



A PROSPECTIVE STUDY ON PREDICTORS OF MORTALITY IN NEONATAL SEPTICEMIA: AT SPECIAL NEWBORN CARE UNIT (SNCU) OF TERTIARY CARE CENTER OF SOUTH GUJARAT

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Abstract

Background: Neonatal sepsis remains a critical contributor to neonatal mortality, especially in low- and middle-income countries. This prospective observational study aimed to identify predictors of mortality in neonates with culture-positive septicemia admitted to a tertiary care Special Newborn Care Unit (SNCU) in South Gujarat.

Methods: This prospective observational study was conducted in a tertiary care SNCU in South Gujarat. Over a 17-month enrollment period (Jan 2024–May 2025), 108 consecutive neonates (age 0–28 days) with culture-confirmed sepsis were included. Data on demographic, clinical, maternal, and laboratory parameters were systematically collected. Early-onset sepsis (EOS) was defined as onset within 72 hours of life. The primary outcome was in-hospital mortality, and predictors were analyzed using Chi-square or Fisher's exact tests.

Results: Overall mortality was 17.6%. Significant predictors included extremely low birth weight (ELBW, 50% mortality), small for gestational age status (SGA, 44.4%), need for resuscitation at birth (46.9%), and mechanical ventilation (48.4%). EOS was associated with significantly higher mortality (35.6%) than LOS (5%). Among maternal factors, eclampsia showed the strongest correlation with neonatal mortality (90%). *Klebsiella pneumoniae* infection had a high mortality rate (75%). In contrast, neonates with CRP positivity and procalcitonin levels between 0.5–2.0 ng/mL had better outcomes.

Conclusion: The study underscores the importance of early identification of risk factors such as birth weight, gestational age, sepsis onset, resuscitation, and pathogen type. Strengthening perinatal care, timely interventions, and focused monitoring in SNCUs are crucial for improving survival in neonates with sepsis.

Keywords: Neonatal Sepsis, Risk Factors, Mortality, *Klebsiella* Infections, Intensive Care Units

Introduction

Neonatal sepsis is a critical global health issue that significantly contributes to neonatal morbidity and mortality, particularly in low- and middle-income countries (LMICs) (1). Globally, it is estimated that over 6.3 million incident cases of neonatal sepsis occurred in 2019 alone, with approximately 230,000 resultant deaths, despite ongoing improvements in healthcare infrastructure (2). The disease

burden remains disproportionately high in sub-Saharan Africa and South Asia, regions with limited access to advanced neonatal care (3).

India alone accounts for a significant portion of global neonatal sepsis-related deaths, largely due to systemic healthcare disparities, delayed diagnosis, and suboptimal infection control practices (4). Despite increased awareness and early intervention protocols, the mortality rate for culture-positive neonatal sepsis can range between 11% to 20% globally, and often higher in resource-limited settings (5).

Early-onset sepsis (EOS), typically occurring within the first 72 hours of life, is often associated with vertical transmission from maternal sources and is linked with higher case fatality rates compared to late-onset sepsis (LOS) (6). Several maternal and neonatal risk factors—such as prematurity, low birth weight, prolonged labor, intrapartum infections, and need for resuscitation—have been consistently reported as independent predictors of poor outcomes in septic neonates (7), (8).

Culture-specific pathogens, especially Gram-negative organisms like *Klebsiella pneumoniae*, have emerged as dominant causes of neonatal sepsis in many tertiary care centers across Asia and Africa, often displaying multidrug resistance and significantly higher mortality rates (4).

Given this context, our study aims to prospectively evaluate predictors of mortality in neonates with culture-positive septicemia in a tertiary care Special Newborn Care Unit (SNCU) in South Gujarat. Identifying and stratifying these risk factors can guide clinicians in early recognition and focused interventions, ultimately improving survival outcomes for this vulnerable population.

Materials and Methods

Study Design and Setting

This prospective observational study was conducted at the Special Newborn Care Unit (SNCU), a regional tertiary care referral center at a teaching hospital in South Gujarat, India. The study was conducted from December 2023 to May 2025, with patient enrollment taking place over a 17-month period from January 2024 to May 2025.

