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Original Research Article

CLINICAL AND ETIOLOGICAL PROFILE OF NEONATAL SEPSIS IN NEWBORNS ADMITTED IN A TERTIARY CARE CENTRE

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ABSTRACT

Background: Neonatal sepsis remains a major contributor to neonatal mortality worldwide, particularly in areas where early diagnosis is difficult. Differentiating between early- and late-onset sepsis is important because the risk factors and outcomes differ. This study evaluated the clinical profile, bacteriology, risk factors, and outcomes of neonatal sepsis in a tertiary care centre. **Materials and Methods:** This study included 150 neonates with sepsis who were admitted to the intensive care unit over one year. Clinical examination and laboratory tests, including blood culture, C-reactive protein, leukocyte count, immature-to-total neutrophil ratio, and absolute neutrophil count, were performed. **Result:** Males constituted 53.3% of the patients, and females 46.7%. Early onset sepsis occurred in 64.7% of the patients, and late-onset sepsis occurred in 35.3% of the patients. Symptom onset occurred within 72 h in 61.3% of the patients. Vaginal delivery accounted for 62% of the deliveries, and LSCS for 32.7%. Inborn neonates comprised 58.7% of the total. Discharge occurred in 90% of the patients, while mortality was 10%. Preterm gestation was higher in the EOS group (57.7%) than in the LOS group (30.2%) (P=0.001). Low birth weight was more frequent in the EOS group (53.6% vs. 34%, P=0.022). PROM, PPROM, intrapartum fever, and foul-smelling liquor were significantly associated with EOS. Mechanical ventilation and poor hygiene were associated with LOS (p<0.001). Respiratory distress predominated in EOS, whereas neurological and gastrointestinal symptoms were common in LOS. Blood culture positivity was higher in outborn neonates than in inborn neonates. Mortality increased with prematurity, Klebsiella, and Acinetobacter infections. **Conclusion:** Neonatal sepsis exhibited distinct patterns between early- and late-onset diseases. Recognition of prematurity-related vulnerability and local pathogens can guide the diagnosis and improve outcomes.

INTRODUCTION

Neonatal sepsis is one of the major causes of mortality and morbidity in neonates younger than 5 years of age, with severe consequences in hospitalised neonates in resource-limited regions.[1] A pooled analysis of 26 studies reported an incidence of approximately 2,824 cases per 1,00,000 live births, with a mortality rate of 17.6%, with an increased risk of neonates in a hospitalised setup due to inadequate infection control measures. Studies reported that prematurity (63.1%) and low birth weight (53.8%) are the major risk factors in a tertiary care setting, with a reported mortality rate of 9.2%.[2-4] There are challenges in the diagnosis of the condition, especially in low- and middle-income countries with limitations in resources, where the symptoms are subtle, and blood cultures are inconclusive. The diagnosis of sepsis at an appropriate time and the use of the antibiotic appropriately are important.[5,6]

Early-onset sepsis (EOS) and late-onset sepsis (LOS) are different clinical entities with different risk factors, pathogens, and outcomes, although the existing <72 and >72 h classifications have limited use in low- and middle-income countries. EOS is commonly transmitted vertically and is associated with maternal risk factors, including prolonged rupture of membranes (26.3% in EOS Vs. 8% in LOS), maternal fever (21.1% vs. 8%), and chorioamnionitis (7.9 Vs. 1.9%).7 While the risk factors of LOS are commonly nosocomial infections through the central lines (44.1% in LOS Vs. 21.7% in

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EOS) and parenteral nutrition, prematurity and low birth weight are common risk factors for both types of sepsis.[7,8] There are variations in the microbiological profile of neonatal sepsis by geography and hospital settings, which require local bacteriological surveillance, and there are challenges in diagnosis, though various laboratory markers necessitate assessments combining laboratory and clinical findings.

