

# A Study of Early Onset Septicemia in Neonates Admitted to NICU of a Tertiary Care Centre in Western India

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## Abstract

**Background:** Early-onset neonatal septicemia remains a major cause of neonatal morbidity and mortality in developing countries. Its rapid progression, nonspecific clinical features, and high risk among preterm and low birth weight neonates make early diagnosis and appropriate management challenging. **Objective:** To determine the incidence, cliniccoepidemiological profile, risk factors, diagnostic parameters, antimicrobial sensitivity patterns, and early outcomes of early-onset neonatal septicemia in neonates admitted to the neonatal intensive care unit. **Methods:** A prospective interventional study was conducted in neonates presenting with clinical features of septicemia within 72 hours of birth and admitted to the NICU of a tertiary care hospital between January and December 2021. Neonates with a positive sepsis screen and/or positive blood culture were enrolled after informed consent. Data on maternal, perinatal, and neonatal risk factors, presenting clinical features, laboratory results, microorganism profile, antimicrobial sensitivity, complications, and early outcomes were systematically recorded and analyzed using SPSS version 27.0. **Results:** Among 2867 NICU admissions, 165 neonates (5.8%) had early onset septicemia (EOS). EOS was significantly associated with outborn status, prematurity (<34 weeks), low birth weight (<1500 g), and male gender ( $p<0.05$ ). Common presentations included poor feeding and respiratory distress. Gram-negative organisms, predominantly *Klebsiella pneumoniae* and *Escherichia coli*, were most frequent. Overall mortality was 30.9%, significantly higher among preterm, low birth weight, outborn, and culture-positive neonates. **Conclusion:** Early-onset neonatal septicemia continues to be a significant cause of morbidity and mortality. Early recognition, appropriate screening, and rational antibiotic use are essential to improve outcomes.

**Keywords:** Early-onset sepsis; Antimicrobial resistance; Neonatal intensive care.

## Introduction

Neonatal septicemia remains one of the leading causes of neonatal morbidity and mortality worldwide, particularly in low- and middle-income countries. Despite advances in obstetric and neonatal care, sepsis continues to account for a substantial proportion of neonatal deaths, especially during the early neonatal period <sup>[1]</sup>. Early-onset neonatal septicemia (EOS) is defined as sepsis occurring within the first 72 hours of life and is primarily acquired through vertical transmission from the mother either before or during delivery <sup>[2]</sup>.

The burden of neonatal sepsis is disproportionately higher in developing countries due to limited access to quality antenatal care, poor intrapartum infection-control practices, delayed referrals, and inadequate neonatal intensive care facilities <sup>[3]</sup>. In India, neonatal sepsis remains a major public health concern and contributes significantly to neonatal mortality, despite the implementation of national newborn health programs. EOS poses a particular challenge

because of its rapid progression, nonspecific clinical presentation, and high fatality rates if not diagnosed and treated promptly <sup>[4]</sup>.

Several maternal, perinatal, and neonatal risk factors have been identified for EOS. These include prematurity, low birth weight, prolonged rupture of membranes, maternal intrapartum fever, chorioamnionitis, multiple per-vaginal examinations, meconium-stained amniotic fluid, and need for resuscitation at birth <sup>[5]</sup>. Preterm and low-birth-weight neonates are especially vulnerable due to immature immune responses, poor skin and mucosal barriers, and reduced inflammatory capacity. Male predominance in neonatal sepsis has also been reported, possibly related to genetic and immunological factors <sup>[6]</sup>.

Clinical manifestations of EOS are often subtle and nonspecific, making early diagnosis difficult. Common presentations include poor feeding, lethargy, respiratory distress, temperature instability, poor perfusion, and apnea <sup>[7]</sup>. These signs frequently overlap with non-infectious neonatal conditions, leading

to diagnostic uncertainty. Although blood culture remains the gold standard for diagnosis, it is time-consuming and has low sensitivity. Therefore, sepsis screening tests are widely used to support early diagnosis and initiation of empirical antibiotic therapy [8].

