International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A Study of the Clinical Profile, Microbiological Pattern, and Outcomes of Neonatal Sepsis in a Tertiary Care Hospital

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Received: 19-11-2025
Accepted: 10-12-2025
Available online: 18-12-2025

ABSTRACT

Background: Neonatal sepsis remains a leading cause of morbidity and mortality in developing countries, particularly in tertiary care settings where preterm and low-birth-weight infants are highly vulnerable. Understanding its clinical profile, microbial pattern, and outcomes is crucial for improving neonatal survival. **Objectives:** To study the clinical profile, causative organisms, antimicrobial patterns, and outcomes of neonatal sepsis in a tertiary care hospital. **Material & Methods:** This observational study included 150 neonates diagnosed with sepsis based on clinical features and laboratory criteria. Detailed maternal and neonatal data were collected. Blood cultures were performed, and outcomes assessed until discharge or death. **Results:** Early-onset sepsis accounted for most cases. Prematurity and low birth weight were major risk factors. Gram-negative organisms predominated, with Klebsiella pneumoniae and Escherichia coli being the most common isolates. The overall survival rate was 88%, with a 12% mortality rate. Higher mortality was associated with prematurity, septic shock, and gram-negative infections. **Conclusion:** Neonatal sepsis continues to pose significant challenges, particularly due to gram-negative pathogens and antimicrobial resistance. Early diagnosis, robust infection control practices, rational antibiotic use, and improved NICU care are essential for reducing sepsis-related mortality.

Keywords: Clinical Profile, Neonatal Sepsis, Preterm, Antimicrobial Resistance, Early Onset Sepsis, Late Onset Sepsis

INTRODUCTION

Neonatal sepsis remains one of the leading causes of morbidity and mortality among newborns worldwide, particularly in low- and middle-income countries. It is defined as a systemic clinical syndrome characterized by signs and symptoms of infection in the first 28 days of life, accompanied by bacteremia or a strong clinical suspicion of infection. Despite advances in perinatal care, early diagnosis, and antimicrobial therapy, sepsis continues to pose a major challenge in neonatal intensive care units (NICUs) due to its varied clinical presentation, rapid progression, and increasing antimicrobial resistance. Globally, an estimated three million cases of neonatal sepsis occur annually, resulting in over 500,000 deaths, with the highest burden in South Asia and Sub-Saharan Africa. (1)

Neonatal sepsis may be categorized as early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), occurring after 72 hours. The etiological and risk factor profiles differ between the two categories. EOS is largely associated with maternal factors such as chorio-amnionitis, prolonged rupture of membranes, maternal fever, and intrapartum colonization with organisms such as Group B Streptococcus and Escherichia coli. (2) In contrast, LOS is

more often related to nosocomial or community-acquired infections and is frequently associated with prolonged hospitalization, invasive procedures, mechanical ventilation, and poor infection control practices. (3)

The clinical manifestations of neonatal sepsis are often subtle and nonspecific, including poor feeding, lethargy, temperature instability, respiratory distress, irritability, seizures, and circulatory dysfunction. These nonspecific features make early diagnosis challenging, particularly in resource-limited settings where advanced diagnostic modalities may not be readily available.(4) Laboratory parameters such as complete blood counts, C-reactive protein, procalcitonin, blood cultures, and sepsis screening tools aid in diagnosis, but each has limitations in sensitivity and specificity. Blood culture remains the gold standard for diagnosis, yet culture positivity rates vary widely from 10–60% due to prior antibiotic exposure, low bacteremia levels, and inadequate laboratory facilities.(5)

The microbiological profile of neonatal sepsis shows wide regional variation and is influenced by local antimicrobial policies, hygiene practices, and healthcare infrastructure. In many Indian tertiary care hospitals, Gram-negative organisms such as Klebsiella pneumoniae, Acinetobacter spp., and Escherichia coli are commonly isolated, whereas Gram-positive organisms such as Staphylococcus aureus and coagulase-negative staphylococci are significant contributors, particularly in LOS.(6) The rising trend of multidrug-resistant (MDR) organisms, including extended-spectrum beta-lactamase (ESBL) producers and carbapenem-resistant strains, has further complicated treatment strategies.(7)

The outcomes of neonatal sepsis depend on early recognition, timely initiation of appropriate antimicrobial therapy, supportive care, gestational age, birth weight, and comorbidities. Preterm and low-birth-weight neonates are particularly vulnerable due to immature immune systems and higher susceptibility to invasive procedures.(8) Mortality from neonatal sepsis in India remains unacceptably high, with reported rates ranging from 20% to 40%, especially in rural and resource-constrained settings.(9) Long-term complications may include neuro-developmental impairment, hearing deficits, visual disturbances, and chronic lung disease, which underscore the importance of prompt and effective management.(10)

With this background, the study aims to assess the clinical profile, microbiological characteristics, and outcomes of neonatal sepsis in a tertiary care teaching hospital, thereby contributing valuable evidence to improve neonatal care practices and reduce sepsis-associated mortality.

