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Original Research Article

Clinico-epidemiological profile of neonatal sepsis admitted to a tertiary care hospital in Rajasthan: an observational study

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ABSTRACT

Background: Neonatal sepsis remains a cause of neonatal morbidity and mortality, particularly in low- and middle-income countries. Early diagnosis is challenging because of nonspecific clinical manifestations and variation in pathogens. This study evaluated the clinico-epidemiological profile of neonatal sepsis in a hospital in Rajasthan.
Methods: This observational study was conducted in the Neonatal Intensive Care Unit of Jawaharlal Nehru Medical College and Associated Hospitals, Ajmer, Rajasthan, from March 2023 to March 2024. A total of 126 neonates aged 0-28 days with suspected neonatal sepsis were enrolled after parental consent. Neonatal characteristics, clinical findings, laboratory investigations, blood culture and antimicrobial susceptibility were recorded. Data were analysed using SPSS version 23.0.
Results: Out of 126 neonates, 74 (58.7%) presented within the first 7 days and 52 (41.3%) between 8 and 28 days. Males constituted 73 (57.9%) cases. Low birth weight was present in 61 (48.4%) neonates. The presenting symptoms were poor feeding (53.2%), respiratory distress (44.4%) and lethargy (42.1%). Poor suckling was observed in 118 (93.7%) and a toxic or sick appearance in 101 (80.2%) neonates. Blood culture was positive in 33% of cases, while 4% died during hospital admission.
Conclusions: Neonatal sepsis predominantly affected male neonates during the first week of life and was frequently associated with low birth weight. Poor feeding, respiratory distress, lethargy, poor suckling and toxic appearance were the predominant clinical features. Early recognition, microbiological evaluation and timely antimicrobial therapy are essential for improving outcomes. Continued surveillance of epidemiological and antimicrobial susceptibility patterns is important for guiding management.

Keywords: Neonatal sepsis, Neonate, Epidemiology, Clinical profile, Blood culture, Neonatal intensive care unit

INTRODUCTION

Neonatal sepsis remains a major cause of neonatal morbidity and mortality worldwide, with a disproportionately high burden in low and middle-income countries.[1,2] Despite advances in neonatal intensive care, infection prevention and antimicrobial therapy, early diagnosis remains challenging because clinical manifestations are often subtle and nonspecific.[1,3] Neonatal sepsis is broadly classified into early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), occurring thereafter.[4] EOS is generally associated with vertical transmission of maternal pathogens, whereas LOS is more commonly related to healthcare-associated or community-acquired infection.[4,5]

The spectrum of causative organisms varies according to geographical region and healthcare setting, with Gram-negative organisms such as *Klebsiella pneumoniae* and

Escherichia coli frequently reported from developing countries.[6-8] The clinical diagnosis of neonatal sepsis is difficult because manifestations such as poor feeding, lethargy, respiratory distress and temperature instability are nonspecific.[1,4] Blood culture remains the reference standard for microbiological confirmation, although its diagnostic yield may be limited by low bacterial load, inadequate sampling and prior antimicrobial exposure.[3] Continuous surveillance of local pathogens and antimicrobial susceptibility patterns is therefore important for guiding empirical therapy and improving neonatal outcomes.[3,9]

Several studies have described the clinical and microbiological characteristics of neonatal sepsis in different regions; however, regional variations in risk factors, pathogen distribution and clinical presentation necessitate institution-specific data.[6-9] Therefore, the present study was undertaken to evaluate the clinico-epidemiological profile, clinical manifestations, associated risk factors and etiological organisms among neonates admitted with suspected sepsis to a tertiary care hospital in Rajasthan.

METHODS

Study design and setting

This hospital-based observational study was conducted in the Neonatal Intensive Care Unit (NICU), Department of Paediatrics, Jawaharlal Nehru Medical College and Associated Group of Hospitals, Ajmer, Rajasthan, India. The study was carried out over a period of one year from March 2023 to March 2024, after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from the parents or legal guardians of all enrolled neonates before inclusion in the study.

Study population

The study included neonates aged 0-28 days admitted to the NICU with clinical suspicion of neonatal sepsis. A total of 126 neonates fulfilling the eligibility criteria were enrolled consecutively during the study period.

Sample size

The sample size was calculated using the prevalence of neonatal sepsis in India (8%) with a 95% confidence level and an allowable error of 5%. The minimum calculated sample size was 113. After considering a 10% non-response rate, the final sample size was increased to 126 neonates.

