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Clinico-Bacteriological Profile and Outcome Analysis of Neonatal Sepsis- A Hospital-Based Study

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Abstract

Background: Neonatal sepsis is a major cause of morbidity and mortality among hospitalised neonates, particularly in resource-limited settings. The clinical presentation is often nonspecific, while the causative organisms and antimicrobial susceptibility patterns vary between healthcare settings. The present study was undertaken to evaluate the clinico-bacteriological profile and outcomes of neonatal sepsis in a tertiary care NICU.

Methods: A descriptive hospital-based observational study was conducted among 150 neonates with suspected neonatal sepsis admitted to the NICU of Karanataka medical College and research institute Hubballi Karnataka, from April 2024 to September 2025. Maternal, perinatal, clinical, laboratory and microbiological parameters were recorded. Neonates were classified into early-onset sepsis (EOS) and late-onset sepsis (LOS). Blood and other relevant cultures were performed as clinically indicated, and antimicrobial susceptibility was assessed. Outcomes including duration of hospitalisation, discharge and mortality were documented. Statistical analysis was performed using appropriate tests, with $p<0.05$ considered statistically significant.

Results: Of the 150 neonates, 85 (56.7%) had EOS and 65 (43.3%) had LOS. Males constituted 54.0% of cases,

while 54.7% had low birth weight and 38.7% were preterm. Respiratory distress was the most common clinical feature (77.3%), followed by lethargy (64.0%) and poor feeding (62.7%). CRP positivity was observed in 69.3% of neonates, while thrombocytopenia occurred in 30.7%. Blood cultures were positive in 53 (35.3%) cases.

Among the reported isolates, Klebsiella pneumoniae was predominant (29.4%), followed by Staphylococcus aureus (17.6%). Among Gram-negative isolates, the highest sensitivity was observed with colistin (96.8%), followed by tigecycline (78.6%) and meropenem (77.4%). PROM was significantly associated with EOS (p=0.0297), while poor feeding was significantly more frequent in LOS (p=0.0082). Overall, 145 (96.7%) neonates were discharged and 5 (3.3%) expired. Blood culture positivity was significantly associated with mortality (p=0.0049).

Conclusion: Neonatal sepsis demonstrated a diverse clinical and bacteriological profile, with Gram-negative organisms predominating and significant antimicrobial resistance observed. Blood culture positivity was strongly associated with mortality. Early recognition, timely microbiological diagnosis and appropriate culture-guided antimicrobial therapy are essential to improve neonatal outcomes.

Keywords: Neonatal Sepsis, Early-Onset Sepsis, Late-Onset Sepsis, Blood Culture, Klebsiella Pneumoniae, Antimicrobial Susceptibility, NICU, Mortality.

Introduction

Neonatal sepsis is a serious systemic infection occurring during the neonatal period and remains an important cause of neonatal morbidity and mortality, particularly in low- and middle-income countries. Early recognition and prompt treatment are essential because neonates may deteriorate rapidly, while the initial clinical manifestations are frequently nonspecific. The World Health Organization emphasizes early identification, appropriate diagnostic evaluation and timely antimicrobial therapy for infants with suspected serious bacterial infection.[1,2]

Neonatal sepsis is commonly categorized according to the age at onset into early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), occurring after 72 hours. EOS is generally associated with maternal and perinatal factors, including premature rupture of membranes (PROM), maternal infection and intra partum complications, whereas LOS is more frequently associated with prolonged hospitalization, invasive procedures and exposure to healthcare-associated organisms. [3,4]

Prematurity and low birth weight are important risk factors for neonatal sepsis because immature immune responses, impaired epithelial barriers and increased requirement for invasive interventions increase susceptibility to infection. In addition, neonatal sepsis may present with respiratory distress, poor feeding, lethargy, apnea, temperature instability, seizures and other nonspecific manifestations.[3,5]

The diagnosis of neonatal sepsis remains challenging because no single clinical or laboratory parameter has sufficient sensitivity and specificity to reliably confirm or exclude infection. Total leukocyte count, platelet count and inflammatory markers such as C-reactive protein (CRP) are commonly used as supportive investigations. However, their diagnostic value depends on the timing of testing and the clinical context. Blood culture remains an important method for microbiological confirmation and identification of the causative organism, although its sensitivity can be affected by

prior antibiotic administration and inadequate blood volume.[2,6]