The etiological agents responsible for EOS vary geographically. In developed countries, Group B Streptococcus and Escherichia coli predominate, whereas in Indian neonatal intensive care units, gram-negative organisms such as Klebsiella, Escherichia coli, and Acinetobacter species are more commonly isolated [9]. Increasing antimicrobial resistance among these pathogens poses a serious challenge and highlights the need for periodic evaluation of local bacteriological profiles and antibiotic sensitivity patterns [10].

In view of the continued burden of EOS and rising antimicrobial resistance, this study was undertaken to evaluate the incidence, clinico-epidemiological profile, associated risk factors, diagnostic parameters, antimicrobial sensitivity patterns, and early outcomes of early-onset neonatal septicemia among neonates admitted to a tertiary care neonatal intensive care unit.

## Materials and Methods

This prospective interventional study was conducted in the Neonatal Intensive Care Unit (NICU) of a tertiary care teaching hospital in Western India over a period of one year, from January 1 to December 31, 2021. All neonates admitted to the NICU during the study period were screened for clinical features suggestive of neonatal septicemia. Early-onset neonatal septicemia (EOS) was defined as sepsis occurring within the first 72 hours of life. Neonates fulfilling the inclusion criteria were enrolled after obtaining written informed consent from parents or guardians.

### Inclusion Criteria

Neonates aged 0–28 days presenting within 72 hours of birth with:

- Clinical suspicion of septicemia, and
- Positive sepsis screen and/or positive blood culture.

### Exclusion Criteria

- Neonates with lethal congenital anomalies
- Neonates with chromosomal disorders incompatible with survival
- Neonates in whom consent was not obtained

During the study period, a total of 2867 neonates were admitted to the NICU. Of these, 682 neonates were clinically suspected to have EOS based on presenting symptoms and risk factors. Sepsis screening and blood cultures were performed in all suspected cases. A total of 165 neonates who had a positive sepsis screen and/or positive blood culture were included in the final analysis. A structured proforma was used to collect data for each enrolled neonate.

The following information was recorded:

**Maternal and Antenatal Factors** - Maternal age, Parity, Antenatal care status, Pregnancy-induced hypertension, Gestational diabetes

mellitus, Antepartum hemorrhage, Maternal fever, Prolonged rupture of membranes (>18 hours), Use of intrapartum antibiotics.

**Intrapartum Factors** - Mode of delivery, Meconium-stained amniotic fluid, Number of per vaginal examinations, Need for neonatal resuscitation at birth.

**Neonatal Factors** - Gender, Gestational age (assessed by New Ballard score), Birth weight, Apgar scores, Inborn or outborn status.

All neonates were thoroughly examined at admission and monitored daily for clinical signs suggestive of sepsis. Clinical features assessed included poor feeding, lethargy, respiratory distress, temperature instability, apnea, abdominal distension, poor perfusion, hypotension, and seizures.

The following investigations were performed as part of the sepsis evaluation:

Complete blood count, Absolute neutrophil count, Immature to total neutrophil ratio, C-reactive protein, Micro-erythrocyte sedimentation rate, Blood culture and sensitivity.

A sepsis screen was considered positive if two or more parameters were abnormal out of the total five (Total Leukocyte Count  $<5,000/\text{mm}^3$ , Absolute Neutrophil Count  $<1800/\text{mm}^3$ , Immature to Total Neutrophil Ratio  $>0.20$ , Micro-ESR  $>15 \text{ mm in the 1st hour}$ , C-Reactive Protein  $\geq 10 \text{ mg/L}$ ).

**Blood Culture and Microbiological Analysis** - Blood samples were collected under strict aseptic precautions prior to initiation of antibiotics. Cultures were processed using standard microbiological techniques. Identification of organisms and antimicrobial susceptibility testing were performed according to Clinical and Laboratory Standards Institute guidelines.

All neonates with suspected EOS were started on empirical antibiotics as per NICU protocol. Antibiotic therapy was modified based on culture and sensitivity results. Supportive management included thermal care, oxygen therapy, intravenous fluids, inotropes, and mechanical ventilation when required.