Inclusion criteria

Neonates aged 0-28 days admitted to the NICU with clinical features suggestive of neonatal sepsis and/or presence of recognized maternal or neonatal risk factors were included in the study.

Exclusion criteria

Neonates with major congenital malformations, neonates receiving palliative care because of poor prognosis, and those whose parents declined consent were excluded from the study.

Diagnostic criteria

Possible serious bacterial infection was diagnosed according to the World Health Organization (WHO)/Integrated Management of Neonatal and Childhood Illness (IMNCI) 2023 guidelines. Neonates presenting with one or more of the following danger signs were considered clinically suspected cases: convulsions; respiratory rate ≥60 breaths/minute; severe chest indrawing; nasal flaring; grunting; bulging anterior fontanelle; multiple skin pustules or large abscess; axillary temperature ≥37.5°C or <35.5°C; lethargy or unconsciousness; and reduced spontaneous movements.

Study procedure

A detailed maternal and neonatal history was recorded using a structured proforma. Information regarding gestational age, birth weight, sex, place and mode of delivery, maternal risk factors, clinical manifestations, and neonatal examination findings was documented.

All neonates underwent comprehensive clinical examination including assessment of vital signs, anthropometry, general physical examination and systemic examination.

Before initiation of empirical antibiotic therapy, blood samples were collected under strict aseptic precautions for laboratory investigations and microbiological analysis.

Laboratory investigations

The following investigations were performed in all enrolled neonates whenever indicated: complete blood count (CBC); C-reactive protein (CRP); peripheral smear for immature neutrophils; immature-to-total neutrophil (I/T) ratio; blood culture and antibiotic susceptibility testing; cerebrospinal fluid (CSF) examination and culture in suspected meningitis; urine microscopy and culture in suspected urinary tract infection; and chest radiography in suspected pneumonia.

A CRP level >10 mg/L and an I/T ratio >0.20 were considered positive.

Blood cultures were processed according to standard microbiological techniques. Positive cultures were further

identified, and antimicrobial susceptibility testing was performed using standard laboratory protocols.

Operational definitions

Clinical sepsis: Presence of clinical features suggestive of neonatal sepsis irrespective of laboratory findings.

Probable sepsis: Clinical sepsis with two or more positive parameters on the sepsis screen.

Culture-proven sepsis: Clinical sepsis with isolation of a pathogenic organism from blood culture.

Outcome measures

The primary objectives of the study were: to evaluate the epidemiological profile of neonatal sepsis; describe the clinical presentation of neonatal sepsis; identify maternal and neonatal risk factors associated with neonatal sepsis; and determine the etiological organisms responsible for neonatal sepsis and their antimicrobial susceptibility patterns.

Statistical analysis

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics version 23.0. Continuous variables were expressed as mean±standard deviation (SD), whereas categorical variables were summarized as frequencies and percentages. The Student's t-test was used to compare continuous variables, while the Chi-square test was used for categorical variables. A $p<0.05$ was considered statistically significant.

RESULTS

A total of 126 neonates with clinically suspected neonatal sepsis were enrolled during the study period. Of these, 74 (58.7%) presented within the first seven days of life, while 52 (41.3%) were admitted between 8 and 28 days of age, indicating that early neonatal sepsis constituted the majority of cases.

Male neonates predominated, accounting for 73 (57.9%) of the study population, whereas 53 (42.1%) were females (male: female ratio 1.38:1). Most neonates (86.5%) were delivered by normal vaginal delivery, while 13.5% were delivered by lower segment caesarean section (LSCS).

Low birth weight (1500–2499 g) was observed in 48.4% of neonates, whereas 43.7% had normal birth weight. Very low birth weight and extremely low birth weight constituted 6.3% and 1.6% of cases, respectively. The mean age at admission was 8.02±7.06 days, mean birth weight was 2440.55±550.08 g, and mean admission weight was 2447.30±893.47 g.

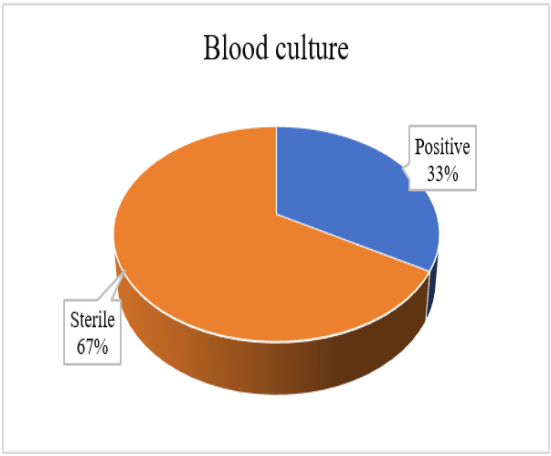


Figure 1: Blood culture among neonates.