The bacteriological profile of neonatal sepsis varies considerably between geographical regions and individual neonatal intensive care units (NICUs). Indian studies have frequently reported predominance of Gram-negative organisms, particularly Klebsiella pneumoniae, Escherichia coli and Acinetobacter spp., although Gram-positive organisms and Candida species also contribute substantially.[7-10] A large Indian cohort study reported that nearly two-thirds of culture-confirmed isolates were Gram-negative, with Acinetobacter, Klebsiella and E. coli being important pathogens.[8]Antimicrobial resistance has emerged as a major challenge in the management of neonatal sepsis. High resistance among Gram-negative organisms to commonly used antibiotics, including third-generation cephalosporin's, amino glycosides and, in some settings, carbapenems, has been documented in Indian NICUs.[7,8,10] Recent Indian data have also demonstrated substantial multidrug resistance among Klebsiella and Acinetobacter isolates, emphasizing the need for continuous surveillance of local antimicrobial susceptibility patterns.[10,11]

Blood culture results are particularly important because microbiological confirmation allows identification of the causative organism and facilitates targeted antimicrobial therapy. Culture-positive sepsis has also been associated with poorer outcomes in several studies.[9,12]

Therefore, evaluation of the local clinico-bacteriological profile is essential for appropriate empirical treatment, antimicrobial stewardship and infection - control planning. The present study was undertaken to assess the clinical profile, maternal and neonatal risk factors, laboratory abnormalities, microbiological spectrum, antimicrobial susceptibility pattern and hospital outcomes of neonates with suspected sepsis admitted to the NICU of Karanataka medical College and research institute Hubballi Karnataka. The study also evaluated differences between early- and late-onset sepsis and examined factors associated with hospital mortality.

Materials and Methods

Study Design and Setting

The present study was conducted as a descriptive, hospital-based observational study to evaluate the clinico-bacteriological profile and outcomes of neonatal sepsis among neonates admitted to the Neonatal Intensive Care Unit (NICU). The study was conducted in the Karanataka medical College and research institute Hubballi Karnataka, a tertiary care teaching hospital providing neonatal intensive care and microbiological diagnostic facilities.

Study Duration

The study was carried out over a period of 18 months, from April 2024 to September 2025.

Study Population

The study population comprised neonates admitted to the Department of Pediatrics and requiring NICU care who were clinically suspected to have neonatal sepsis based on relevant clinical features and/or laboratory findings during the study period.

Inclusion Criteria

The following neonates were included:

1. Neonates admitted to the NICU of Karanataka medical College and research institute Hubballi Karnataka, during the study period.
2. Neonates with suspected sepsis based on clinical features and/or laboratory indicators.
3. Neonates whose parents or legal guardians provided informed consent.

Exclusion Criteria

The following neonates were excluded:

1. Neonates with major congenital anomalies.
2. Neonates whose parents or legal guardians declined informed consent.

Sampling Method

All consecutive neonates fulfilling the eligibility criteria were enrolled using consecutive sampling until the predetermined sample size was achieved. This approach enabled inclusion of eligible cases presenting during the study period and provided a representative assessment of the clinical and microbiological spectrum of neonatal sepsis at the study centre.

Sample Size

Based on hospital records, approximately 12 suspected neonatal sepsis cases were admitted per month. Over the 18-month study period, the expected number of eligible cases was approximately 216.

The sample size was estimated using Yamane's formula for a known population size:

where:

- n = required sample size
- N = estimated population size (216)
- e = margin of error (0.05)

Based on the calculated estimate and considering feasibility of recruitment during the study period, the final sample size was fixed at 150 neonates.

Study Group and Classification

All enrolled neonates constituted a single cohort of suspected neonatal sepsis. For descriptive analysis, cases were classified according to the timing of presentation into:

- **Early-onset sepsis (EOS):** sepsis presenting within the first 72 hours of life.
- **Late-onset sepsis (LOS):** sepsis presenting after 72 hours of life.

Study Parameters

The following maternal, neonatal, laboratory, microbiological and outcome parameters were recorded.

Maternal and Perinatal Parameters

Maternal and obstetric variables included:

- Maternal parity
- Premature rupture of membranes (PROM)
- Duration of PROM >18 hours
- Foul-smelling liquor
- More than three per-vaginal examinations during labour
- Intra partum fever (>100.4°F)
- Maternal urinary tract infection
- Prolonged labour
- Place of delivery
- Mode of delivery

Prolonged labour was defined according to parity as >24 hours in Primigravida and >10 hours in multigravida.