### Outcome Measures

The primary outcome measure was survival or death during NICU stay. Secondary outcomes included duration of hospital stay, need for respiratory support, and development of complications such as shock, disseminated intravascular coagulation, or acute kidney injury.

### Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 27.0. Continuous variables were expressed as mean  $\pm$  standard deviation, and categorical variables as frequencies and percentages. Chi-square test and Z test were used to analyze categorical variables. A p-value  $<0.05$  was considered statistically significant.

## Results

**Table 1: Incidence and Epidemiological Correlates of Early Onset Septicemia (EOS)**

Parameter	Category	EOS (N=165)	Non-EOS (N=2702)	Incidence (%)	p-value
Overall incidence	All NICU admissions (N=2867)	165	2702	5.8%	
Place of delivery	Inborn	42	937	4.3%	0.015
	Outborn	123	1765	6.5%	
Gestational age	<34 weeks	70	625	10.1%	<0.0001
	≥34 weeks	95	2077	4.4%	

Birth weight	<1500 g	78	527	12.9%	<0.001
	≥1500 g	87	2175	3.8%	
Gender	Male	97	1210	7.4%	0.0004
	Female	68	1492	4.4%	
Mode of delivery	Vaginal delivery	91	1477	5.8%	0.902
	LSCS	74	1225	5.7%	

A total of 2867 neonates were admitted to the NICU during the study period, of whom 165 (5.8%) were diagnosed with early onset septicemia (EOS). The remaining 2702 neonates served as the non-EOS group. EOS was significantly more common among outborn neonates compared to inborn neonates (6.5% vs 4.3%;  $p = 0.015$ ). Prematurity emerged as a major risk factor, with neonates born at <34 weeks gestation showing a significantly higher incidence of

EOS (10.1%) compared to those born at ≥34 weeks (4.4%;  $p < 0.0001$ ). Similarly, low birth weight (<1500 g) neonates had a markedly higher incidence of EOS (12.9%) compared to those weighing ≥1500 g (3.8%;  $p < 0.001$ ). Male neonates were significantly more affected than females (7.4% vs 4.4%;  $p = 0.0004$ ). No statistically significant association was observed between EOS and mode of delivery (vaginal delivery vs LSCS;  $p = 0.902$ )

**Table II: Clinical Presentation in Early Onset Septicemia (EOS)**

Clinical Feature	Number	Percentage (%)
Poor feeding	116	70.3
Respiratory distress	108	65.5
Lethargy	74	44.8
Poor perfusion/pulse	54	32.7
Abdominal distension	48	29.1
Temperature instability	42	25.5
Apnoea	37	22.4
Bleeding manifestations	34	20.6
Sclerema and mottling	33	20.0
Vomiting	30	18.2
Decreased urine output	27	16.4
Convulsions	25	15.2
Altered sensorium	21	12.7
Cyanosis	16	9.7
Excessive cry	14	8.5

The most common clinical manifestations among neonates with EOS were poor feeding (70.3%), respiratory distress (65.5%), and lethargy (44.8%). Signs of systemic compromise such as poor perfusion (32.7%), abdominal distension (29.1%), and temperature instability (25.5%) were also frequently observed. Neurological

manifestations included apnoea (22.4%), convulsions (15.2%), and altered sensorium (12.7%). Hemorrhagic manifestations were present in 20.6% of cases, while sclerema and mottling were observed in 20.0% of neonates.

**Table III: Correlation between Sepsis Screen and Blood Culture in Prediction of EOS**

Sepsis Screen	Blood Culture Positive	Blood Culture Negative	Total
Positive	71	80	151
Negative	14	517	531

Of the 165 EOS cases, 151 neonates had a positive sepsis screen, of whom 71 were culture positive, while 80 were culture negative. Among neonates with a negative sepsis screen, 14 were culture

positive and 517 were culture negative, indicating that although the sepsis screen had good sensitivity, blood culture positivity was limited.