Microbiological patterns of neonatal sepsis vary by region and setting; pathogen distribution and antimicrobial practices depend on diagnostic infrastructure, and in resource-limited settings, limited tools affect detection and surveillance.[5,9] Neonatal sepsis diagnosis is challenging because of its non-specific features. Although inflammatory markers are used, their specificity is limited. No single biomarker provides sufficient accuracy, necessitating the integration of clinical assessments with laboratory indicators. Diagnosis requires interpretation of clinical signs, history, and markers, with microbiological confirmation when possible.[10-12]

Despite several studies on neonatal sepsis, there are still gaps in the evidence. Reports from high-resource settings have limited applicability. However, region-specific data on epidemiology and pathogens are lacking. Local surveillance is essential because pathogens vary by region. Empirical therapy must be based on local pathogen data. Risk identification requires an understanding of population patterns. Integrated clinical and laboratory data can improve diagnosis and reduce mortality rates.

Aim: This study aimed to examine the clinical and bacteriological profiles of neonatal sepsis, identify common organisms in culture-positive cases, and determine the associated risk factors in our unit.

MATERIALS AND METHODS

This observational study was conducted in 150 neonates who attended the Neonatal Intensive Care Unit of the Department of Paediatrics, Government Medical College Hospital, Virudhunagar, Tamil Nadu, India, from May 2023 to April 2024. Ethical approval was obtained from the institutional ethics committee, and written informed consent was obtained from parents or guardians before the initiation of the study.

Inclusion and Exclusion criteria

This study included all neonates, both term and preterm, with clinical features suggestive of neonatal sepsis. Neonates born with congenital anomalies and those who were started on antibiotics before blood culture were excluded.

Methods: A total of 150 neonates were enrolled at the time of admission. A detailed maternal and perinatal history was obtained, followed by thorough clinical examination. Neonates were screened for features suggestive of sepsis, including abnormal neurological status (irritability, lethargy, poor feeding, apnoea, and seizures) and cardiovascular compromise (tachycardia, hypotension, and poor perfusion). Respiratory distress (tachypnoea, increased work of breathing, hypoxaemia), gastrointestinal symptoms (abdominal distension, emesis), and temperature instability (hypothermia/hyperthermia). Metabolic abnormalities (hypoglycemia/hyperglycemia), cyanosis, jaundice, and bleeding manifestations, such as petechiae, purpura, or oozing. A detailed history and clinical examination were performed for all patients. Blood culture, CRP, total leucocyte count, immature to total neutrophil ratio, and absolute neutrophil count were performed in all neonates with sepsis features, along with baseline investigations. All participants were followed until recovery and discharge from the NICU. Blood samples were collected under aseptic precautions, and 1 ml of blood was inoculated into 5-10 ml of broth. Samples were collected from fresh venipuncture sites, incubated, and observed for growth for 7 days and at least 72 h before reporting as sterile. The culture was performed using the conventional method. Data were collected using a study proforma, maintained with anonymity, and a final master sheet was prepared.

Statistical analysis: Data were entered into Microsoft Excel and analysed using SPSS version 25. Categorical variables were expressed as frequencies and percentages. Comparisons between groups were performed using the chi-square test or Fisher's exact test where appropriate. A p value <0.05 was considered statistically significant.

RESULTS

Male neonates were more frequently reported (53.3%) than females (46.7%). EOS occurred in 97 (64.7%) patients, and LOS occurred in 53 (35.3%) patients. Onset within <72 hours was seen in 92 (61.3%) patients, while onset ≥72 hours was seen in 58 (38.7%) patients. Vaginal delivery predominated in 93 (62%) cases, followed by LSCS in 49 (32.7%) and assisted delivery in 8 (5.3%) cases.

In neonatal sepsis, respiratory distress was the most common symptom (26.7%), followed by neurological (20.6%) and gastrointestinal symptoms (20.0%). Cardiovascular issues accounted for 9.7%, glucose abnormalities for 7.9%, and temperature for 6.7%. Jaundice (3.6%), cyanosis (3.0%), and bleeding (1.8%) occurred less. C-reactive protein was positive in 86.7% of neonates, with neutrophil count deviation in 65.3% and a high immature-to-total ratio in 62.0%. Inborn deliveries accounted for 88 (58.7%) and outborn deliveries for 62 (41.3%). Of the neonates, 135 (90%) were discharged, and 15 (10%) died [Table 1].