Neonatal Parameters

The following neonatal characteristics were recorded:

- Birth weight
- Gestational age
- APGAR score at 1 and 5 minutes
- Cry at birth
- Requirement for resuscitation
- Requirement for artificial ventilation
- Tachypnea (respiratory rate >60/minute)
- Grunting
- Chest retractions
- Oxygen desaturation
- Apnea
- Temperature instability
- Poor feeding/refusal to feed

- Seizures

Apnea was defined as cessation of breathing for >20 seconds without desaturation or >10 seconds when associated with desaturation.

Temperature instability was defined as a temperature <36.5°C or >37.5°C.

Laboratory Parameters

Laboratory investigations included:

- Hemoglobin
- Total leukocyte count
- Differential leukocyte count
- Platelet count
- C-reactive protein (CRP)
- Blood glucose

The predefined abnormal laboratory values included:

- Total leukocyte count <4,000 cells/mm³ or >20,000 cells/mm³
- Platelet count <1.5 lakh/mm³
- CRP >6 mg/L

Microbiological Parameters

Microbiological evaluation included:

- Blood culture and antibiotic sensitivity testing
- Urine culture
- Pus culture, where clinically indicated
- Cerebrospinal fluid (CSF) analysis and culture, where indicated

The organisms isolated and their antimicrobial susceptibility patterns were recorded.

Study Procedure

All neonates admitted with suspected sepsis were evaluated at admission. A detailed maternal and perinatal history was obtained using a structured proforma. Relevant obstetric risk factors were documented from maternal interviews and obstetric records.

Each neonate underwent a detailed clinical examination, including assessment of vital signs, respiratory status, feeding, neurological status and other clinical features suggestive of sepsis. Gestational age, birth weight, APGAR scores and requirement for resuscitation or ventilatory support were documented.

Relevant laboratory investigations were performed according to the institutional NICU protocol. Blood samples for culture were collected using strict aseptic precautions, preferably before initiation of antibiotic therapy whenever clinically feasible. Additional cultures and CSF investigations were performed when indicated by the clinical condition of the neonate.

Neonates received supportive and definitive treatment according to standard institutional NICU protocols. They were followed throughout their hospital stay, and clinical course, complications, duration of hospitalisation and outcome were recorded.

Data Collection

Data were collected using a pre-designed and pre-tested structured proforma. Information was obtained from maternal interviews, obstetric records, neonatal case sheets, laboratory reports and microbiological records. Data were recorded at admission and updated throughout the hospital stay. All collected information was reviewed for completeness and consistency before analysis.

Outcome Measures

The primary outcome measures were the clinico-bacteriological profile and outcome of neonatal sepsis.

The following outcomes were assessed:

- Clinical morbidity and complications
- Microbiologically confirmed infection
- Organisms isolated from clinical specimens
- Antibiotic susceptibility pattern
- Requirement for ventilatory support

- Duration of NICU stay
- Survival/discharge
- Mortality

Statistical Analysis

Data were entered and compiled in Microsoft Excel and analysed using SPSS software. Qualitative variables were expressed as frequencies and percentages, while quantitative variables were summarised using mean and standard deviation.

Appropriate statistical tests were applied for comparison of categorical and quantitative variables wherever applicable. The association between categorical variables was assessed using the Chi-square test or Fisher's exact test, as appropriate. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study was initiated after obtaining approval from the Institutional Ethics Committee of Karanataka medical College and research institute Hubballi karnataka. Written informed consent was obtained from the parents or legal guardians of all enrolled neonates.

Patient confidentiality was maintained throughout the study, and collected data were used exclusively for research purposes. No additional financial burden or intervention-related risk was imposed on the participants, as investigations and treatment were undertaken as part of routine neonatal care. Participation was voluntary, and parents or guardians were permitted to withdraw their neonate from the study at any time without affecting the standard of medical care.

Results and Observations

A total of 150 neonates with suspected neonatal sepsis admitted to the NICU of Karanataka medical College and research institute Hubballi Karnataka, during the study period were included in the analysis. The findings are presented below in 12 consolidated tables.

