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# Clinical and microbiological profile, treatment requirements, and short-term outcomes of neonatal sepsis: a hospital-based prospective observational cohort study.

***Dr .N. Santosh Kumar[1*], Dr. Vidya Singaravelu[2]***



*[1]Senior Resident, Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India*

*[2]Professor and Head, Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India*

## Abstract

### Background

Neonatal sepsis remains a major cause of neonatal morbidity and mortality, particularly among preterm, low-birth-weight, and outborn neonates. Local surveillance is important because clinical presentation, pathogen distribution, treatment needs, and outcomes vary across neonatal units.

### Objectives

To describe the demographic and perinatal profile, clinical manifestations, microbiological findings, treatment requirements, complications, and short-term in-hospital outcomes of neonates with sepsis.

### Methods

This prospective hospital-based observational cohort study was conducted in the Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, from October 2025 to March 2026. Consecutively admitted neonates aged 0-28 days with suspected sepsis underwent clinical and laboratory assessment, including blood culture, and were followed until discharge or death.

### Results

Among 56 neonates assessed, 50 were analysed. Mean gestational age was 35.9 ± 3.1 weeks; 44.0% were preterm, 48.0% had low birth weight, and 56.0% were outborn. Poor feeding (72.0%), lethargy (66.0%), and respiratory distress (62.0%) were common. Blood cultures were positive in 36.0%; 66.7% of isolates were Gram-negative, with Klebsiella pneumoniae predominant. Respiratory support was required in 58.0%, including invasive ventilation in 30.0%. Complications included septic shock (20.0%), acute kidney injury (12.0%), disseminated intravascular coagulation (8.0%), and meningitis (6.0%). Forty-nine neonates (98.0%) improved and were discharged; one died (2.0%).

### Conclusion

Neonatal sepsis in this cohort showed frequent respiratory compromise and Gram-negative predominance. Most neonates recovered with antimicrobial therapy and supportive care; mortality was low, although the small number of deaths precluded reliable mortality-predictor analysis.

### Recommendations

Neonatal units should strengthen infection prevention, obtain blood cultures before antibiotics whenever feasible, maintain updated local antibiograms, and escalate supportive care promptly in clinically deteriorating neonates.

***Keywords:*** *neonatal sepsis; blood culture; Klebsiella pneumoniae; low birth weight; septic shock; neonatal mortality*

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***Corresponding Author:*** *Dr N. Santosh Kumar*
***Email:*** **santhosh.632@gmail.com**
*Senior Resident, Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India.*

## Introduction

Neonatal sepsis is a systemic infectious illness occurring during the first 28 days of life and remains a major contributor to neonatal morbidity, prolonged hospitalisation, and death. Its clinical recognition is difficult because early manifestations are subtle and overlap with prematurity, respiratory disease, metabolic disturbances, and other neonatal conditions. Poor feeding, reduced activity, temperature instability, respiratory distress, apnoea, impaired perfusion, and seizures can represent evolving infection, but no single sign reliably confirms the diagnosis [1].

The burden is greatest in low- and middle-income settings, where prematurity, low birth weight, delayed referral, limited microbiological capacity, and high rates of antimicrobial resistance converge. Global evidence shows that neonatal and paediatric sepsis incidence and mortality remain substantial, with marked geographic variation and limited population-based data from many resource-constrained regions [2]. In India, multicentre surveillance has demonstrated an important contribution of sepsis to neonatal deaths and a predominance of Gram-negative organisms, including Acinetobacter, Klebsiella, and Escherichia coli [3].

Microbiological diagnosis is clinically valuable because blood culture identifies causative organisms and permits targeted antimicrobial therapy. However, culture positivity is influenced by blood volume, collection technique, prior antibiotic exposure, intermittent bacteraemia, and laboratory infrastructure. Culture-negative clinical sepsis therefore remains common. At the same time, resistance among Gram-negative neonatal pathogens increasingly threatens the effectiveness of conventional empirical regimens, reinforcing the need for unit-specific surveillance and antimicrobial stewardship [4-6].

Mortality is determined not only by the pathogen but also by host vulnerability and illness severity. Prematurity, low birth weight, shock, respiratory failure, metabolic acidosis, thrombocytopenia, delayed presentation, and the need for invasive support have repeatedly been associated with adverse outcomes [7,8]. Early identification of these features can guide monitoring, escalation, counselling, and resource allocation.

The present study was conducted to describe the clinical and microbiological profile of neonatal sepsis in a tertiary-care paediatric department in Hyderabad. The primary objective was to determine short-term in-hospital outcomes. Secondary objectives were to describe perinatal risk factors, presenting manifestations, laboratory abnormalities, bloodstream isolates, treatment requirements, and complications.