Sample Size Calculation

The sample size was determined using data on SNCU admissions from the previous six months. Based on a previous study, the proportion of patients with septicemia (P) was taken as 35.2% (0.352). With a 95% confidence level, the corresponding Z-score ($Z_{\alpha/2}$) was 1.96. An allowable error (L) of 9% (0.09) was set for the study. The sample size was calculated using the formula: $n = (Z_{\alpha/2}^2 * P * Q) / L^2$, where $Q=1-P$. The calculation yielded a required sample size of 108 neonates.

Study Population

A total of 108 neonates with culture-proven septicemia were enrolled in the study. Eligibility was limited to neonates aged 0 to 28 days who presented with clinical signs of sepsis and had a positive blood culture report during their SNCU admission. Exclusion criteria included neonates with major congenital malformations incompatible with life, those diagnosed with culture-negative sepsis, and those referred post-treatment from external facilities without laboratory evidence of septicemia.

Data Collection

Data were recorded on a pre-designed structured proforma after obtaining informed written consent from parents or legal guardians. Demographic variables such as gestational age, sex, birth weight, mode and place of delivery, and maternal conditions (including eclampsia, fever, prolonged rupture of membranes, and meconium-stained amniotic fluid) were collected. Clinical symptoms at admission were also documented, including poor feeding, lethargy, hypothermia, apnea, seizures, respiratory distress, poor perfusion, and shock. Information regarding perinatal events—such as the need for resuscitation, use of inotropes, and mechanical ventilation—was gathered. Laboratory investigations included C-reactive protein (CRP), procalcitonin (PCT), complete blood count, and blood culture.

Each neonate was followed from admission until final outcome, either discharge or death. Sepsis was classified based on onset as Early-Onset Sepsis (EOS), occurring within 72 hours of birth, and Late-Onset Sepsis (LOS), occurring after 72 hours.

Microbiological Evaluation

Blood cultures were obtained under sterile conditions before initiating antibiotic therapy. Specimens were processed using automated systems (e.g., VITEK), and bacterial identification and antibiotic susceptibility testing were carried out as per Clinical and Laboratory Standards Institute (CLSI) guidelines.

Statistical Analysis

Statistical analysis was performed using SPSS version 27. Categorical variables were expressed as frequencies and percentages. Associations between mortality and potential predictors were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations

This study was approved by the Institutional Ethics Committee of SMIMER, Surat. Written informed consent was obtained from the parents or legal guardians of all enrolled neonates. The study adhered to ethical principles in accordance with the Declaration of Helsinki.

Results

This study was conducted over a 17-month period in the neonatal intensive care unit (NICU) of a tertiary care hospital. A total of 108 neonates with culture-proven sepsis were enrolled based on predefined inclusion criteria. All subjects were thoroughly assessed for demographic, clinical, microbiological, and outcome variables.

Neonatal Characteristics

Among the 108 neonates, 62 (57%) were male and 46 (43%) were female. The majority, 73 (68%), were preterm, while the remaining 35 (32%) were term births. Birth weight analysis revealed that 2 neonates (0.9%) were extremely low birth weight (ELBW), 30 (27.8%) were very low birth weight (VLBW), and 43 (39.8%) were low birth weight (LBW). Only 33 (30.6%) neonates had normal birth weight. Most babies were inborn (83.3%) as opposed to outborn (15.7%). In terms of gestational growth status, 54.6% were appropriate for gestational age (AGA), 25% were small for gestational age (SGA), and 20.4% were large for gestational age (LGA) (Table 1).