Table 1: Sociodemographic and Baseline Characteristics of Study Neonates

Variable	Category	No.	Percentage
Gender	Male	81	54.0
	Female	69	46.0
Gestational age	Early preterm (<32 weeks)	19	12.7
	Late preterm (32–36 weeks)	39	26.0
	Term (≥37 weeks)	92	61.3
Birth weight	Low birth weight (<2500 g)	82	54.7
	Normal birth weight (≥2500 g)	68	45.3
Mode of delivery	NVD	92	61.3
	LSCS	58	38.7
Place of delivery	Inborn	123	82.0
	Out born	27	18.0
Sepsis type	Early-onset sepsis	85	56.7
	Late-onset sepsis	65	43.3

Observation

Of the 150 neonates, 81 (54.0%) were males and 69 (46.0%) were females. Term neonates constituted the majority (61.3%), while 38.7% were preterm. Low birth weight was present in 54.7% of neonates. Most neonates were delivered vaginally (61.3%) and were inborn (82.0%). Early-onset sepsis was more frequent than late-onset sepsis (56.7% vs. 43.3%).

Table 2: Maternal Risk Factors Associated with Neonatal Sepsis

Maternal risk factor	Present, n (%)
PROM	40 (26.7)
Multiple PV examinations	33 (22.0)
Maternal fever	23 (15.3)
Maternal UTI	10 (6.7)

Observation

PROM was the most frequently observed maternal risk factor (26.7%), followed by multiple PV examinations (22.0%), maternal fever (15.3%), and maternal UTI (6.7%).

Table 3: Clinical Features of Neonates with Suspected Sepsis

Clinical feature	Number	Percentage
Respiratory distress	116	77.3
Lethargy	96	64.0
Poor feeding	94	62.7
Fever	29	19.3
Apnea	29	19.3
Convulsions	25	16.7
Hypothermia	24	16.0
Bleeding manifestations	7	4.7

Observation

Respiratory distress was the most common clinical manifestation, occurring in 77.3% of neonates, followed by lethargy (64.0%) and poor feeding (62.7%). Fever and apnea were each observed in 19.3% of cases. Bleeding manifestations were uncommon (4.7%).

Table 4: APGAR Score and Septic Screen Findings

Parameter	Category	Number	Percentage
APGAR at 5 min	<7	36	24.0
	≥7	114	76.0
Leucopenia	<4,000/cu.mm	18	12.0
Leucocytosis	>20,000/cu.mm	34	22.7
Thrombocytopenia	<1.5 lakh/cu.mm	46	30.7
CRP	Positive	104	69.3

Observation

A low 5-minute Apgar score was observed in 24.0% of neonates. Among septic screen parameters, CRP positivity was the most frequent abnormality (69.3%), followed by thrombocytopenia (30.7%), leucocytosis (22.7%), and leucopenia (12.0%).

Table 5: Blood Culture and Organisms Isolated

Culture finding	Number	Percentage
Blood culture positive	53	35.3
Blood culture negative	97	64.7

Organisms among reported isolates (n=51, excluding 2 no-growth reports)

Organism	Number	Percentage
Klebsiella pneumoniae	15	29.4
Staphylococcus aureus	9	17.6
Candida krusei	6	11.8
Escherichia coli	6	11.8
Acinetobacter spp.	5	9.8
Pseudomonas aeruginosa	3	5.9
Enterococcus spp.	3	5.9
Candida spp.	1	2.0
CONS	1	2.0
Citrobacter spp.	1	2.0
NFGNB	1	2.0

Observation

Blood culture positivity was documented in 35.3% of neonates. Among the 51 reported isolates, Klebsiella pneumoniae was the predominant organism (29.4%), followed by Staphylococcus aureus (17.6%). Gram-negative organisms predominated, accounting for 31 of the 51 reported isolates (60.8%).

Table 6: Antimicrobial Sensitivity Pattern of Gram-Negative Isolates (n=31)

Antibiotic	Tested	Sensitive, n (%)	Resistant, n (%)
Amikacin	31	22 (71.0)	9 (29.0)
Gentamicin	30	15 (50.0)	15 (50.0)
Meropenem	31	24 (77.4)	7 (22.6)
Imipenem	30	22 (73.3)	8 (26.7)
Piperacillin–tazobactam	31	18 (58.1)	13 (41.9)
Ceftriaxone	27	6 (22.2)	21 (77.8)
Colistin	31	30 (96.8)	1 (3.2)
Tigecycline	28	22 (78.6)	6 (21.4)
Ciprofloxacin	29	11 (37.9)	18 (62.1)

Observation

Among Gram-negative isolates, the highest sensitivity was observed with colistin (96.8%), followed by tigecycline (78.6%), meropenem (77.4%), and imipenem (73.3%). The highest resistance was observed against ceftriaxone (77.8%), followed by ciprofloxacin (62.1%).

