.9%)	34 (60.7%)	152	**<0.001***
Non-survival	2 (4.4%)	4 (5.1%)	22 (39.3%)	28	
Total	**45**	**79**	**56**	**180**	

DISCUSSION

Neonatal sepsis continues to be one of the leading causes of neonatal morbidity and mortality worldwide, particularly in developing countries. It accounts for approximately 30–50% of neonatal deaths, highlighting the substantial burden of this condition on neonatal health systems. Early diagnosis and timely initiation of appropriate antibiotic therapy along with supportive management can significantly reduce the morbidity and mortality associated with neonatal sepsis. Several risk factors such as prematurity, low birth weight, maternal infections, and perinatal complications have been implicated in increasing susceptibility to neonatal infections. The present study was conducted in a tertiary care hospital to evaluate the clinical profile, risk factors, microbiological etiology, management, and outcome of neonates with sepsis admitted to the NICU.

Gender distribution: In the present study, male neonates constituted the majority of cases (60.6%), while 39.4% were females, demonstrating a male predominance among neonates with sepsis. Similar findings have been reported in several previous studies. Berhane M et al observed that 57.9% of neonates with sepsis were males, indicating a higher susceptibility among male neonates

[11]. The reason for this gender difference is not fully understood; however, it has been suggested that genetic and immunological factors may contribute to the increased vulnerability among males. The gene responsible for immunoglobulin synthesis is located on the X chromosome, which may provide relatively better immunological protection to female neonates. Ella Hammad et al also reported that male gender was associated with an increased risk of neonatal sepsis, along with low birth weight and low Apgar scores [12].

Gestational age: Prematurity is a well-recognized risk factor for neonatal sepsis. In the present study, 66.7% of neonates were preterm, while 30% were term neonates, indicating that preterm infants constituted the majority of sepsis cases. This increased susceptibility among preterm neonates can be attributed to their immature immune system, reduced complement activity, and impaired neutrophil function. Additionally, preterm neonates frequently require invasive procedures and prolonged NICU stays, which further increase the risk of infection. Similar observations have been reported by Tallur SS et al, who explained that the immature immune defense mechanisms in preterm neonates predispose them to severe infections [13].

Birth weight: Low birth weight is another important determinant of neonatal sepsis. In the present study, 44.4% of neonates had low birth weight, while 20% had very low birth weight. Only 32.2% of neonates had normal birth weight. These findings suggest that low birth weight neonates constitute a significant proportion of sepsis cases. Berhane M et al also reported that 51.4% of neonates with sepsis had birth weight less than 2500 g [11]. Similarly, Zanatun Nyma et al demonstrated that neonates weighing less than 2.5 kg had more than three times higher risk of developing sepsis compared with neonates with normal birth weight [14]. The increased vulnerability of low birth weight infants may be attributed to immature immune responses, reduced barrier function of the skin and mucosa, and frequent exposure to invasive procedures during NICU care.

Mode of delivery: The present study observed that 71.7% of neonates were delivered by cesarean section, while 28.3% were delivered by normal vaginal delivery. This finding differs from the observations reported by Berhane M et al, where 63% of mothers delivered vaginally [11]. Some studies have suggested that neonates delivered by cesarean section may have increased risk of infection due to delayed establishment of normal microbial flora and higher likelihood of NICU admission. Sathyamurti et al also reported a higher prevalence of neonatal sepsis among infants delivered by cesarean section compared with vaginal delivery [15].

Early onset and late onset sepsis: In the present study, early onset sepsis accounted for 78% of cases, whereas 22% of neonates presented with late onset sepsis. Early onset sepsis was also significantly associated with culture-proven infection in a considerable proportion of cases. The predominance of early onset sepsis may be attributed to ascending infections from the maternal genital tract, prolonged rupture of membranes, and contamination during delivery or resuscitation procedures. Neonates are particularly vulnerable during the first few days of life due to their immature immune responses and limited ability to mount effective inflammatory reactions, which predisposes them to severe infections during the early neonatal period.

Diagnostic classification: In the present study, probable sepsis was the most common diagnosis (44.4%), followed by culture-proven sepsis (31.1%) and clinical sepsis (24.4%). This finding reflects the common challenge in neonatal practice where clinical suspicion of sepsis often exceeds the number of microbiologically confirmed cases. Blood cultures may remain negative due to prior antibiotic exposure, inadequate sample volume, or low bacterial load in neonates. Therefore, sepsis screening parameters and clinical judgment play an important role in diagnosing neonatal sepsis.