Table 1: Baseline Neonatal and Perinatal Characteristics (N=108)

Characteristic	Category	Frequency (N)	Percentage (%)
Gender of Babies	Female	46	43%
	Male	62	57%
Gestational Age	Preterm	73	68%
	Term	35	32%
Birth Weight	ELBW (<1000 gms)	2	0.90%
	VLBW (1000-1500 gms)	30	27.80%
	LBW (1500-2500 gms)	43	39.80%
	Normal (>2500 gms)	33	30.60%
Place of Birth	Out Born	17	15.7%
	Inborn	90	83.3%
Gestational Growth Status	Appropriate for Gestational Age (AGA)	59	54.6%
	Small for Gestational Age (SGA)	27	25.0%
	Large for Gestational Age (LGA)	22	20.4%

Birth Asphyxia	No	70	65%
	Yes	38	35%
Need for Neonatal Resuscitation	Yes	32	29.6%
	No	76	70.4%
Type of Oxygen Support Required	Nasal Cannula	14	13.0%
	Oxygen Hood	16	14.8%
	Continuous Positive Airway Pressure (CPAP)	25	23.1%
	Ventilator	31	28.7%
	High Flow Nasal Cannula (HFNC)	11	10.2%

Perinatal and Resuscitative Events

Birth asphyxia was reported in 38 neonates (35%), whereas 70 (65%) did not show evidence of asphyxia. A total of 32 neonates (29.6%) required neonatal resuscitation at birth, while the remaining 76 (70.4%) did not. Regarding respiratory support, 31 (28.7%) required mechanical ventilation, 25 (23.1%) received continuous positive airway pressure (CPAP), 16 (14.8%) used oxygen hoods, 14 (13%) were supported with nasal cannula, and 11 (10.2%) received high-flow nasal cannula (HFNC).

Maternal and Obstetric Factors

Maternal age was distributed as follows: 8.3% were aged 18–20 years, 43.5% between 20–25 years, and 48.1% above 25 years. The majority were primigravida (55.6%). Almost all mothers received tetanus toxoid (TT) vaccination (95.4%) and adequate antenatal care (96.3% had ≥ 4 visits). Cesarean delivery was the predominant mode (64.8%), compared to 35.2% vaginal deliveries. Obstetric complications included prolonged labor in 15.7%, premature rupture of membranes (PROM) in 22.2%, and meconium-stained liquor in 25%. Maternal fever occurred in 12%, PIH in 11.1%, pre-eclampsia in 10.2%, and eclampsia in 1.9% (Table 2).

Table 2: Maternal and Obstetric Factors (N=108)

Characteristic	Category	Frequency (N)	Percentage (%)
Age of Mother	18-20 years	9	8.3%
	20-25 years	47	43.5%
	>25 years	52	48.1%
Gravida Status	Primigravida	60	55.6%
	Multigravida	48	44.4%
Tetanus Toxoid (TT) Vaccination	Received	103	95.4%
Antenatal Care (ANC) Visits	No	3	2.8%
	Yes (≥ 4 visits)	104	96.3%
Mode of Delivery	Lower Segment Cesarean Section (LSCS)	70	64.8%
	Vaginal Delivery (VD)	38	35.2%
Obstetric Complications	Prolonged Labour (>18 hrs)	17	15.7%
	Premature Rupture of Membranes (PROM)	24	22.2%
	Leaking Per Vagina (PV)	15	13.9%
	Meconium-Stained Liquor	27	25.0%
	Maternal Fever	13	12.0%
	Chorioamnionitis	2	1.9%
	Pregnancy-Induced Hypertension (PIH)	12	11.1%
	Pre-eclampsia	11	10.2%
	Eclampsia	2	1.9%
	Gestational Diabetes Mellitus (GDM)	7	6.5%

Clinical Features in Neonates

Clinical manifestations varied across neonates. The most commonly observed symptoms were poor perfusion (23.1%), feeding intolerance (21.3%), and refusal to feed (20.4%). Shock was present in

18.5%, sclerema in 13.9%, and respiratory distress features like tachypnea (13%), hypothermia (12%), and apnea (7.4%) were also significant. Other less common symptoms included hypoglycemia (5.6%), fever (4.6%), bleeding manifestations (6.5%), convulsions (2.8%), and icterus (3.7%).