Table 7: Antimicrobial Sensitivity Pattern of Gram-Positive Isolates (n=13)

Antibiotic	Tested	Sensitive, n (%)	Resistant, n (%)
Vancomycin	13	13 (100.0)	0 (0.0)
Linezolid	13	13 (100.0)	0 (0.0)
Teicoplanin	13	13 (100.0)	0 (0.0)
Clindamycin	10	7 (70.0)	3 (30.0)
Erythromycin	10	3 (30.0)	7 (70.0)
Cotrimoxazole	10	5 (50.0)	5 (50.0)
Doxycycline	12	9 (75.0)	3 (25.0)
Oxacillin	10	4 (40.0)	6 (60.0)

Observation

All Gram-positive isolates were sensitive to vancomycin, line zolid, and teicoplanin. Doxy cycline showed 75.0% sensitivity. Oxacillin resistance was observed in 60.0% of tested isolates, indicating a substantial proportion of methicillin-resistant S. aureus among the tested S. aureus isolates.

Table 8: Antifungal Sensitivity Pattern of Fungal Isolates (n=7)

Antifungal agent	Tested	Sensitive, n (%)	Resistant, n (%)
Voriconazole	7	7 (100.0)	0 (0.0)
Caspofungin	7	7 (100.0)	0 (0.0)
Micafungin	7	7 (100.0)	0 (0.0)
Anidulafungin	6	5 (83.3)	1 (16.7)
Fluconazole	7	0 (0.0)	7 (100.0)
Amphotericin B	7	4 (57.1)	3 (42.9)
Flucytosine	6	2 (33.3)	4 (66.7)

Observation

The fungal isolates demonstrated 100% sensitivity to voriconazole, caspofungin, and micafungin. All tested isolates were resistant to fluconazole. Amphotericin B showed 57.1% sensitivity.

Table 9: Association of Selected Risk Factors and Clinical Features with Sepsis Type

Variable	EOS n (%)	LOS n (%)	p-value
Male gender	49 (57.6)	32 (49.2)	0.2521
Early preterm	10 (11.8)	9 (13.8)	
Late preterm	22 (25.9)	17 (26.2)	0.8423
Term	53 (62.4)	39 (60.0)	
LBW	48 (56.5)	34 (52.3)	0.5412
LSCS	32 (37.6)	26 (40.0)	0.7856
Inborn	68 (80.0)	55 (84.6)	0.4123
PROM	29 (34.1)	11 (16.9)	0.0297*
Maternal fever	15 (17.6)	8 (12.3)	0.3412
Multiple PV examinations	21 (24.7)	12 (18.5)	0.3156
Maternal UTI	7 (8.2)	3 (4.6)	0.5124
Lethargy	52 (61.2)	44 (67.7)	0.3512
Poor feeding	45 (52.9)	49 (75.4)	0.0082*
Fever	18 (21.2)	11 (16.9)	0.5623
Respiratory distress	68 (80.0)	48 (73.8)	0.2845
Hypothermia	15 (17.6)	9 (13.8)	0.5124
Convulsions	17 (20.0)	8 (12.3)	0.1856
Apnea	19 (22.4)	10 (15.4)	0.2945
Bleeding	5 (5.9)	2 (3.1)	0.7012

*Statistically significant at $p<0.05$.

Observation

PROM was significantly more frequent among neonates with EOS than LOS (34.1% vs. 16.9%, p=0.0297). Poor feeding was significantly more common in LOS than EOS (75.4% vs. 52.9%, p=0.0082). Other assessed maternal, demographic, and clinical variables did not show statistically significant associations with sepsis type.

