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Original Research Article

Clinico-Microbiological Profile and Outcomes of Neonatal Sepsis in A Tertiary Care NICU

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Abstract

Background: Neonatal sepsis is a major cause of neonatal morbidity and mortality, particularly in developing countries.

Aim: To evaluate the clinico-microbiological profile and outcomes of neonatal sepsis in a tertiary care NICU.

Materials and Methods: This prospective observational study was conducted in the Department of Paediatrics at Chirayu Medical College & Hospital, Bhopal, over 6 months (September 2025–February 2026). A total of 80 neonates with suspected sepsis were included. Clinical features, blood culture findings, and outcomes were analysed.

Results: Culture positivity was observed in 34 (42.5%) cases. Early-onset and late-onset sepsis were nearly equally distributed. Respiratory distress (65%), feeding intolerance (57.5%), and lethargy (50%) were the most common clinical features. Gram-negative organisms predominated, with Klebsiella pneumoniae (41.2%) being the most common isolate, followed by Staphylococcus aureus (29.4%) and Escherichia coli (17.6%). All neonates (100%) recovered and were discharged, with no mortality observed.

Conclusion: Neonatal sepsis in this setting was predominantly caused by Gram-negative organisms and presented with nonspecific clinical features. Early diagnosis and effective NICU management were associated with favourable outcomes.

Keywords: Neonatal Sepsis, NICU, Microbiological Profile, Gram-Negative Bacteria, Outcomes.

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Introduction

Neonatal sepsis is a life-threatening systemic infection occurring in infants within the first 28 days of life and remains a major contributor to neonatal morbidity and mortality worldwide, particularly in low- and middle-income countries [1]. Despite advances in neonatal care, sepsis accounts for a significant proportion of neonatal deaths, especially in resource-limited settings where early diagnosis and management remain challenging [2,3].

Neonatal sepsis is broadly classified into early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), occurring after 72 hours [2]. EOS is commonly associated with vertical transmission of pathogens from the maternal genital tract, whereas LOS is usually attributed to nosocomial or community-acquired infections [4]. The distinction between EOS and LOS is important as it influences the likely causative organisms and guides empirical antibiotic therapy. The clinical presentation of neonatal sepsis is often subtle and nonspecific, including symptoms such as respiratory distress, lethargy, temperature instability, poor feeding, and apnea [5]. This nonspecificity frequently leads to delays in diagnosis and initiation of appropriate treatment, thereby increasing the risk of adverse outcomes. Laboratory parameters such as C-reactive protein (CRP), complete blood count, and procalcitonin are commonly used as supportive diagnostic tools; however, none are sufficiently sensitive or specific when used alone [6].

Blood culture remains the gold standard for the diagnosis of neonatal sepsis, although it has

limitations such as low sensitivity, prior antibiotic exposure, and delayed reporting of results [1,7]. Furthermore, the microbial spectrum of neonatal sepsis varies geographically and temporally, with a predominance of Gram-negative organisms reported in many developing countries, in contrast to Gram-positive organisms in developed regions [8]. The emergence of multidrug-resistant organisms further complicates management and contributes to increased morbidity, mortality, and healthcare costs [9].

Understanding the local bacteriological profile and antibiotic sensitivity patterns is essential for guiding empirical therapy and improving neonatal outcomes. Periodic surveillance studies are therefore necessary to monitor trends in causative organisms and resistance patterns.

In this context, the present study was undertaken to evaluate the clinicomicrobiological profile and outcomes of neonatal sepsis in a tertiary care neonatal intensive care unit (NICU).

Materials and Methods

Study Design: Prospective observational study.

Study Setting: Department of Paediatrics, NICU, Chirayu Medical College & Hospital, Bhopal.

Study Duration: 6 months (September 2025 – February 2026).

Sample Size: 80 neonates.

Inclusion Criteria

1. Neonates (0–28 days) with clinical suspicion of sepsis
2. Admitted to NICU during study period

Exclusion Criteria

1. Neonates with major congenital anomalies
2. Neonates already on prolonged antibiotic therapy prior to admission

Data Collection

Data was collected using a structured proforma including:

- Demographic details
- Perinatal history
- Clinical features
- Laboratory investigations
- Blood culture results
- Outcomes

Laboratory Investigations

- Complete blood count (CBC)
- C-reactive protein (CRP)
- Blood culture and sensitivity

Outcome Measures

- Survival
- Mortality
- Duration of hospital stay

Statistical Analysis: Data were analyzed using descriptive statistics. Results were expressed as percentages and proportions.

Results

Of the 80 cases of suspected neonatal sepsis included in the present study, organisms were isolated in 34 (42.5%) cases, while 46 (57.5%) cases were unconfirmed by culture [Table/Fig-1].