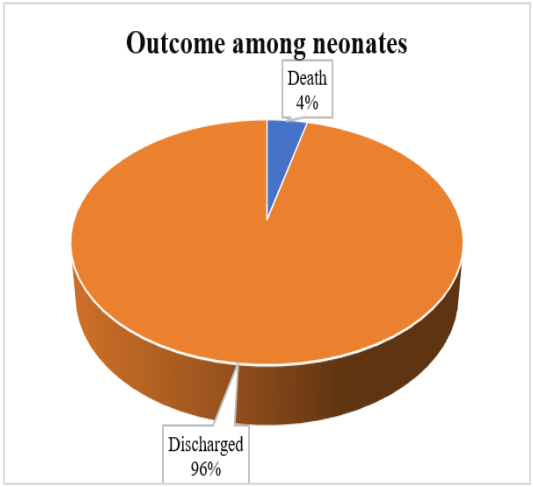


Figure 2: Outcome among neonates.

Table 1: Demographic and birth characteristics of neonates (n=126).

Variables	Number (%)
Age (days)	
1–7	74 (58.7)
8–28	52 (41.3)
Sex	
Male	73 (57.9)
Female	53 (42.1)
Mode of delivery	
NVD	109 (86.5)

Continued.

Variables	Number (%)
LSCS	17 (13.5)
Birth weight	
ELBW (<1000 g)	2 (1.6)
VLBW (1001–1500 g)	8 (6.3)
LBW (1501–2499 g)	61 (48.4)
Normal (2500–4000 g)	55 (43.7)

Table 2: Clinical presentation of neonatal sepsis (n=126).

Clinical feature	Number (%)
Poor feeding	67 (53.2)
Respiratory distress	56 (44.4)
Lethargy	53 (42.1)
Fever	22 (17.5)
Seizures	21 (16.7)
Abdominal distension	20 (15.9)
Vomiting/diarrhoea	16 (12.7)
Bleeding manifestations	6 (4.8)
Poor suckling	118 (93.7)
Feeble cry	40 (31.7)
Limp muscle tone	38 (30.2)

Table 3: Clinical examination findings in neonatal sepsis (n=126).

Examination findings	Number (%)
Sick/toxic appearance	101 (80.2)
Chest indrawing	55 (43.7)
Poor breastfeeding	38 (30.2)
Skin pinch positive	20 (15.9)
Jaundice	15 (11.9)
Bulging anterior fontanelle	4 (3.2)
Skin pustules	2 (1.6)

DISCUSSION

Neonatal sepsis remains an important cause of neonatal morbidity and mortality, particularly in resource-limited settings.[1,2] The present study evaluated the clinico-epidemiological profile of 126 neonates with suspected sepsis admitted to a tertiary care hospital in Rajasthan.

In the present study, 58.7% of neonates presented within the first seven days of life, indicating that early neonatal presentation constituted the majority of cases. A similar predominance of early-onset disease has been reported in studies from Ethiopia and India.[10,11] This pattern is consistent with the established association of early-onset sepsis with maternal and perinatal risk factors and vertical transmission.[4,5]

Male predominance was observed in the present study, with males accounting for 57.9% of cases. A similar male predominance has been reported in studies from Egypt and South India.[11,12] The biological basis for sex differences in neonatal susceptibility to infection has been proposed in the literature, although the observed predominance may also reflect differences in study populations and healthcare-seeking patterns.[1]

Low birth weight was present in 48.4% of neonates, while 6.3% had very low birth weight and 1.6% had extremely low birth weight. A substantial proportion of low-birth-weight neonates has also been reported in other neonatal sepsis studies.[8,12] Low birth weight and prematurity are recognized risk factors for neonatal infection because of immature immune function and increased exposure to invasive procedures and intensive care.[1,4]

Poor feeding was the most common presenting symptom in the present study, occurring in 53.2% of neonates, followed by respiratory distress in 44.4% and lethargy in 42.1%. Studies from India and other settings have similarly reported feeding difficulty, respiratory manifestations and lethargy among common clinical features of neonatal sepsis.[6,11,13,14]

In the study by Kumar et al tachypnoea and chest retractions were reported in 63% and 40% of neonates, respectively, while lethargy and refusal to feed were reported in 35% and 22%; these findings differed from the frequencies observed in the present study.[6] Differences may reflect variation in case definitions, gestational age, timing of presentation and study setting.