Clinical profile of neonates: Respiratory distress was the most common presenting clinical feature (48.3%) in the present study. Other common manifestations included birth asphyxia (19.4%), low birth weight (18.9%), and lethargy (12.8%). These findings are consistent with previous studies. Tallur SS et al and Chacko Betty et al reported that respiratory distress is one of the most frequent clinical manifestations of neonatal sepsis [13]. Similarly, Berhane M et al observed that rapid breathing, fever, poor feeding, respiratory distress, and hypothermia were the most common presenting features in neonates with sepsis [11]. Sathyamurti et al also reported that poor feeding, respiratory distress, and temperature instability were common symptoms among neonates with sepsis [15].

Maternal risk factors: Maternal risk factors play an important role in the development of neonatal sepsis. In the present study, pregnancy induced hypertension, need for neonatal resuscitation, gestational diabetes mellitus, prolonged rupture of membranes, and maternal fever were identified as significant risk factors associated with neonatal sepsis. Similar findings have been reported in other studies. Zanatun Nyma et al found that maternal infections were strongly associated with neonatal sepsis [14]. Ella Hammad et al also reported that chorioamnionitis, prolonged rupture of membranes, and multiple vaginal examinations during labor increased the risk of neonatal infection [12]. Berhane M et al similarly observed that PROM, maternal fever, and need for neonatal resuscitation were commonly associated with neonatal sepsis [11].

Management: Management of neonatal sepsis often requires aggressive supportive care. In the present study,

58.9% of neonates required mechanical ventilation, while 32.2% required inotropic support. Combined use of inotropes and mechanical ventilation was required in 33.3% of neonates, indicating severe illness requiring intensive care. A significantly higher proportion of neonates with culture-proven sepsis required advanced supportive management. These findings highlight the severity of illness among neonates admitted to NICU with sepsis.

Outcome: The overall mortality rate in the present study was 15%. Most neonates (85%) were discharged successfully following treatment. However, a large proportion of deaths occurred among neonates with culture-proven sepsis, indicating that microbiologically confirmed infections were associated with worse outcomes. These findings are consistent with earlier studies. Chacko Betty et al reported a case fatality rate of 19.4%, while Tallur SS et al observed a higher mortality rate of 47.5% among neonates with sepsis in their study [13]. According to Roberton's Textbook of Neonatology, the mortality rate associated with late onset sepsis in neonatal intensive care units is approximately 15%, which is comparable to the findings of the present study [16][17].

Microbiological profile: In the present study, Candida species were the most commonly isolated organisms (37%), followed by Pseudomonas and Klebsiella species (17% each). Other organisms identified included Burkholderia cepacia, coagulase negative Staphylococcus, Escherichia coli, and MRSA. These findings indicate a significant contribution of both fungal and gram-negative bacterial infections in neonatal sepsis. According to the National Neonatal Perinatal Database (NNPD) report, Klebsiella and Staphylococcus aureus were among the most common organisms isolated in neonatal sepsis across Indian centers [18]. Similarly, Sathyamurti et al also reported Klebsiella as the predominant organism causing neonatal sepsis in their study [15]. The predominance of fungal infections observed in the present study may reflect prolonged NICU stay, extensive antibiotic use, and invasive procedures, which increase the risk of opportunistic infections.

The present study demonstrated a significantly higher mortality among neonates with culture-proven sepsis compared to those with clinical or probable sepsis. Nearly two-fifths of neonates with culture-proven sepsis did not survive, highlighting the severe clinical course associated with microbiologically confirmed infection. In contrast, neonates with clinical and probable sepsis had relatively favorable outcomes, with survival rates exceeding 94%. This difference may be explained by the greater severity of systemic infection and higher bacterial load typically observed in culture-positive cases, which often require intensive supportive care and may progress rapidly to septic shock or multi-organ dysfunction. Similar observations have been reported in several studies where culture-proven neonatal sepsis was associated with higher mortality compared to clinically suspected sepsis, emphasizing the importance of early identification and prompt management of severe infections in neonatal intensive care units[]

CONCLUSION

The present study highlights the clinical and epidemiological profile of neonates with sepsis admitted to a tertiary care NICU. Neonatal sepsis was found to occur more frequently among male neonates, preterm infants, and those with low birth weight, indicating that prematurity and low birth weight remain major risk factors for neonatal infections. Early onset sepsis constituted the majority of cases, suggesting that perinatal and maternal factors play a significant role in the development of neonatal sepsis.

Clinical manifestations such as respiratory distress, refusal to feed, lethargy, vomiting, abdominal distension, jaundice, and convulsions were commonly observed, particularly among neonates with culture-proven sepsis. Maternal risk factors including maternal fever, prolonged rupture of membranes, pregnancy-induced hypertension, intrapartum fever, gestational diabetes mellitus, and need for neonatal resuscitation were more frequently associated with culture-positive infections, highlighting the importance of careful antenatal and intrapartum monitoring.