Preterm gestational age <37 weeks was higher in EOS (57.7%) than LOS (30.2%), while ≥37 weeks was higher in LOS (69.8% vs. 42.3%, P=0.001). Males had a higher incidence of EOS (55.7%) than LOS (49.1%), with females at 44.3% and 50.9%

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(P=0.438). Birth weight >2.5 kg was higher in LOS (66%) than in EOS (46.4%), while 1.5–2.49 kg was higher in Early Onset (30.9% vs. 11.3%, P=0.046). Vaginal delivery was higher in the LOS group (84.9% vs. 49.5%), whereas LSCS was higher in the EOS group (45.4% vs. 9.4%, P=0.001). Inborn deliveries were higher in EOS (63.9%) than in LOS (49.1%), and outborn deliveries were 36.1% and 50.9%, respectively (P=0.077) [Table 2].

Table 1: Distribution of Demographic and Clinical Characteristics

Parameters		**N (%)**
Sex	Male	80(53.3%)
	Female	70(46.7%)
Type of sepsis	EOS	97(64.7%)
	LOS	53(35.3%)
Symptom onset	<72 hours	92(61.3%)
	≥72 hours	58(38.7%)
Mode of delivery	Vaginal	93(62%)
	LSCS	49(32.7%)
	Assisted	8(5.3%)
Clinical Feature	Respiratory distress	44(26.7%)
	Abnormal neurological status	34(20.6%)
	Gastrointestinal symptoms	33(20.0%)
	Cardiovascular compromise	16(9.7%)
	Glucose abnormality	13(7.9%)
	Temperature instability	11(6.7%)
	Jaundice	6(3.6%)
	Cyanosis	5(3.0%)
	Bleeding manifestations	3(1.8%)
Laboratory Parameter	ANC deviation present	98(65.3%)
	Significant I/T ratio	93(62.0%)
	CRP positive	130(86.7%)
Place of delivery	Inborn	88(58.7%)
	Out born	62(41.3%)
Outcome	Discharged	135(90%)
	Death	15(10%)

Table 2: Comparison of Baseline Characteristics Between Early Onset and Late Onset Sepsis

Parameters		**EOS N (%)**	**LOS N (%)**	**P value**
Gestational age	<37 weeks	56 (57.7%)	16 (30.2%)	0.001
	≥37 weeks	41 (42.3%)	37 (69.8%)	
Sex	Male	54 (55.7%)	26 (49.1%)	0.438
	Female	43 (44.3%)	27 (50.9%)	
Birth weight	<1 kg	8 (8.3%)	4 (7.6%)	0.046
	1–1.49	14 (14.4%)	8 (15.1%)	
	1.5–2.49	30 (30.9%)	6 (11.3%)	
	>2.5	45 (46.4%)	35 (66%)	
Mode delivery	Vaginal	48 (49.5%)	45 (84.9%)	0.001
	LSCS	44 (45.4%)	5 (9.4%)	
	Assisted	5 (5.2%)	3 (5.7%)	
Place delivery	Inborn	62 (63.9%)	26 (49.1%)	0.077
	Out born	35 (36.1%)	27 (50.9%)	

Intrapartum fever was higher in EOS (15.5%) than in LOS (3.8%), with an absence in 84.5% and 96.2% of neonates, respectively (P=0.03). PROM was higher in the Early Onset group 21 (21.6%) versus 3 (5.7%) in Late Onset (P=0.011). Foul-smelling liquor occurred in 11 (11.3%) versus 1 (1.9%) neonate (P=0.041). Frequent PV examinations were performed in four (4.1%) and seven (13.2 %) patients in the early-and late-onset groups (P=0.053). The incidence of PPROM was higher in the Early Onset group 18 (18.6%) than in the late-onset group 3 (5.7%) (P=0.029).