## Methodology

### Study design

This was a hospital-based prospective observational cohort study in which consecutively enrolled neonates with suspected sepsis were assessed at admission and followed prospectively until discharge or in-hospital death. Clinical management was determined by the treating paediatric and neonatal teams; the investigators did not allocate treatment or alter routine care.

### Study size

The minimum sample size was estimated using the single-proportion formula $n = Z^2p(1-p)/d^2$. An anticipated blood-culture positivity of 15.3% among clinically suspected neonatal sepsis cases was taken from Siddiqui et al. [9]. Using a 95% confidence level ($Z = 1.96$) and an absolute precision of 10% ($d = 0.10$), $n = (1.96)^2 \times 0.153 \times 0.847/(0.10)^2 = 49.78$. The required sample was therefore rounded up to 50 neonates. Consecutive eligible neonates were enrolled until this target was achieved.

### Study setting and period

The study was conducted in the Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India, from October 2025 to March 2026. The department provides neonatal emergency assessment, inpatient care, non-invasive and invasive respiratory support, vasoactive therapy, microbiological testing, and treatment of referred and inborn neonates.

### Study population and recruitment

Neonates aged 0-28 days who were admitted with suspected sepsis during the study period were assessed for eligibility. Consecutive sampling was used. All eligible neonates presenting during the six-month period were considered, and the final sample comprised participants with complete initial clinical and laboratory evaluation.

#### Inclusion criteria

Neonates were eligible when the treating clinician suspected sepsis on the basis of compatible clinical manifestations, perinatal risk factors, or laboratory abnormalities and initiated a diagnostic sepsis evaluation with antimicrobial treatment.

### Exclusion criteria

Neonates with major congenital anomalies, incomplete essential clinical information, or transfer before completion of the initial evaluation were excluded.

### Definitions

Early-onset sepsis was defined as sepsis presenting within the first 72 hours of life, and late-onset sepsis as presentation after 72 hours through 28 completed days. Preterm birth was defined as gestational age below 37 completed weeks. Low birth weight was defined as birth weight below 2.5 kg, and very low birth weight as below 1.5 kg. Thrombocytopenia was defined as a platelet count below 150,000 cells/mm³. Culture-negative clinical sepsis was assigned when compatible clinical and laboratory findings

prompted treatment but blood culture did not yield a clinically significant pathogen.

## Data collection

A structured case-record form captured gestational age, birth weight, sex, place of birth, onset category, maternal intrapartum fever, prolonged rupture of membranes, foul-smelling amniotic fluid, resuscitation at birth, and presenting manifestations. Clinical assessment included feeding, activity, respiratory status, temperature stability, perfusion, apnoea, seizures, and abdominal distension. Laboratory data included C-reactive protein, leukocyte count, platelet count, acid-base status, and blood-culture results.

## Microbiological assessment

Blood cultures were obtained before empirical antibiotics whenever clinically feasible. Organisms considered clinically significant were recorded by species or organism group. Antimicrobial therapy was modified according to culture and susceptibility findings when an isolate was recovered. Detailed isolate-level susceptibility data were not available in the supplied dataset and were therefore not analysed in this manuscript.

## Treatment and outcome assessment

Treatment requirements included continuous positive airway pressure, invasive mechanical ventilation, vasoactive support, and blood-product transfusion. Recorded complications included septic shock, acute kidney injury, disseminated intravascular coagulation, and meningitis. Participants were followed until discharge or death during hospitalisation. The short-term outcomes assessed were survival status at discharge and duration of hospital stay.

## Measures to address bias

Selection bias was reduced through consecutive assessment using predefined eligibility criteria. Clinical and laboratory variables were recorded using a uniform case-record form. The use of routine clinical practice could introduce variation in investigation timing and treatment decisions. Culture-negative sepsis was susceptible to diagnostic misclassification, while referral status and prior antibiotic exposure could influence culture yield and disease severity.

## Statistical analysis

Continuous variables were summarised as mean ± standard deviation or median with interquartile range, according to distribution. Categorical variables were reported as number and percentage. Because only one in-hospital death occurred, formal survivor-versus-non-survivor comparisons and multivariable mortality modelling were not performed.

## Ethical considerations

The study was conducted after approval from the Institutional Ethics Committee of Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad. Written informed consent was obtained from a parent or legally authorised guardian. Confidentiality was protected through coded records, and clinical management was not altered for research purposes. Reporting was aligned with the STROBE recommendations for observational studies [13].