Table 10: Association of Laboratory Parameters with Sepsis Type

Laboratory parameter	EOS n (%)	LOS n (%)	p-value
Leucopenia	6 (7.1)	12 (18.5)	0.0523
Leucocytosis	21 (24.7)	13 (20.0)	0.4512

Thrombocytopenia	25 (29.4)	21 (32.3)	0.6234
CRP positive	61 (71.8)	43 (66.2)	0.4123

Observation

CRP positivity was common in both EOS and LOS groups. None of the evaluated laboratory parameters showed a statistically significant association with sepsis type. Leucopenia was more frequent in LOS (18.5%) than EOS (7.1%) was, although this difference did not reach statistical significance (p=0.0523).

Table 11: Outcome and Duration of Hospital Stay

Outcome/duration	Number	Percentage
Outcome		
Discharged	145	96.7
Expired	5	3.3
Duration of hospital stay		
1–5 days	4	2.7
6–10 days	49	32.7
11–15 days	41	27.3
>15 days	55	36.7

Observation

A favourable hospital outcome was observed in the majority of neonates, with 145 (96.7%) discharged and 5 (3.3%) deaths. Hospital stay ranged from 3 to 45 days. More than 15 days of hospitalisation was the most common duration category (36.7%).

Table 12: Association of Selected Factors with Hospital Outcome

Variable	Discharged n (%)	Expired n (%)	p-value
Male	78 (53.8)	3 (60.0)	0.8512
Early preterm	17 (11.7)	2 (40.0)	
Late preterm	38 (26.2)	1 (20.0)	0.1523
Term	90 (62.1)	2 (40.0)	
LBW	79 (54.5)	3 (60.0)	0.6723
LSCS	56 (38.6)	2 (40.0)	0.8912
Inborn	120 (82.8)	3 (60.0)	0.2134
EOS	83 (57.2)	2 (40.0)	0.3845
LOS	62 (42.8)	3 (60.0)	
PROM	39 (26.9)	1 (20.0)	0.6512
Maternal fever	22 (15.2)	1 (20.0)	0.5234
Multiple PV examinations	32 (22.1)	1 (20.0)	0.9123
Lethargy	92 (63.4)	4 (80.0)	0.6512
Poor feeding	90 (62.1)	4 (80.0)	0.5845
Respiratory distress	111 (76.6)	5 (100.0)	0.5812
Fever	28 (19.3)	1 (20.0)	0.9999
Hypothermia	22 (15.2)	2 (40.0)	0.1234
Convulsions	23 (15.9)	2 (40.0)	0.1456
Apnea	27 (18.6)	2 (40.0)	0.1789
Bleeding	6 (4.1)	1 (20.0)	0.1523
Leucopenia	17 (11.7)	1 (20.0)	0.5234
Leucocytosis	32 (22.1)	2 (40.0)	0.2845
Thrombocytopenia	43 (29.7)	3 (60.0)	0.1234
CRP positive	100 (69.0)	4 (80.0)	0.9999
Blood culture positive	48 (33.1)	5(100.0)	0.0049*

*Statistically significant at p<0.05.

No statistically significant association was observed between demographic characteristics, birth characteristics, maternal risk factors, clinical features, or septic screen parameters and hospital outcome. However, blood culture positivity was significantly associated with mortality (p=0.0049). All five neonates who expired had positive blood cultures, compared with 33.1% of discharged neonates.

Discussion

The present study evaluated 150 neonates with suspected neonatal sepsis admitted to the NICU of Karanataka medical College and research institute Hubballi Karnataka, during an 18-month period. The study assessed demographic and perinatal characteristics, maternal risk factors, clinical manifestations, laboratory findings, microbiological profile, anti-microbial susceptibility and hospital outcomes. The findings demonstrate the continued importance of neonatal sepsis as a major NICU problem and highlight the contribution

of Gram-negative organisms and antimicrobial resistance.

In the present study, males constituted 54.0% of the study population, while females constituted 46.0%, showing a modest male predominance. Similar male predominance has been reported in several Indian studies of neonatal sepsis.[8,9] The observed difference, however, should not be interpreted as evidence of a direct causal relationship between sex and neonatal sepsis.