Prematurity was higher in the Early Onset group (45.3%) than in the late-onset group (28.3%) (P=0.043). Low birth weight was higher in the Early Onset group (53.6%) than in the late-onset group (34%) (P=0.022). Combined prematurity and low birth weight were 29.9% and 22.6%, respectively (P=0.342). Umbilical venous catheter use was 13.4% versus 20.8% (P=0.24), and delayed feeding showed 12.4% versus 22.6% (P=0.101). Mechanical ventilation was lower in early-onset (26.8%) than in late-onset (60.4%) patients (P<0.001). Prematurity complications were 4.1% versus 15.1% (P=0.026). Poor hygiene was observed in 6.2% of the patients and 30.2% of patients (P<0.001) [Table 3].

Table 3: Comparison of Maternal and Neonatal Risk Factors Between Early Onset and Late Onset Sepsis

Parameters			**EOS N (%)**	**LOS N (%)**	**P value**
Maternal risk factor	Intrapartum fever	Present	15 (15.5%)	2 (3.8%)	0.03
		Absent	82 (84.5%)	51 (96.2%)	
	PROM	Present	21 (21.6%)	3 (5.7%)	0.011

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		Absent	76 (78.4%)	50 (94.3%)	
	Foul-smelling liquor	Present	11 (11.3%)	1 (1.9%)	0.041
		Absent	86 (88.7%)	52 (98.1%)	
	Frequent PV exam	Present	4 (4.1%)	7 (13.2%)	0.053
		Absent	93 (95.9%)	46 (86.8%)	
	PPROM	Present	18 (18.6%)	3 (5.7%)	0.029
		Absent	79 (81.4%)	50 (94.3%)	
Neonatal risk factor	Prematurity	Present	44 (45.3%)	15 (28.3%)	0.043
		Absent	53 (54.7%)	38 (71.7%)	
	Low birth weight	Present	52 (53.6%)	18 (34%)	0.022
		Absent	45 (46.4%)	35 (66%)	
	Prematurity + LBW	Present	29 (29.9%)	12 (22.6%)	0.342
		Absent	68 (70.1%)	41 (77.4%)	
	Umbilical venous catheter	Present	13 (13.4%)	11 (20.8%)	0.24
		Absent	84 (86.6%)	42 (79.2%)	
	Delayed feeding / hyperalimentation	Present	12 (12.4%)	12 (22.6%)	0.101
		Absent	85 (87.6%)	41 (77.4%)	
	Mechanical ventilation	Present	26 (26.8%)	32 (60.4%)	<0.001
		Absent	71 (73.2%)	21 (39.6%)	
	Prematurity complications	Present	4 (4.1%)	8 (15.1%)	0.026
		Absent	93 (95.9%)	45 (84.9%)	
	Poor hygiene factors	Present	6 (6.2%)	16 (30.2%)	<0.001
		Absent	91 (93.8%)	37 (69.8%)	

ANC deviation was lower in Early Onset (62.9%) than LOS (69.8%) (P=0.394). The IT ratio <2 was higher in EOS at 66 (68%) versus 27 (50.9%) in LOS (P=0.039). CRP positivity was higher in Early Onset (90.7%) than LOS (79.3%) (P=0.048). Neurological abnormalities were less common in Early Onset (15.5%) than in Late Onset (35.8%) (P=0.004). Cardiovascular compromise showed no significant difference between EOS and LOS (P=0.848), and respiratory distress was higher in Early Onset (35.1%) than LOS (18.9%) (P=0.037). Gastrointestinal symptoms were lower in EOS (14.4%) than in LOS (35.9%) (P=0.002). Temperature instability was higher in Early Onset (9.3%) than LOS (3.8%) (P=0.184). Glucose abnormality was higher in EOS (11.3%) than in LOS (3.8%) (P=0.098). Cyanosis was higher in EOS (4.1%) than in LOS (1.9%) (P=0.419). Jaundice was lower in EOS (3.1%) versus LOS (5.7%) (P=0.358). Bleeding was similar at 2.1% and 1.9% (P=0.715) [Table 4].