# Results

## Participant enrolment

During the study period, 56 neonates with suspected sepsis were assessed for eligibility. Six were excluded: three had major congenital anomalies, two had incomplete clinical information, and one was transferred before completion of the initial evaluation. The remaining 50 neonates were included in the final analysis.

## Baseline demographic and perinatal characteristics

The mean gestational age was 35.9 ± 3.1 weeks, and 22 neonates (44.0%) were preterm. Mean birth weight was 2.31 ± 0.72 kg. Low birth weight was documented in 24 neonates (48.0%), including eight (16.0%) weighing below 1.5 kg. Twenty-nine neonates (58.0%) were male. Early-onset sepsis accounted for 31 cases (62.0%), and 28 neonates (56.0%) were outborn. Prolonged rupture of membranes exceeding 18 hours was reported in 14 cases (28.0%), maternal intrapartum fever in eight (16.0%), and foul-smelling amniotic fluid in seven (14.0%) (Table 1).

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**Table 1.** *Demographic, perinatal, and clinical characteristics of the study population (N=50)*

| Characteristic | Value |
|---|---|
| Gestational age, weeks | 35.9 ± 3.1 |
| Preterm birth | 22 (44.0%) |
| Term birth | 28 (56.0%) |
| Birth weight, kg | 2.31 ± 0.72 |
| Birth weight <2.5 kg | 24 (48.0%) |
| Birth weight <1.5 kg | 8 (16.0%) |
| Male | 29 (58.0%) |
| Female | 21 (42.0%) |
| Early-onset sepsis | 31 (62.0%) |
| Late-onset sepsis | 19 (38.0%) |
| Place of birth: Inborn | 22 (44.0%) |
| Place of birth: Outborn | 28 (56.0%) |
| Prolonged rupture of membranes >18 hours | 14 (28.0%) |
| Maternal intrapartum fever | 8 (16.0%) |
| Foul-smelling amniotic fluid | 7 (14.0%) |
| Resuscitation required at birth | 13 (26.0%) |

Data are presented as mean ± standard deviation or number (percentage).

## Clinical presentation and laboratory findings

Poor feeding was the most frequent presenting manifestation, occurring in 36 neonates (72.0%). Lethargy or reduced activity was present in 33 (66.0%), respiratory distress in 31 (62.0%), and temperature instability in 24 (48.0%). Impaired peripheral perfusion was documented in 15 neonates (30.0%), apnoea in 12 (24.0%), abdominal distension in nine (18.0%), and seizures in eight (16.0%). Septic shock requiring fluid resuscitation and vasoactive support developed in ten neonates (20.0%).

C-reactive protein was elevated in 34 neonates (68.0%), an abnormal total leukocyte count was recorded in 27 (54.0%), thrombocytopenia in 22 (44.0%), and metabolic acidosis in 16 (32.0%) (Table 2).

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**Table 2.** *Clinical manifestations and laboratory abnormalities*

| Finding | Number (%) |
|---|---|
| Poor feeding | 36 (72.0%) |
| Lethargy or reduced activity | 33 (66.0%) |
| Respiratory distress | 31 (62.0%) |
| Temperature instability | 24 (48.0%) |
| Impaired peripheral perfusion | 15 (30.0%) |
| Apnoea | 12 (24.0%) |
| Abdominal distension | 9 (18.0%) |
| Seizures | 8 (16.0%) |
| Elevated C-reactive protein | 34 (68.0%) |
| Abnormal leukocyte count | 27 (54.0%) |
| Thrombocytopenia | 22 (44.0%) |
| Metabolic acidosis | 16 (32.0%) |

## Microbiological profile

Blood cultures yielded a clinically significant pathogen in 18 neonates, corresponding to a culture-positivity rate of 36.0%. The remaining 32 neonates (64.0%) were classified as culture-negative clinical sepsis. Gram-negative organisms accounted for 12 of 18 isolates (66.7%), Gram-positive organisms for five (27.8%), and Candida species for one (5.6%). Klebsiella pneumoniae was the leading isolate, identified in six cases (33.3% of positive cultures), followed by Escherichia coli and coagulase-negative staphylococci, with three isolates each (Table 3).

**Table 3.** *Distribution of blood-culture isolates (n=18)*

| Organism group | Isolate | Number | % of positive cultures |
|---|---|---|---|
| Gram-negative organisms | | 12 | 66.7 |
| | Klebsiella pneumoniae | 6 | 33.3 |
| | Escherichia coli | 3 | 16.7 |
| | Acinetobacter species | 2 | 11.1 |
| | Pseudomonas aeruginosa | 1 | 5.6 |
| Gram-positive organisms | | 5 | 27.8 |
| | Coagulase-negative staphylococci | 3 | 16.7 |
| | Staphylococcus aureus | 2 | 11.1 |
| Fungal organism | Candida species | 1 | 5.6 |

Percentages use 18 culture-positive neonates as the denominator.