Material and Methods

Study Design & Setting

A **hospital-based** prospective **observational study** was conducted to evaluate the clinical profile, etiological agents, and outcomes of neonatal sepsis. The study was carried out in the **Neonatal Intensive Care Unit (NICU)** and **Postnatal Ward** of the Department of Pediatrics at a tertiary care teaching hospital in North India over a period of 12 months from October 2024 to September 2025. The hospital caters to both rural and urban populations and functions as a referral center for high-risk pregnancies and critically ill neonates.

Study Population

All neonates admitted to the NICU with **clinical suspicion of sepsis** or **laboratory confirmed sepsis** were considered for inclusion in the study. A total of 150 neonates were finally included in the study based on convenient sampling technique meeting the inclusion criteria.

Inclusion Criteria

Neonates fulfilling any of the following criteria were included in the study:

1. Age **0–28 days** at the time of admission.
2. Presence of **clinical signs suggestive of sepsis**, such as:
    - Poor feeding
    - Lethargy or irritability
    - Temperature instability
    - Respiratory distress, apnea, or grunting
    - Seizures
    - Jaundice or mottling
    - Poor perfusion
3. **Positive sepsis screen**, defined as ≥2 of the following:
    - Abnormal total leukocyte count
    - Elevated C-reactive protein (CRP)
    - Elevated procalcitonin
    - Immature-to-total neutrophil ratio >0.2
4. **Positive blood culture**, confirming bacterial or fungal growth.

Exclusion Criteria

Neonates were excluded if they had:

1. Major congenital anomalies or genetic syndromes.
2. Perinatal asphyxia Grade III (severe HIE), where clinical features could mimic sepsis.
3. Incomplete medical records or refusal of consent by parents/guardians.
4. Neonates transferred after receiving >48 hours of antibiotic therapy outside.

Data Collection Procedure

- Identification and Enrollment of Cases

Eligible neonates were identified at admission by the NICU medical team. Written informed consent was obtained from parents or guardians.

- Clinical Assessment

A detailed clinical evaluation was performed, including:

- Gestational age
- Birth weight
- APGAR scores
- Mode of delivery
- Maternal risk factors (PROM, fever, UTI, chorioamnionitis, etc.)
- Onset of symptoms (early v/s late onset sepsis)
- Clinical manifestations at presentation

- Laboratory Investigations

The following tests were performed for all suspected sepsis cases:

1. **Complete Blood Count (CBC)**
2. **CRP levels** and, when feasible, **procalcitonin**
3. **Blood culture and sensitivity testing**
4. **Sepsis screen parameters**
5. Additional tests based on clinical judgment:
    - Lumbar puncture (CSF analysis)
    - Chest radiograph
    - Serum electrolytes
    - Arterial blood gases
6. Blood cultures were processed using an automated system (e.g., BACTEC/BacTAlert) and organisms identified by standard microbiological methods.

- Treatment Protocol

Neonates with suspected or proven sepsis received:

- Empirical antibiotic therapy according to hospital NICU protocol (e.g., ampicillin + gentamicin or piperacillin-tazobactam, depending on severity).
- Antibiotics were modified according to **culture and sensitivity reports**.
- Supportive care included:
    - Oxygen therapy or mechanical ventilation
    - Intravenous fluids
    - Inotropes if required
    - Phototherapy or exchange transfusion for jaundice
    - Management of shock, seizures, or metabolic derangements

Outcome Measures

- Primary Outcome: **In-hospital mortality** among neonates with sepsis.
- Secondary Outcomes: Clinical complications, Length of NICU stay, Pattern of organisms and antibiotic susceptibility, Comparison between EOS and LOS profiles

Statistical Analysis

Data obtained was entered into Microsoft Excel and analyzed using **SPSS** version 21. Descriptive statistics such as mean, standard deviation, median, frequencies, percentage were evaluated. Chi-square test was used for categorical variables and a **p-value <0.05** was considered statistically significant.