Microbiological Profile

Blood culture revealed that *Acinetobacter* was the most frequently isolated pathogen (33.3%), followed by coagulase-negative *Staphylococci* (30.6%), *E. coli* (10.2%), and *S. aureus* (9.3%). Other isolates included *Pseudomonas* (6.5%), MRSA (3.7%), *Klebsiella* (3.7%), and *Enterobacter* (2.8%) (Table 3).

Table 3: Clinical Features, Microbiology, and Outcomes (N=108)

Characteristic	Category	Frequency (N)	Percentage (%)
Clinical Features at Admission	Not taking feed	22	20.4%
	Feeding intolerance	23	21.3%
	Poor perfusion	25	23.1%
	Shock	20	18.5%
	Sclerema	15	13.9%
	Tachypnea	14	13.0%
	Hypothermia	13	12.0%
	Apnea	8	7.4%
	Abdominal Distension	8	7.4%
	Bleeding manifestation	7	6.5%
	Hypoglycaemia	6	5.6%
	Fever	5	4.6%
	Icterus	4	3.7%
	Convulsion	3	2.8%
Blood Culture Pathogens	<i>Acinetobacter</i>	36	33.33%
	Coagulase-Negative <i>Staphylococci</i> (CoNS)	33	30.56%
	<i>Escherichia coli</i> (<i>E. coli</i>)	11	10.19%
	<i>Staphylococcus aureus</i> (<i>S. aureus</i>)	10	9.26%
	<i>Pseudomonas</i>	7	6.48%
	<i>Klebsiella</i>	4	3.70%
	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	4	3.70%
	<i>Enterobacter</i>	3	2.78%
Outcome of Patients	Discharge	86	79.6%
	Death	19	17.6%
	DAMA (Left Against Medical Advice)	3	2.8%

Outcomes and Mortality Analysis

Of the 108 neonates, 86 (79.6%) were discharged, 19 (17.6%) died, and 3 (2.8%) left against medical advice (DAMA). Mortality was strongly associated with birth weight; ELBW neonates had 50% mortality, VLBW 32.1%, LBW 16.7%, and normal weight neonates had the lowest mortality at 6.1% ($p = 0.039$). Gender did not significantly impact mortality ($p = 0.9844$). Preterm infants had higher mortality (22.9%) compared to term infants (8.6%), though this was not statistically significant ($p = 0.1277$). SGA neonates had a significantly higher mortality rate (44.4%) than AGA (8.5%) or LGA (10.5%) infants ($p = 0.0002$).

Early-onset sepsis (EOS) was associated with significantly higher mortality (35.6%) than late-onset sepsis (LOS, 5%) ($p = 0.0002$). Interestingly, birth asphyxia was not significantly associated with mortality ($p = 0.3223$), but the need for resuscitation at birth was highly significant—46.9% mortality in resuscitated babies versus only 5.5% in non-resuscitated ($p < 0.001$).

Oxygen Support and Outcomes

Mechanical ventilation was associated with 48.4% mortality, and nasal cannula with 50% mortality. HFNC was the safest, with 0% mortality. Oxygen hood and CPAP showed intermediate outcomes with 37.5% and 26.1% mortality, respectively.

Maternal and Laboratory Predictors

Maternal factors such as eclampsia were strongly associated with neonatal death (90% mortality, $p < 0.001$), while gravida status showed statistical significance—primigravida mothers had lower neonatal mortality (10.2% vs 28.3% in multigravida, $p = 0.01689$). Other factors like maternal age, ANC visits, and delivery mode were not significant.

Among lab markers, CRP positivity was associated with improved survival, showing only 7.0% mortality compared to 25.8% in CRP-negative neonates ($p = 0.02733$). Similarly, procalcitonin (PCT) levels between 0.5–2.0 ng/mL were linked to the best outcomes (2.6% mortality, $p = 0.004$), while levels >2 –10 ng/mL were associated with higher mortality (33.3%). Haemoglobin, platelet count, WBC, and ANC levels showed no statistically significant mortality association.