Ramírez Carillo et al reported tachypnoea and euthermia among the commonly observed clinical features in their study of early neonatal sepsis, with tachypnoea reported in approximately 54% of cases.[13] The relatively high frequency of respiratory manifestations in both studies emphasizes that respiratory distress may be an important presenting feature of neonatal sepsis, although it is not specific to infection and may also occur with respiratory disorders of the newborn.

On clinical examination, a sick or toxic appearance was observed in 80.2% of neonates, while chest indrawing was present in 43.7%. Poor suckling was particularly frequent, being observed in 93.7% of cases. These findings reinforce the importance of careful clinical assessment because neonatal sepsis frequently presents with nonspecific clinical signs rather than a single characteristic manifestation.[1,3,4] The blood culture positivity rate in the present study was 33.3%. Comparable culture positivity rates have been reported by Sarasam et al, Shehab El-Din et al, Samaga and Jatsho et al with reported rates of approximately 35-41%.[7,8,12,15] The variation in culture positivity between studies may be influenced by prior antibiotic exposure, blood volume obtained for culture, timing of sampling, case definition and differences in laboratory practices.[3]

In the present study, *Staphylococcus aureus* was the most frequently isolated organism, accounting for 9.5% of all enrolled neonates, followed by Pseudomonas species (7.1%) and *Klebsiella* species (5.6%). Zakariya et al also reported Staphylococcus aureus among the important bacterial isolates in a tertiary-care hospital in South India.[11] However, pathogen distribution differs substantially between healthcare settings. For example, studies from other regions have reported a greater predominance of *Klebsiella*, coagulase-negative staphylococci and other gram-negative organisms.[7,8,9,12] Such differences highlight the importance of local microbiological surveillance when selecting empirical antimicrobial therapy.

The distribution of organisms in the present study also differs from the findings of the systematic review and meta-analysis by Yu et al in which coagulase-negative *staphylococci*, *Escherichia coli* and *Klebsiella* species were among the major pathogens reported across neonatal sepsis studies.[9] Differences in pathogen distribution may reflect geographical variation, differences between early and late-onset sepsis, referral patterns, infection-control practices and healthcare-associated exposures.

Maternal intrapartum fever and prolonged rupture of membranes were important maternal risk factors in the present study. Among neonates born to mothers with rupture of membranes exceeding 18 hours, mortality was 19.2%, compared with no mortality among those born after rupture of membranes of less than 18 hours, and this difference was statistically significant. Prolonged rupture of membranes is a recognized risk factor for early-onset neonatal infection because of increased opportunity for ascending infection and vertical transmission of pathogens.[4,5]

Intrapartum fever was present in 25.4% of mothers, and mortality was 15.6% among neonates born to mothers with intrapartum fever compared with no deaths among neonates without this history; the difference was statistically significant. Maternal infection and intrapartum maternal risk factors have been consistently associated with an increased risk of early-onset neonatal infection.[5] Overall mortality in the present study was 4%. Mortality was higher among culture-positive neonates than culture-negative neonates, at 9.5% and 1.2%, respectively; however, this difference was not statistically significant. Mortality and outcome in neonatal sepsis are influenced by several factors, including gestational age, birth weight, severity of illness, pathogen, timing of recognition and availability of intensive care.[1,16]

The present study has the strength of a prospective observational design with systematic assessment of clinical and epidemiological characteristics. However, it was conducted at a single tertiary-care centre with a relatively small sample size, which may limit the generalizability of the findings. Larger multicentre studies incorporating detailed antimicrobial susceptibility data and standardized microbiological methods would provide a broader understanding of neonatal sepsis epidemiology and outcomes.

CONCLUSION

Neonatal sepsis continues to be an important cause of neonatal morbidity in tertiary care settings. In the present study, early-onset sepsis was more common than late-onset sepsis, with a predominance among male and low birth weight neonates. Poor feeding, respiratory distress, lethargy, poor suckling, and toxic appearance were the most frequent clinical manifestations.

Early identification of these clinical features, combined with appropriate laboratory evaluation and prompt initiation of empirical antibiotic therapy, remains essential for improving neonatal outcomes. Continuous surveillance of the clinical profile and local epidemiological patterns is necessary for developing effective diagnostic and therapeutic strategies. Further large-scale multicentre studies are recommended to strengthen the evidence and improve the management of neonatal sepsis.

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