Results

A total of **150 neonates** diagnosed with suspected or confirmed sepsis were included in the study.

Table 1: Baseline Characteristics of Study Population (n = 150)

Variable	Number (n)	Percentage (%)
Gender		
Male	88	58.7
Female	62	41.3
Gestational Age		
Preterm (<37 weeks)	64	42.7
Term (≥37 weeks)	86	57.3
Birth Weight Category		
<1500 g (VLBW)	22	14.7
1500–2499 g (LBW)	67	44.7
≥2500 g	61	40.6
Mode of Delivery		
Vaginal delivery	102	68
Cesarean section	48	32

- Majority were **male (58.7%)** and **term neonates (57.3%).**

Table 2: Clinical Features at Presentation

Clinical Feature	Number (n)*	Percentage (%)
Respiratory distress	92	61.3
Poor feeding	78	52
Lethargy/irritability	71	47.3
Fever/hypothermia	63	42
Jaundice	58	38.7
Seizures	21	14
Abdominal distension	18	12

**Multiple Responses*

- Most common symptom: respiratory distress (61.3%).

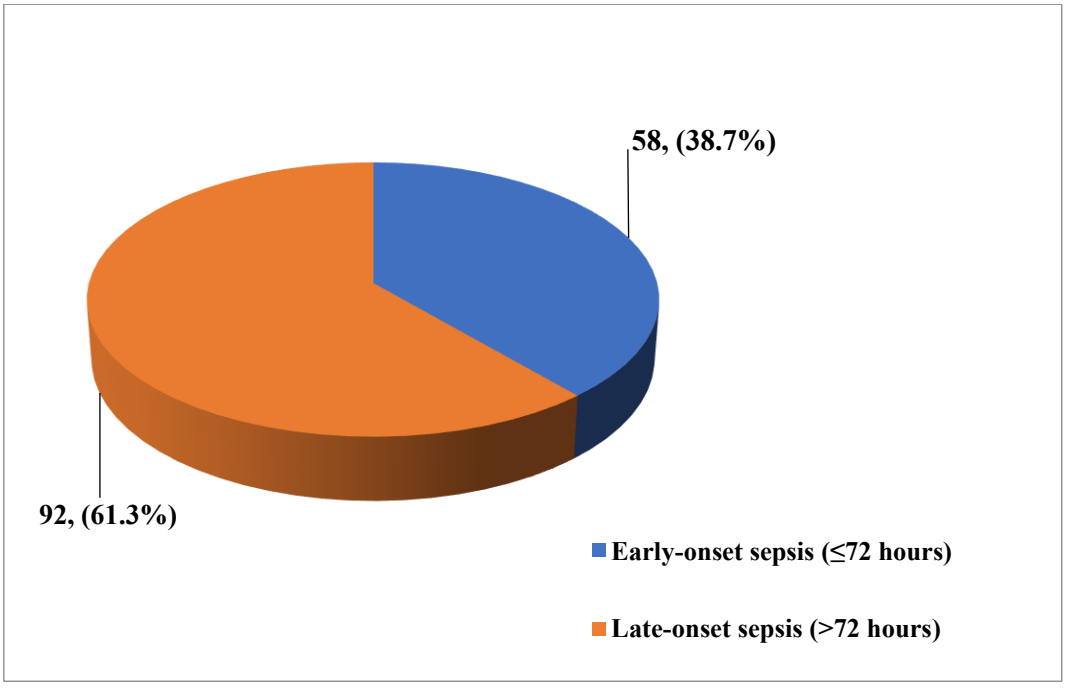

Fig.1: Distribution of Type of Sepsis

- Late-onset sepsis constituted the majority (61.3%).