Table 1: Distribution of cases of neonatal sepsis

Category	Total (n=80)
Confirmed cases of sepsis	34
Unconfirmed by culture	46

Among the study population, male neonates (48; 60%) outnumbered female neonates (32; 40%). Among confirmed cases, 20 were males and 14 were females, whereas among unconfirmed cases, 28 were males and 18 were females.

Table 2: Gender distribution of cases of neonatal sepsis

Gender	Total cases (n=80)	Confirmed (n=34)	Unconfirmed (n=46)
Male infants	48	20	28
Female infants	32	14	18

Based on the timing of onset, early-onset sepsis (≤72 hours) was observed in 42 (52.5%) neonates, while late-onset sepsis (>72 hours to 28 days) was seen in 38 (47.5%) cases. Among confirmed cases, early-onset sepsis was present in 18 (52.9%) neonates and late-onset sepsis in 16 (47.1%) neonates.

Table 3: Early onset and late onset (EOS and LOS) sepsis

Onset	Suspected (n=80)	Confirmed (n=34)
≤72 hours	42 (52.5%)	18 (52.9%)
>72 hours–28 days	38 (47.5%)	16 (47.1%)

Clinical features in suspected cases were predominantly nonspecific. Respiratory distress was the most common presenting feature, observed in 52 (65%) neonates, followed by feeding intolerance in 46 (57.5%) and lethargy in 40 (50%). Temperature instability was noted in 36 (45%) neonates, while seizures were observed in 12 (15%) cases.

Table 4: Clinical features in suspected cases of neonatal sepsis (n=80)

Age	Respiratory distress	Feeding intolerance	Lethargy	Temperature instability	Seizures
≤72 hours	28	24	22	20	6
>72 hours–28 days	24	22	18	16	6
Total (%)	**52 (65%)**	**46 (57.5%)**	**40 (50%)**	**36 (45%)**	**12 (15%)**

In confirmed cases of neonatal sepsis (n=34), respiratory distress remained the most common feature (64.7%), followed by feeding intolerance (58.8%) and lethargy (52.9%). The clinical pattern was similar across early and late onset sepsis.

Table 5: Clinical features in confirmed cases of neonatal sepsis (n=34)

Age	Respiratory distress	Feeding intolerance	Lethargy	Temperature instability	Seizures
≤72 hours	12	10	10	8	3
>72 hours–28 days	10	10	8	8	3
Total (%)	**22 (64.7%)**	**20 (58.8%)**	**18 (52.9%)**	**16 (47.1%)**	**6 (17.6%)**

Among the culture-positive cases, Gram-negative organisms predominated. Klebsiella pneumoniae was the most frequently isolated organism, accounting for 14 (41.2%) cases, followed by Staphylococcus aureus in 10 (29.4%) and Escherichia coli in 6 (17.6%) cases. Enterococcus faecalis and Pseudomonas aeruginosa were isolated in 2 (5.9%) cases each.

Table 6: Organisms isolated in neonatal sepsis (n=34)

Organism	≤72 hours	>72 hours–28 days	Total (%)
Klebsiella pneumoniae	8	6	14 (41.2%)
Staphylococcus aureus	5	5	10 (29.4%)
Escherichia coli	3	3	6 (17.6%)
Enterococcus faecalis	1	1	2 (5.9%)
Pseudomonas aeruginosa	1	1	2 (5.9%)
Total	**18**	**16**	**34**

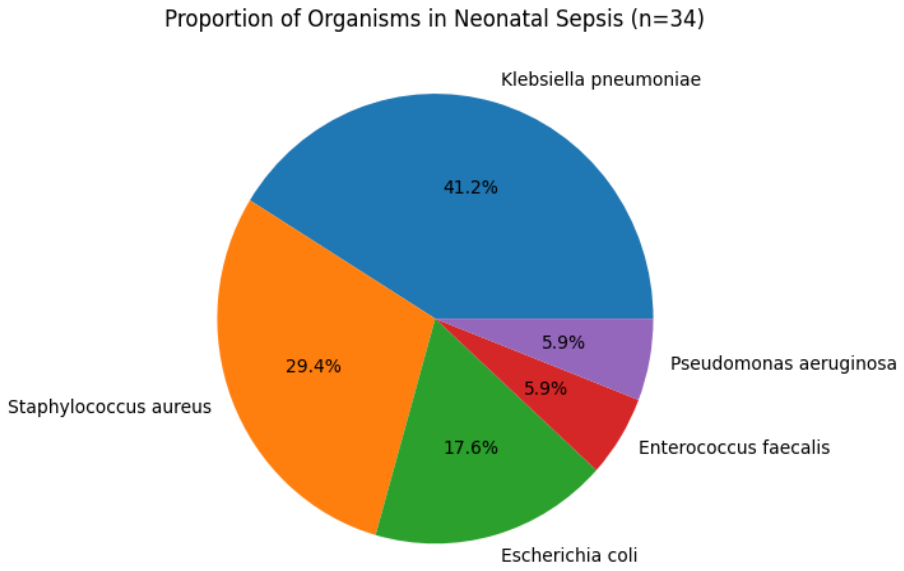

Figure-1: Proportion of organisms isolated in neonatal sepsis showing predominance of Klebsiella pneumoniae (41.2%), followed by Staphylococcus aureus (29.4%), Escherichia coli (17.6%), Enterococcus faecalis (5.9%), and Pseudomonas aeruginosa (5.9%).