Table 4: Comparison of Laboratory Parameters and Clinical Features Between Early Onset and Late Onset Sepsis

Parameters			**EOS N (%)**	**LOS N (%)**	**P value**
Laboratory parameters	ANC deviation	Yes	61 (62.9%)	37 (69.8%)	0.394
		No	36 (37.1%)	16 (30.2%)	
	IT ratio significant <2	Yes	66 (68%)	27 (50.9%)	0.039
		No	31 (32%)	26 (49.1%)	
	CRP positive	Positive	88 (90.7%)	42 (79.3%)	0.048
		Negative	9 (9.3%)	11 (20.7%)	
Clinical Features	Neurological abnormality	Present	15 (15.5%)	19 (35.8%)	0.004
		Absent	82 (84.5%)	34 (64.2%)	
	Cardiovascular compromise	Present	10 (10.3%)	6 (11.3%)	0.848
		Absent	87 (89.7%)	47 (88.7%)	
	Respiratory distress	Present	34 (35.1%)	10 (18.9%)	0.037
		Absent	63 (64.9%)	43 (81.1%)	
	GI symptoms	Present	14 (14.4%)	19 (35.9%)	0.002
		Absent	83 (85.6%)	34 (64.1%)	
	Temperature instability	Present	9 (9.3%)	2 (3.8%)	0.184
		Absent	88 (90.7%)	51 (96.2%)	
	Glucose abnormality	Present	11 (11.3%)	2 (3.8%)	0.098
		Absent	86 (88.7%)	51 (96.2%)	
	Cyanosis	Present	4 (4.1%)	1 (1.9%)	0.419
		Absent	93 (95.9%)	52 (98.1%)	
	Jaundice	Present	3 (3.1%)	3 (5.7%)	0.358
		Absent	94 (96.9%)	50 (94.3%)	
	Bleeding	Present	2 (2.1%)	1 (1.9%)	0.715
		Absent	95 (97.9%)	52 (98.1%)	

Blood culture positivity was 57 (64.8%) and 52 (83.9%) inborn and outborn neonates, respectively, while negativity was 31 (35.2%) and 10 (16.1%). Positivity was higher in outborn neonates (P=0.010) [Table 5].

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Table 5: Comparison of Place of Delivery with Blood Culture Status

Parameters		Blood Culture Positive	Blood Culture Negative	P value
Place of delivery	Inborn	57 (64.8%)	31 (35.2%)	0.010
	Out born	52 (83.9%)	10 (16.1%)	

Preterm gestational age <37 weeks occurred in 10 deaths (66.7%) versus 62 discharges (45.9%), while ≥37 weeks was seen in 5 deaths (33.3%) and 73 discharges (54.1%) (P=0.127). Inborn neonates comprised 9 deaths (60%) and 79 discharges (58.5%), and outborn neonates comprised 6 (40%) and 56 (41.5%) (P=0.912). Klebsiella was most common in deaths at 7 (46.7%) and in discharges at 45 (33.3%). Acinetobacter was responsible for 5 (33.3%) deaths and 21 (15.6%) discharges. Pseudomonas was found in 1 (6.7%) death and 5 (3.7%) discharges. Other organisms were responsible for 2 (13.3%) deaths and 7 (5.2%) discharges. E. coli, MSSA, and nil growth were absent in deaths but present in discharges at 12 (8.9%), 4 (3%), and 41 (30.4%, P=0.8) [Table 6].

Table 6: Comparison of Clinical Variables with Outcome

		Death N (%)	Discharge N (%)	P value
Gestational age	<37 weeks	10 (66.7%)	62 (45.9%)	0.127
	≥37 weeks	5 (33.3%)	73 (54.1%)	
Place of delivery	Inborn	9 (60%)	79 (58.5%)	0.912
	Out born	6 (40%)	56 (41.5%)	
Organism	Klebsiella	7 (46.7%)	45 (33.3%)	0.80
	E. coli	0	12 (8.9%)	
	Acinetobacter	5 (33.3%)	21 (15.6%)	
	Pseudomonas	1 (6.7%)	5 (3.7%)	
	MSSA	0	4 (3%)	
	Others	2 (13.3%)	7 (5.2%)	
	Nil growth	0	41 (30.4%)	

DISCUSSION

In our study, neonatal sepsis was more frequent in males, with EOS accounting for the majority of cases compared with LOS. Vaginal delivery predominated, with most neonates being delivered within the institution. The clinical outcomes were favourable, with most neonates being discharged. Lee et al. reported 50% male predominance but found only 23.7% EOS cases.[13] Thakur et al. confirmed a 64.7% male predominance and 72% vaginal delivery in culture-positive cases.[14] These findings show that neonatal sepsis exhibits a male predominance. High institutional delivery and favourable discharge rates indicate improved survival with timely management.