A considerable proportion of neonates required advanced supportive care including mechanical ventilation and inotropic support, indicating the severity of illness among NICU-admitted neonates with sepsis. The overall mortality rate observed in the present study was 15%, with a higher proportion of deaths occurring among neonates with culture-proven sepsis.
Microbiological analysis revealed that Candida species were the most frequently isolated pathogens, followed by Pseudomonas and Klebsiella species, indicating a significant burden of both fungal and gram-negative bacterial infections in neonatal sepsis.

Overall, the findings emphasize the need for early identification of high-risk neonates, strict infection control practices, timely initiation of appropriate antimicrobial therapy, and improved perinatal care in order to reduce the burden of neonatal sepsis and associated mortality in tertiary care settings.

CONFLICT OF INTEREST: None to declare
SOURCES OF FUNDING: None.

REFERENCES

1. Kim F, Polin RA & Hooven TA Neonatal Sepsis. Bmj 371, m3672 (2020).
2. Shane AL, Sá nchez PJ & Stoll BJ Neonatal Sepsis. Lancet 390, 1770– 1780 (2017).

3. Cantey JB & Baird SD Ending the Culture of Culture-Negative Sepsis in the Neonatal Icu. Pediatrics 140 (2017).
4. Zaidi AK et al. Effect of Case Management on Neonatal Mortality Due to Sepsis and Pneumonia. BMC Public Health 11 Suppl 3, S13 (2011).
5. Stoll BJ & Shane AL in Nelson Textbook of Pediatrics Vol. 20 (Kliegman R, Stanton B, St Geme J, Schor N & Behrman R eds.) Ch. 109, 794 (Elsevier, 2013).
6. Weston EJ et al. The Burden of Invasive Early-Onset Neonatal Sepsis in the United States, 2005–2008. Pediatr Infect Dis J 30, 937–941 (2011).
7. Osrin D, Vergnano S & Costello A Serious Bacterial Infections in Newborn Infants in Developing Countries. Curr Opin Infect Dis 17, 217–224 (2004).
8. Oza S, Lawn JE, Hogan DR, Mathers C & Cousens SN Neonatal Cause- of-Death Estimates for the Early and Late Neonatal Periods for 194 Countries: 2000–2013. Bull World Health Organ 93, 19–28 (2015)
9. Brown JVE, Meader N, Wright K, Cleminson J & McGuire W Assessment of C-Reactive Protein Diagnostic Test Accuracy for Late-Onset Infection in Newborn Infants: A Systematic Review and Meta-Analysis. JAMA pediatrics 174, 260–268 (2020).
10. Hedegaard SS, Wisborg K & Hvas AM Diagnostic Utility of Biomarkers for Neonatal Sepsis--a Systematic Review. Infectious diseases (London, England) 47, 117–124 (2015)
11. Berhane M, Gidi NW, Eshetu B, Gashaw M, Tesfaw G, Wieser A, et al. Clinical Profile of Neonates Admitted with Sepsis to Neonatal Intensive Care Unit of Jimma Medical Center, A Tertiary Hospital in Ethiopia. Ethiop J Health Sci. 2021;31(3):485-494.
12. El-Gilany A, Hammad S. Obstetric outcomes of teenagers and older mothers: Experience from Saudi Arabia. Int J Collab Res Intern Med Public Health. 2012;4(6):901.
13. Tallur SS, Kasturi AV. Clinico-bacteriological study of neonatal septicemia in Hubli. Indian J Pediatr. 2000;67(3):169-174.
14. Nyma Z, Rahman M, Hasan SM, Roby NU, Khanam F, Alam ME, et al. Prevalence and Associated Risk Factors of Sepsis among Neonates Admitted into Neonatal Intensive Care Units of Public Hospitals in Dhaka. Cureus. 2020;12(3).
15. Sathyamurthi B, Leela KV, Narayanababu R, Padmanaban, Sreedevi S, Sujatha, et al. Clinical and Bacteriological Profile of Neonatal Sepsis in a Tertiary Care Hospital. Int J Sci Stud. 2016;4(8):57-60.
16. Rennie JM, editor. Rennie & Roberton's Textbook of Neonatology. 5th ed. Edinburgh: Elsevier Churchill Livingstone; 2012.
17. Zakariya BP, Bhat V, Harish BN, Babu TA, Joseph NM. Neonatal sepsis in a tertiary care hospital in South India: bacteriological profile and antibiotic sensitivity pattern. Indian J Pediatr. 2011;78(4):413-417.
18. National Neonatology Forum of India. National Neonatal Perinatal Database (NNPD) 2002–2003. New Delhi: NNF India; 2005.