All neonates (100%) recovered and were discharged in stable condition, with no mortality observed during the study period.

Overall, respiratory distress, feeding intolerance, and lethargy were the most common clinical features observed in both suspected and confirmed cases. Gram-negative organisms predominated among culture-positive isolates. Notably, all neonates had favourable outcomes with complete recovery.

Discussion

Neonatal sepsis continues to be a major contributor to neonatal morbidity and mortality worldwide, particularly in developing countries, where early diagnosis remains challenging due to its nonspecific clinical presentation [1,2]. The present study provides insight into the clinicomicrobiological profile and outcomes of neonatal sepsis in a tertiary care NICU setting.

The culture positivity rate in this study was 42.5%, which falls within the range reported in previous studies (30–60%) [3,4]. Variability in culture yield across studies can be attributed to factors such as prior antibiotic exposure, timing and volume of blood sampling, and differences in microbiological techniques [5]. The moderate culture positivity observed in the present study highlights that a substantial proportion of clinically suspected cases remain culture-negative, thereby necessitating reliance on clinical and laboratory parameters for diagnosis [6].

A male predominance (60%) was observed in the present study, which is consistent with findings reported in earlier studies [7]. This has been attributed to sex-linked immunological differences, including the presence of immune-regulating genes on the X chromosome, rendering male neonates more susceptible to infections [8].

In the present study, early-onset sepsis (EOS) and late-onset sepsis (LOS) were almost equally distributed. While several studies report a higher incidence of EOS [9], others have demonstrated a comparable distribution between EOS and LOS, reflecting the increasing contribution of nosocomial infections in NICU settings [4, 10]. This finding suggests that both perinatal and hospital-acquired factors play a significant role in the epidemiology of neonatal sepsis in the present setting.

The clinical presentation of neonatal sepsis in this study was largely nonspecific. Respiratory distress was the most common presenting feature, followed by feeding intolerance and lethargy. Similar observations have been reported in previous studies, where respiratory distress, poor feeding, and reduced activity were identified as sensitive indicators of neonatal sepsis [4, 11]. The nonspecific nature of these symptoms underscores the importance of maintaining a high index of suspicion and initiating early empirical therapy in suspected cases [6]. Microbiologically, Gram-negative organisms predominated in the present study, with Klebsiella pneumoniae being the most common isolate (41.2%), followed by Staphylococcus aureus and Escherichia coli. This pattern is consistent with findings from developing countries, where Gram-negative organisms are the leading cause of neonatal sepsis [4, 12]. The predominance of Klebsiella may be attributed to its ability to survive in hospital environments, form biofilms, and develop antimicrobial resistance, making it a common pathogen in NICU-associated infections [13].

The presence of Enterococcus faecalis and Pseudomonas aeruginosa, although less frequent, is clinically significant as these organisms are commonly associated with nosocomial infections and may exhibit multidrug resistance [14]. Their isolation highlights the importance of stringent infection control measures and rational antibiotic use in NICU settings.

A notable finding of the present study was the absence of mortality, with all neonates (100%) recovering and being discharged. This contrasts with previously reported mortality rates ranging from 10% to 30% in neonatal sepsis [2, 12]. The favourable outcomes observed in this study may be attributed to early recognition of clinical signs, prompt initiation of appropriate antimicrobial therapy, availability of advanced neonatal intensive care facilities, and continuous monitoring [15]. Additionally, strict adherence to infection control protocols and effective supportive care may have contributed to improved survival outcomes.

However, the absence of mortality should be interpreted with caution, as it may also be influenced by the relatively small sample size, case selection, and institutional practices. Larger multicentric studies are required to validate these findings and assess their generalisability.

Overall, the present study highlights that neonatal sepsis continues to be predominantly caused by Gram-negative organisms and presents with nonspecific clinical features. Early diagnosis, timely intervention, and robust NICU care can significantly improve clinical outcomes.

Limitations

The present study has certain limitations. It was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalisability of the findings.

Additionally, antibiotic sensitivity patterns and long-term follow-up outcomes were not assessed.

Conclusion

Neonatal sepsis in the present study was predominantly caused by Gram-negative organisms, with respiratory distress being the most common clinical presentation. Early diagnosis and effective NICU management were associated with excellent outcomes and zero mortality.

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