Table 3: Hematological and Sepsis Screen Parameters

Parameter	Abnormal n (%)*
Leukocytosis / Leukopenia	69 (46%)
Elevated CRP (>10 mg/L)	104 (69.3%)
Procalcitonin elevated	88 (58.7%)
I/T ratio >0.2	61 (40.7%)
Positive sepsis screen (≥2 parameters)	112 (74.7%)

*Multiple Responses

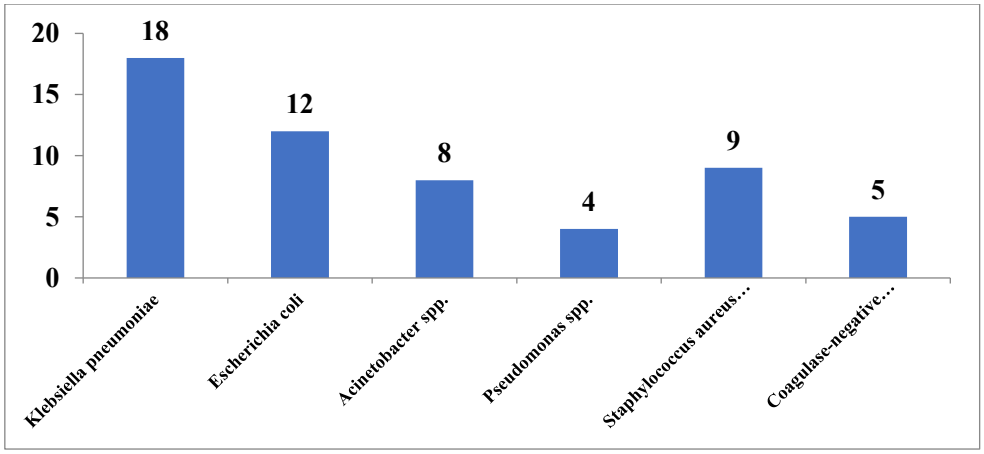

Fig. 2: Microbiological Profile of Culture-Positive Cases (n = 56)

- Blood cultures were positive in **56 of 150 neonates (37.3%).**
- **Klebsiella pneumoniae** was the predominant organism (32.1%).

Table 4: Complications Observed Among Neonates (n = 150)

Complication	Number (n)	Percentage (%)
Septic shock	24	16
Meningitis	13	8.7
Pneumonia	31	20.7
NEC (≥Stage II)	7	4.7
DIC	6	4
Acute kidney injury	11	7.3

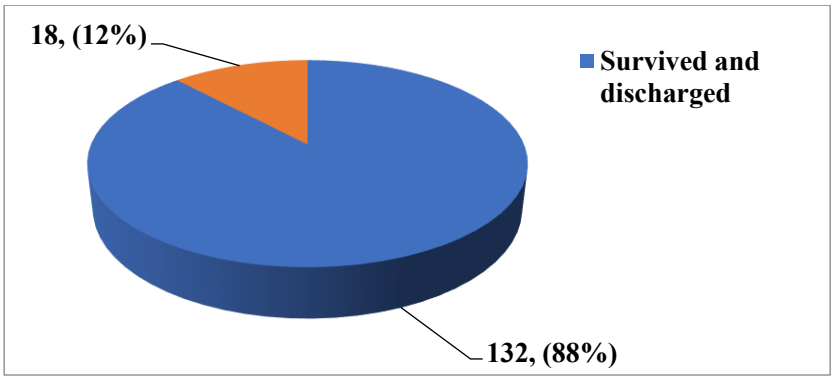

Fig. 3: Treatment Outcome

The **overall mortality rate was 12%.*

Table 5: Comparison of Survivors v/s Non-survivors

Mortality was significantly higher among preterm neonates, VLBW babies, culture-positive sepsis, and those requiring mechanical ventilation.

Parameter	Survivors (n=132)	Non-survivors (n=18)	p-value
Preterm (%)	39.4%	72.2%	<0.01*
VLBW (%)	10.6%	38.8%	<0.01*
Positive blood culture (%)	30.3%	61.1%	<0.05*
Presence of shock (%)	9%	61%	<0.001*
Mechanical ventilation (%)	22%	78%	<0.001*

**Statistically significant*

- Overall mortality was 12%, higher in preterm and VLBW neonates

Discussion

In the present study involving 150 neonates, we analyzed demographic patterns, clinical features, microbiological profile, and outcomes of neonatal sepsis in a tertiary care hospital. The findings highlight important trends that align with national and global data.

In our study, the majority of neonates were males (58.7%). This male preponderance has been consistently observed in previous studies and may be attributed to the presence of sepsis-related genes on the X-chromosome, making male neonates more susceptible to infections (11, 12). The proportion of preterm babies was high (42.7%), which is clinically significant since prematurity is a well-known risk factor for sepsis due to immature immunity, poor skin barrier, and increased requirement of invasive procedures (13).