**Table IV: Distribution of Organisms According to Place of Delivery in EOS**

Organism	Inborn (%)	Outborn (%)
E. coli	4 (23.5)	9 (13.2)
Klebsiella pneumoniae	1 (5.9)	25 (36.8)
Pseudomonas	1 (5.9)	4 (5.9)
Staphylococcus aureus	1 (5.9)	8 (11.8)
CONS	6 (35.3)	6 (8.8)
Streptococcus	1 (5.9)	3 (4.4)

Among culture-positive EOS cases, Gram-negative organisms predominated, especially in outborn neonates. Klebsiella pneumoniae was the most common organism in outborn neonates (36.8%), followed by Escherichia coli (13.2%). In contrast,

coagulase-negative staphylococci (CONS) were more frequently isolated among inborn neonates (35.3%). Other organisms isolated included Staphylococcus aureus, Pseudomonas, and Streptococcus species.

**Table V: Combined Outcome and Mortality Analysis in Early Onset Septicemia**

Parameter	Category	Discharge (%)	DAMA (%)	Expiry (%)	p-value
Overall Outcome	All EOS cases (N=165)	104 (63.0)	10 (6.1)	51 (30.9)	-
Place of delivery	Inborn	32 (30.8)	-	8 (15.7)	0.043
	Outborn	72 (69.2)	-	43 (84.3)	
Gestational Age	<37 weeks	55 (53.9)	-	46 (90.2)	<0.00001
	≥37 weeks	47 (46.1)	-	5 (9.8)	
Birth Weight	<2500 g	68 (65.3)	-	46 (90.2)	0.001
	≥2500 g	36 (24.7)	-	5 (9.8)	
Culture positivity	Culture positive	45 (43.3)	-	35 (68.6)	<0.0029
	Culture negative	59 (56.7)	-	16 (31.4)	

Of the 165 EOS cases, 104 neonates (63.0%) were discharged, 10 (6.1%) left against medical advice, and 51 (30.9%) expired. Mortality was significantly higher among outborn neonates (84.3% of deaths;  $p = 0.043$ ), preterm neonates ( $<37$  weeks) (90.2%;  $p < 0.00001$ ), and low birth weight neonates ( $<2500$  g) (90.2%;  $p = 0.001$ ). Culture-positive neonates also had significantly higher mortality (68.6%) compared to culture-negative neonates (31.4%;  $p < 0.0029$ ).

## Discussion

Early-onset neonatal septicemia (EOS) continues to be a major contributor to neonatal morbidity and mortality, particularly in low and middle income countries. The present study provides valuable insights into the incidence, risk factors, microbiological profile, and early outcomes of EOS among neonates admitted to a tertiary care neonatal intensive care unit, thereby contributing region-specific evidence to the existing literature.

In the present study, the overall incidence of EOS among all NICU admissions was 5.8%, which is comparable to reports from other Indian tertiary care centers. Verma et al. reported an incidence of 7.6% from Rajasthan, while Grace Lalana observed a slightly higher incidence of 8.9% from Bangalore [11,12]. The relatively lower incidence observed in the present study may be attributed to differences in referral patterns, antenatal care coverage, and infection-control practices.

A significantly higher proportion of EOS cases were observed among outborn neonates (74.5%) compared to inborn neonates, with a statistically significant difference ( $p = 0.015$ ). This finding is consistent with previous Indian studies and highlights the increased vulnerability of outborn babies due to unclean delivery practices, delayed referral, inadequate intrapartum monitoring, and lack of early neonatal stabilization.

Prematurity emerged as a major risk factor in the present study, with nearly two-thirds (67%) of EOS cases occurring in preterm neonates. This observation is comparable to studies by Pankaj et al. and Verma et al., who also reported a higher burden of EOS among preterm infants [13,11]. Similar findings were noted by Kumar et al. and Bharad et al., who documented a predominance of preterm neonates among neonatal sepsis cases [14,15].