## Treatment requirements, complications, and outcomes

All neonates received empirical intravenous antimicrobial therapy after appropriate cultures were obtained. Treatment was modified according to culture and antimicrobial susceptibility findings when an organism was isolated. Twenty-nine neonates (58.0%) required respiratory support: 14 (28.0%) received continuous positive airway pressure and 15 (30.0%) required invasive mechanical ventilation. Ten neonates (20.0%) received vasoactive support, and nine (18.0%) received blood products.

The principal complications were septic shock in ten neonates (20.0%), acute kidney injury in six (12.0%), disseminated intravascular coagulation in four (8.0%), and meningitis in three (6.0%). Forty-nine neonates (98.0%) improved and were discharged. One neonate died, producing an in-hospital case-fatality rate of 2.0%. Median hospital stay was 9 days (interquartile range 6-13 days) (Table 4).

**Table 4.** *Treatment requirements, complications, and short-term outcomes*

| Variable | Number (%) or summary |
|---|---|
| Any respiratory support | 29 (58.0%) |
| Continuous positive airway pressure | 14 (28.0%) |
| Invasive mechanical ventilation | 15 (30.0%) |
| Vasoactive drug support | 10 (20.0%) |
| Blood-product transfusion | 9 (18.0%) |
| Septic shock | 10 (20.0%) |
| Acute kidney injury | 6 (12.0%) |
| Disseminated intravascular coagulation | 4 (8.0%) |
| Meningitis | 3 (6.0%) |
| Discharged after clinical improvement | 49 (98.0%) |
| In-hospital mortality | 1 (2.0%) |
| Hospital stay, days | 9 (6-13) |

Hospital stay is presented as median (interquartile range).

## Mortality outcome

Only one of the 50 neonates died during hospitalisation. This single event was insufficient for reliable statistical comparison between survivors and non-survivors; therefore, mortality-associated factors and independent predictors were not estimated.

# Discussion

## Key findings

This study describes a clinically vulnerable neonatal sepsis cohort with high frequencies of prematurity, low birth weight, and referral from outside the study hospital. Poor feeding, lethargy, and respiratory distress were the leading manifestations. More than one-third of blood cultures were positive, two-thirds of isolates were Gram-negative, and Klebsiella pneumoniae was the predominant pathogen. Respiratory support was required in 58.0% of neonates. Forty-nine neonates recovered and were discharged, while one died, corresponding to an in-hospital mortality rate of 2.0%.

## Clinical and perinatal profile

The prominence of poor feeding, lethargy, respiratory distress, temperature instability, and perfusion abnormalities reinforces the non-specific clinical expression of neonatal sepsis. These manifestations resemble those reported in Indian referral cohorts, where respiratory distress, reduced activity, hypothermia, and impaired circulation commonly accompany severe infection [7]. The high proportion of preterm and low-birth-weight neonates is clinically important because immature innate and adaptive immunity, reduced transplacental antibody acquisition, fragile skin and mucosal barriers, and frequent invasive care increase susceptibility to infection [1].

More than half of the neonates were outborn. Referral can introduce delays in recognition and treatment, variable infection-prevention practices, prior antimicrobial exposure, and physiological deterioration during transport. The observed

maternal risk factors, including prolonged rupture of membranes, intrapartum fever, and foul-smelling liquor, support careful maternal and neonatal assessment in early-onset disease, although this study was not designed to estimate causal risk.

## Culture positivity and pathogen distribution

The 36.0% culture-positivity rate was higher than the 15.3% reported in a recent prospective study of clinically suspected neonatal sepsis in northern India [9] and the 17.7% pathogen-positive proportion in the multicountry NeoOBS cohort [6]. Differences in referral severity, eligibility thresholds, prior antibiotic use, blood volume, culture systems, and contamination classification can substantially influence yield. Culture-negative clinical sepsis remained common, illustrating the limited sensitivity of blood culture and the continuing dependence on integrated clinical and laboratory assessment.

Gram-negative organisms constituted 66.7% of isolates, closely resembling the 64% Gram-negative proportion in the Delhi Neonatal Infection Study and the 62.9% proportion in NeoOBS [3,6]. Klebsiella pneumoniae was the leading pathogen, consistent with multicentre and single-centre reports from India and other low- and middle-income settings [3,5,9]. This pattern has major therapeutic implications because Klebsiella and Acinetobacter frequently exhibit resistance to conventional empirical agents and, in some centres, to carbapenems [4,5,10]. The present dataset did not contain isolate-level susceptibility results, so resistance patterns cannot be inferred from organism identity alone.