Term neonates accounted for 61.3% of the study population, whereas 38.7% were preterm. Low birth weight was present in 54.7% of neonates. The substantial proportion of preterm and low-birth-weight neonates is consistent with the recognized susceptibility of these neonates to infection because of immature immune mechanisms, impaired barrier function and increased requirement for invasive supportive care. [3,5]

EOS was more common than LOS in the present study, accounting for 56.7% and 43.3% of cases, respectively. A similar predominance of EOS has been reported in several Indian studies. A Delhi cohort reported that approximately two-thirds of sepsis episodes occurred within the first 72 hours of life, while another Indian study reported EOS in 59% of culture-positive cases. [8,10]

PROM was the most frequently identified maternal risk factor in the present study, occurring in 26.7% of neonates, followed by multiple per-vaginal examinations (22.0%), maternal fever (15.3%) and maternal UTI (6.7%). Importantly, PROM was significantly more frequent among EOS cases than LOS cases (34.1% vs. 16.9%; p=0.0297). This finding supports the established relationship between prolonged rupture of membranes and early neonatal infection, as ascending infection may expose the fetus to pathogenic organisms before or during delivery. [3,4]

Respiratory distress was the commonest clinical manifestation in the present study, occurring in 77.3% of neonates, followed by lethargy (64.0%) and poor feeding (62.7%). Fever was present in only 19.3%, while hypothermia occurred in 16.0%. These findings highlight the nonspecific clinical presentation of neonatal sepsis. WHO guidance recognizes fast breathing, lethargy, feeding difficulty, convulsions and abnormal temperature among important clinical manifestations that should raise suspicion of serious bacterial infection. [1,2]

Poor feeding was significantly more common in LOS than EOS (75.4% vs. 52.9%; p=0.0082). This finding may reflect the progressive systemic manifestations frequently observed in late-onset infection among hospitalized neonates. Since feeding difficulty may also occur in prematurity and other neonatal disorders, it should be interpreted together with other clinical and laboratory findings.

Regarding laboratory investigations, CRP positivity was the most common abnormality and was observed in 69.3% of neonates. Thrombocytopenia was present in 30.7%, leukocytosis in 22.7% and leukopenia in 12.0%. CRP positivity did not differ significantly between EOS and LOS. These findings support the role of inflammatory markers as adjunctive investigations rather than standalone diagnostic tests. Current guidance emphasizes combining clinical assessment with appropriate diagnostic investigations when evaluating suspected neonatal sepsis. [1,2,6]

Blood culture was positive in 53 of 150 neonates, giving a culture positivity rate of 35.3%. Culture-negative sepsis constituted 64.7% of suspected cases. The lower microbiological confirmation rate among clinically suspected cases is not unexpected because blood culture

sensitivity may be influenced by the amount of blood collected, timing of collection and previous exposure to antibiotics. Consequently, clinical management of suspected neonatal sepsis cannot depend exclusively on a positive culture. [6]

Among the 51 reported isolates, Klebsiella pneumoniae was the predominant organism (29.4%), followed by Staphylococcus aureus (17.6%), Candida krusei (11.8%) and Escherichia coli (11.8%). Gram-negative organisms constituted 60.8% of the reported isolates. This finding is comparable with several Indian studies demonstrating predominance of Gram-negative organisms in neonatal sepsis. Viswanathan et al. reported Gram-negative organisms in 71.6% of culture-positive cases, with K. pneumoniae being the most common isolate.[7] Similarly, a recent multicentre study from Bengaluru reported Klebsiella as the most common pathogen and found that Gram-negative organisms accounted for approximately 60% of neonatal sepsis.[11]

The predominance of Klebsiella pneumoniae in the present study is particularly noteworthy. Similar findings have been reported from northern and eastern India, where Klebsiella has repeatedly emerged as an important pathogen in neonatal bloodstream infections.[7,9,10] The variation in the relative contribution of Gram-positive organisms, Gram-negative organisms and fungi between studies may reflect differences in patient characteristics, infection-control practices, antibiotic exposure and local NICU ecology.

The antimicrobial susceptibility pattern in the present study demonstrated substantial resistance among Gram-negative isolates. Colistin showed the highest sensitivity (96.8%), followed by tigecycline (78.6%), meropenem (77.4%) and imipenem (73.3%). In contrast, ceftriaxone showed 77.8% resistance and ciprofloxacin showed 62.1% resistance.

Similar high resistance to commonly used antibiotics has been reported in Indian neonatal units. Viswanathan et al. reported high resistance to ampicillin, gentamicin, amikacin and cefotaxime among Gram-negative isolates.[7] Another Indian study found high levels of resistance among Klebsiella isolates, including resistance to Amino glycosides and carbapenems.[10]

The high resistance observed against ceftriaxone in the present study is clinically important because resistance to third-generation cephalosporins limits the usefulness of these agents for empirical therapy. Recent Indian multicentre data demonstrated that multidrug-resistant organisms are common in neonatal sepsis and that initial empirical antibiotic therapy may not provide adequate coverage in a substantial proportion of cases.[11] These observations reinforce the importance of institutional anti biograms, culture-guided therapy and antimicrobial stewardship.