Furthermore, neonates born before 34 weeks of gestation were found to have a significantly higher risk of EOS ( $p < 0.0001$ ). This finding is in agreement with studies by Murthy et al. and Alam et al., which identified extreme prematurity as an independent risk factor for neonatal sepsis [16,16]. The increased susceptibility of preterm neonates can be attributed to immature immune responses, impaired skin and mucosal barriers, reduced transplacental transfer of maternal antibodies, and the frequent need for invasive interventions.

Low birth weight was another important determinant of EOS in this cohort. Approximately 74.5% of EOS cases occurred in

neonates weighing less than 2500 grams, with the highest incidence seen among very low birth weight and extremely low birth weight infants. Similar associations have been reported by Verma et al. and Ghosh and Basu, reinforcing the well-established relationship between low birth weight and neonatal sepsis [11,17]. Although prematurity and low birth weight often coexist, gestational age appears to play a more dominant role in determining EOS risk.

A clear male predominance (58.8%) was observed among EOS cases in the present study, and this association was statistically significant. Comparable findings have been reported by Neeraj Singh et al., Pankaj et al., and Mamta Jajoo et al. [18,13,19]. Additionally, a meta-analysis by Murthy et al. demonstrated male gender as a significant risk factor for neonatal sepsis [16]. This increased susceptibility in males may be related to genetic, hormonal, and immunological differences, including X-linked immune regulatory mechanisms.

Regarding mode of delivery, a higher proportion of EOS cases were observed among vaginally delivered neonates compared to those delivered by caesarean section. This finding is comparable to studies by Neeraj Singh et al., Pankaj et al., and Assa NP et al., which also reported a greater incidence of EOS following vaginal delivery [18,13,20]. Increased exposure to maternal genital tract flora, especially in the presence of prolonged rupture of membranes or intrapartum infection, may explain this observation.

The diagnostic utility of the sepsis screen in the present study reinforces its role as a useful screening and rule-out tool, particularly in resource-limited settings. Although blood culture remains the gold standard, its low sensitivity and delayed results necessitate reliance on clinical assessment combined with sepsis screen parameters for early initiation of empirical antibiotic therapy.

The microbiological profile observed in this study reflects the changing epidemiology of EOS in developing countries, with a predominance of gram-negative organisms, consistent with reports from Indian NICUs and the Delhi Neonatal Infection Study (DeNIS) collaboration [21]. The rising prevalence of multidrug-resistant organisms further underscores the need for periodic surveillance of local bacteriological patterns and formulation of unit-specific antibiotic policies.

Overall, the findings of the present study emphasize the importance of early recognition, prompt initiation of appropriate antimicrobial therapy, rational antibiotic stewardship, and optimal supportive care. Strengthening antenatal care services, promoting institutional deliveries, improving intrapartum infection-control practices, and ensuring timely referral of high-risk neonates remain critical strategies to reduce the burden of early-onset neonatal septicemia.

## Conclusion

Early-onset neonatal septicemia continues to be a major cause of morbidity and mortality, particularly among preterm, low birth

weight, and outborn neonates. Early identification of risk factors, prompt diagnosis using sepsis screening and blood culture, and judicious use of antibiotics are essential to improve neonatal outcomes.

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## Declarations

### Conflict of Interest

None declared

### Funding / Financial Support

Nil

### Contributors

Dhara K. Gosai contributed to the conception and design of the study, supervision of data collection, interpretation of data, and critical revision of the manuscript for important intellectual content.

Gargi H. Pathak contributed to study design, clinical oversight, monitoring of patient management, and critical review of the manuscript.

Jigar K. Jain contributed to acquisition of data, statistical analysis, interpretation of results, drafting of the manuscript, and correspondence with the journal.

Amit Das contributed to data collection, patient recruitment and management, literature review, and assistance in manuscript preparation.

All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work.

### Ethical Clearance

The study was approved by the Institutional Ethics Committee of B J Medical College and Civil Hospital, Ahmedabad. Written informed consent was obtained from the parents or legal guardians of all enrolled neonates prior to participation in the study.

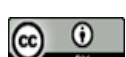
### Trial Details

Not applicable.

(This was an observational study and was not registered as a clinical trial.)

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