Late-onset sepsis (LOS) constituted 61.3% of cases in our study, which is comparable to findings from studies in India and Southeast Asia where LOS ranges from 55–70% (14, 15). Higher LOS incidence often reflects nosocomial infections and prolonged hospitalization in NICUs where invasive devices, mechanical ventilation, and parenteral nutrition increase infection risk.

Respiratory distress (61.3%), poor feeding (52%), lethargy (47.3%), and fever or temperature instability (42%) were the most common clinical manifestations. Similar findings have been documented by Kaiser et al., emphasizing that symptoms of neonatal sepsis are nonspecific and may overlap with other neonatal illnesses, making early diagnosis challenging (16).

The blood culture positivity rate in our study was 37.3%, which falls within the reported range of 20–40% in most Indian studies (17, 18). Culture positivity varies widely due to prior antibiotic exposure, timing of sample collection, and laboratory capabilities. Despite the limitations of blood culture, it remains the gold standard for confirming sepsis.

Among culture-positive cases, **Klebsiella pneumoniae** was the most frequently isolated pathogen (32.1%), followed by **Escherichia coli** (21.4%) and **Acinetobacter spp.** (14.3%). The predominance of Gram-negative organisms is consistent with reports from India and other developing countries where NICU-acquired infections are common (19, 20). In contrast, Gram-positive organisms like Staphylococcus aureus and CONS accounted for a smaller proportion (16.1% and 8.9%, respectively). The high prevalence of Gram-negative organisms highlights a pressing need for strict infection-control practices.

Antibiotic resistance was notable in our findings. Gram-negative isolates displayed high sensitivity to carbapenems (71%) and moderate sensitivity to amikacin (63%), whereas sensitivity to third-generation cephalosporins was low. This pattern is similar to trends reported by the National Neonatal Perinatal Database (NNPD), which emphasizes rising multidrug resistance in NICUs (21). Gram-positive organisms showed high susceptibility to vancomycin (86%) and linezolid (92%). Judicious use of antibiotics and routine antimicrobial surveillance are essential to reduce the spread of resistant strains.

Complications were frequent, with pneumonia (20.7%), septic shock (16%), meningitis (8.7%), and AKI (7.3%) being the most observed. Studies by Lawn et al. also highlight that sepsis-related complications significantly increase mortality and long-term neurological impairment (22). In our analysis, septic shock and need for mechanical ventilation were strongly associated with mortality, emphasizing their prognostic significance.

The overall mortality rate in our study was **12%,** which is comparable to rates reported from other tertiary care centers in India, ranging from 10–20% (23, 24). Mortality was significantly higher among preterm neonates, VLBW infants, and

those with culture-positive sepsis—findings consistent with global literature (25). The immature immune system in preterm babies and the virulence of Gram-negative organisms likely contribute to poorer outcomes.

Early-onset sepsis accounted for fewer deaths than LOS, which aligns with Mayers et al. who reported that LOS, particularly with Gram-negative pathogens, carries a higher mortality risk due to delayed identification and potential nosocomial sources (26).

Recommendations

1. Strengthen Infection Control Measures: Strict hand hygiene, aseptic techniques, and standardized NICU protocols should be reinforced to reduce hospital-acquired infections.
2. Regular Microbial Surveillance: Periodic monitoring of organism patterns and antibiotic susceptibility profiles is essential to update empirical therapy guidelines.
3. Early Identification of High-Risk Neonates: Routine screening of preterm, low-birth-weight, and maternal risk-factor cases can enable timely intervention.
4. Rational Antibiotic Use: Antimicrobial stewardship programs should be implemented to prevent resistance and ensure optimal therapy.

Limitations

1. Sample size & Observational Design: Larger sample sizes may provide more robust statistical significance & Causality cannot be established, and unmeasured confounders may influence outcomes.
2. Antibiotic Exposure Prior to Sampling: Some neonates may have received antibiotics before culture, affecting organism detection.
3. Short Follow-up Period: Long-term neuro-developmental outcomes were not assessed.
4. Exclusion of Certain High-Risk Groups: Neonates referred late or with incomplete records were excluded, potentially causing selection bias.

Conclusion

Despite timely diagnosis and standardized treatment, mortality remained significant, underscoring the challenges in managing severe infections and antimicrobial resistance. Improved infection control practices, rational antibiotic use, early recognition of risk factors, and strengthened neonatal intensive care services are essential to improving outcomes. Continuous surveillance and periodic assessment of microbial patterns are crucial for guiding effective therapy.

Conflict of Interest: None
Source of Funding: None

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