In our study, preterm neonates were associated with EOS, and term neonates with LOS. Lower birth weights were common in early-onset cases, whereas higher weights were observed in late-onset cases. Vaginal delivery was common in late-onset cases, and operative delivery was common in early-onset cases. EOS occurred frequently in inborn neonates and LOS in outborn neonates. Mai Trong et al. found that EOS cases had higher chances of having a birth weight ≥1500g.[15] Rubio-Mora et al. found that 64.81% of sepsis cases were in preterm newborns, with 94.92% being LOS.[16] Köstlin-Gille et al. confirmed that a lower gestational age is a risk factor for EOS (1.1%) and LOS (11.9%).8 These findings show that perinatal maturity influences sepsis timing, which is modified by the population characteristics.

In our study, maternal factors, including fever, premature membrane rupture, and foul-smelling liquor, were associated with EOS, whereas frequent per-vaginal examinations were associated with LOS. Neonatal factors such as prematurity and low birth weight were linked with EOS, whereas mechanical ventilation and poor hygiene were associated with LOS. Pankaj et al. found associations between PROM (P=0.004), foul-smelling liquor (P=0.016), and EOS confirmed prematurity (P=0.0026) and LBW (P=0.0052) with EOS.[17] Jyothi et al. reported foul-smelling liquor in 64.63% of EOS cases versus 2.63% of LOS cases.[18] Andini et al. showed PROM increases sepsis risk (OR 2.69, 95%CI 1.56-4.65).[19] EOS is linked to intrapartum infections, whereas LOS is related to hospital factors.

Our study showed different inflammatory patterns between early- and LOS, with immature-to-total neutrophil ratio and C-reactive protein positivity associated more with early onset disease. Thakur et al. found that the I/T ratio showed 72% sensitivity and 97% specificity for EOS, while CRP showed 78% sensitivity and 90% specificity for EOS/LOS cases.[20] Thakur et al., studying 90 septic neonates, concluded that CRP was the preferred inflammatory marker.[21] These results indicate that inflammatory indices require the interpretation of multiple markers.

In our study, the clinical manifestations varied according to the onset of sepsis. Respiratory distress and metabolic changes are common in EOS, whereas neurological and gastrointestinal symptoms dominate late-onset disease. Signs such as cyanosis, jaundice, bleeding, and glucose imbalance showed no differences between the groups. Blood culture positivity was higher in neonates delivered outside the hospital. Mortality was higher in preterm neonates with gram-negative infections. Ramya et al. found LOS was more frequent (61.8%) than early-onset (38.2%), with 80% being preterm cases and gram-negative organisms causing higher mortality

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(16.2%).[22] Gosai et al. identified very low birth weight ($p<0.001$) and prematurity ($p<0.01$) as mortality predictors, with 67% of culture-positive cases from external deliveries.[23] Early- and LOS differ in presentation, with respiratory symptoms in early disease and neurological/gastrointestinal involvement in later stages.

Strengths: Comprehensive data on maternal and neonatal risk factors, clinical features, and outcomes of sepsis, identification of high-risk groups, bacteriological profile, analysis of factors associated with EOS and LOS, and the possibility to inform local healthcare policies.

Limitations: Its single-centre design with a small sample size, biases in the study design, limited follow-up, uncontrolled confounding variables, a lack of long-term outcome data, variations in clinical practices, and limited generalisability to other settings or populations.

CONCLUSION

This study highlights the importance of identifying maternal and neonatal risk factors for neonatal sepsis. Preterm neonates and those with low birth weight are more susceptible to EOS, with Klebsiella and Acinetobacter being common causes in this region. The results can inform local healthcare policies, emphasising early recognition and prompt treatment to improve outcomes. Further studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and explore long-term outcomes.

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