Among Gram-positive isolates, all tested isolates were sensitive to vancomycin, linezolid and teicoplanin. Oxacillin resistance was detected in 60% of tested isolates, suggesting a substantial proportion of methicillin - resistant staphylococcal isolates. Indian studies have similarly reported methicillin resistance among S. aureus and coagulase-negative staphylococci in neonatal sepsis.[8,10] However, the relatively small number of Gram-positive isolates in the present study warrants cautious interpretation.

Fungal isolates accounted for a smaller proportion of bloodstream isolates. In the present study, seven fungal isolates were evaluated. All were sensitive to voriconazole, caspofungin and micafungin, while all demonstrated resistance to fluconazole. Because of the

small number of isolates, these findings should be considered centre-specific and interpreted cautiously. Nevertheless, the presence of fungal bloodstream infection emphasizes the importance of considering invasive fungal infection in high-risk NICU patients.

The overall hospital outcome in the present study was favourable, with 145 (96.7%) neonates discharged and 5 (3.3%) neonates dying. This mortality was lower than that reported in some Indian studies of culture-proven or severe neonatal sepsis. For example, a central Indian study reported a mortality of 28.6%, while another northern Indian cohort reported lower survival among neonates with Gram-negative sepsis.[9,12] Differences may be explained by variation in case severity, referral patterns, gestational age, birth weight, availability of intensive care and antimicrobial susceptibility patterns.

The most important outcome-related finding in the present study was the significant association between blood culture positivity and mortality. All five neonates who expired had positive blood cultures, compared with 33.1% of discharged neonates (p=0.0049). This observation is consistent with previous Indian studies reporting higher case fatality among culture-positive neonates.[12,13] Culture-positive infections may therefore identify neonates with clinically significant bloodstream infection and potentially greater disease severity.

No statistically significant association was identified between mortality and sex, gestational age, low birth weight, mode of delivery, place of delivery, EOS/ LOS classification, maternal risk factors, clinical manifestations or septic-screen abnormalities. However, these findings should be interpreted cautiously because only five deaths occurred in the study. The small number of outcome events considerably limits the statistical power to detect predictors of mortality.

Hospitalisation beyond 15 days was observed in 36.7% of neonates, making it the most frequent duration category. Prolonged NICU stay may reflect disease severity, requirement for respiratory or supportive care and treatment of bloodstream infection. At the same time, prolonged hospitalisation can increase exposure to healthcare-associated pathogens and antimicrobial selection pressure, further emphasising the importance of infection prevention and antimicrobial stewardship.

Overall, the present study demonstrates that neonatal sepsis at the study centre was characterised by a predominance of respiratory and nonspecific systemic manifestations, frequent CRP positivity, a blood-culture positivity rate of 35.3%, predominance of Gram-negative organisms and substantial antimicrobial resistance. PROM was significantly associated with EOS, whereas poor feeding was significantly more common in LOS. Most importantly, blood culture positivity was significantly associated with mortality. These findings support the need for early recognition, timely blood culture collection, appropriate empirical antimicrobial therapy based on local susceptibility data, subsequent culture-directed treatment and continued strengthening of NICU infection-control practices.

Conclusion

Neonatal sepsis remains an important cause of morbidity and mortality in NICU-admitted neonates. In the present study, early-onset sepsis was more common, with low birth weight and prematurity being frequent characteristics. Respiratory distress, lethargy and poor feeding were the predominant clinical manifestations, while CRP positivity was the most common laboratory abnormality. Blood culture positivity was observed in 35.3% of cases, with Klebsiella pneumoniae being the predominant isolate and considerable antimicrobial

resistance among Gram-negative organisms. PROM was significantly associated with early-onset sepsis, whereas poor feeding was more frequent in late-onset sepsis. Overall mortality was 3.3%, and blood culture positivity was significantly associated with mortality. Early recognition, timely culture-based diagnosis, appropriate antimicrobial therapy and continuous surveillance of local bacterial resistance patterns are essential for improving neonatal sepsis outcomes.

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