## Treatment requirements and clinical outcome

The observed in-hospital mortality rate of 2.0% was lower than the mortality reported in the NeoOBS cohort and in several outborn neonatal sepsis studies [6,7,11,12]. Direct comparison should be cautious because the present study included only 50 neonates and one death, while referral severity, birth-weight distribution, pathogen resistance, treatment availability, and outcome definitions vary considerably across settings.

Respiratory support was required in more than half of the cohort, including invasive ventilation in 30.0%, and one-fifth required vasoactive therapy. These treatment requirements indicate substantial acute illness despite the favourable overall survival. However, the occurrence of only one death precluded meaningful assessment of whether shock, acidosis, thrombocytopenia, low birth weight, culture positivity, or invasive ventilation were associated with mortality in this sample.

Accordingly, the study should be interpreted primarily as a descriptive account of clinical presentation, microbiology, treatment intensity, complications, and short-term outcome. Larger cohorts with more outcome events are required to identify independent mortality predictors and to distinguish the effects of host vulnerability, pathogen characteristics, antimicrobial resistance, and treatment delays.

## Clinical implications

The findings support a structured unit-level response. Blood culture should be collected before antibiotics whenever this does not delay treatment. Empirical protocols should be reviewed against a regularly updated local antibiogram, followed by prompt narrowing or adjustment when microbiological results become available. Neonates with low birth weight, thrombocytopenia, acidosis, impaired perfusion, escalating oxygen requirement, or shock require early senior review and rapid access to respiratory and vasoactive support. Infection-prevention bundles, hand hygiene, device-care practices, transport stabilisation, and antimicrobial stewardship are central to reducing preventable sepsis and resistance [4-6,10].

## Generalizability

The findings are most applicable to tertiary neonatal units managing a mixed inborn and outborn population in settings similar to the study centre. Pathogen distribution, culture yield, and mortality can change over time and between hospitals; therefore, the results should not be used as a substitute for local surveillance in other institutions.

## Conclusion

Neonatal sepsis in this tertiary-care cohort was characterised by frequent low birth weight, early-onset presentation, respiratory compromise, inflammatory marker elevation, thrombocytopenia, and Gram-negative bloodstream infection. Klebsiella pneumoniae was the most common isolate. More than half of the neonates required respiratory support. Forty-nine of 50 neonates improved and were discharged, while one died, yielding an in-hospital mortality rate of 2.0%. Early recognition of physiological deterioration, timely microbiological evaluation, effective supportive care, infection prevention, and locally informed antimicrobial stewardship remain essential. Mortality predictors could not be assessed because only one death occurred.

## Limitations

The study involved a small sample from a single centre, and only one death occurred, preventing reliable survivor-versus-non-survivor comparisons or multivariable mortality analysis. Consecutive hospital recruitment does not represent community incidence. Clinical sepsis definitions and routine investigations can introduce diagnostic variability, while prior antibiotics could reduce culture yield. Detailed antimicrobial susceptibility data, timing of antibiotics, pathogen-specific outcomes, and long-term neurodevelopmental follow-up were unavailable.

## Recommendations

The neonatal unit should maintain continuous microbiological and antimicrobial-resistance surveillance, audit blood-culture collection quality, and update empirical antibiotic protocols using local susceptibility data. Low-birth-weight and outborn neonates require intensified early monitoring. Shock, metabolic acidosis,

thrombocytopenia, and worsening respiratory status should trigger immediate escalation because they indicate severe physiological compromise. Multicentre studies with larger samples, standardised sepsis definitions, detailed susceptibility profiles, adequate mortality events, multivariable modelling, and post-discharge follow-up are needed.



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## Conflict of interest

The authors declare no conflict of interest.

## Author contributions

**NSK** contributed to conceptualisation, study design, participant evaluation, data collection, data organisation, literature review, interpretation, and manuscript drafting. **VS** contributed to clinical supervision, methodology, interpretation of findings, critical revision, and overall manuscript oversight.

## Data availability

De-identified data supporting the findings of this study are available from the corresponding author upon reasonable request

## Author biographies

Dr N. Santosh Kumar is a Senior Resident in the Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India. He is involved in paediatric and neonatal clinical care, academic activities, and clinical research.

Dr Vidya Singaravelu is Professor and Head of the Department of Paediatrics, Neelima Institute of Medical Sciences, Ghatkesar, Hyderabad, Telangana, India. She is involved in departmental leadership, undergraduate and postgraduate teaching, paediatric clinical care, neonatal services, and research supervision.

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