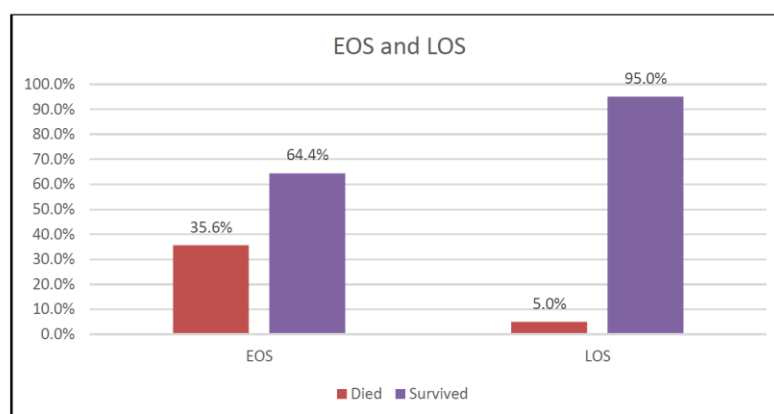
Pathogen and Outcome Associations

Klebsiella infection showed a significant association with high mortality (75%, $p = 0.03649$), while other pathogens, including *Acinetobacter* and CONS, had higher absolute numbers but their association with mortality was not statistically significant. Low prevalence of pathogens like MRSA and *Enterobacter* limited statistical interpretation (Table 4, Figure 1).

Table 4: Mortality Rates by Key Predictors

Predictor	Category	Total Neonates (N)	Deaths (N)	Mortality Rate (%)	P-Value
Birth Weight	ELBW (<1000 gms)	2	1	50.00%	0.039
	VLBW (<1500-1000gms)	28	9	32.14%	
	LBW (1500-2500gms)	42	7	16.67%	
	Normal (>2500 gms)	33	2	6.06%	
Gestational Growth Status	Small for Gestational Age (SGA)	27	12	44.4%	0.0002
	Appropriate for Gestational Age (AGA)	59	5	8.5%	
	Large for Gestational Age (LGA)	19	2	10.5%	
Sepsis Onset	Early-Onset Sepsis (EOS)	45	16	35.6%	0.0002
	Late-Onset Sepsis (LOS)	60	3	5.0%	
Need for Resuscitation	Yes	32	15	46.9%	0.000001615
	No	73	4	5.5%	
Maternal Eclampsia	Yes	10	9	90.0%	0.00000334
	No	104	19	18.3%	
Pathogen Type	<i>Klebsiella</i>	4	3	75.0%	0.03649
Oxygen Delivery Method	Mechanical Ventilator	31	15	48.4%	0.000000779
	Nasal Cannula	14	7	50.0%	0.0008658
	Oxygen Hood	16	6	37.5%	0.02853
Procalcitonin (PCT) Level	>2 to <10 ng/mL	27	9	33.3%	0.004
	0.5-2.0 ng/mL	39	1	2.6%	
	<0.5 ng/mL	39	9	23.1%	
CRP Level	Negative	62	16	25.8%	0.02733
	Positive	43	3	7.0%	
Gravida Status	Primigravida	59	6	10.2%	0.01689
	Multigravida	46	13	28.3%	

Figure 1. Comparison of Mortality Between Early-Onset and Late-Onset Neonatal Sepsis



Discussion

This study investigated the clinical and demographic factors associated with neonatal sepsis and its outcomes among 108 neonates admitted to a tertiary care NICU. The findings provide important insights into key predictors of neonatal mortality and morbidity, aligning with and expanding upon findings from other global studies.

Neonatal Characteristics and Mortality

Low birth weight and prematurity emerged as significant risk factors for mortality in our cohort. Neonates classified as ELBW and VLBW had the highest mortality rates—50% and 32.1%, respectively. This trend is consistent with global data indicating that very low birth weight significantly increases the risk of sepsis-related mortality. For example, Bhat and Kumar (2009) observed higher mortality and prolonged ventilation needs in VLBW neonates with early-onset sepsis (EOS), emphasizing their vulnerability (9).

Gestational age also played a role in outcomes. Although preterm neonates had a higher mortality (22.9%) than term neonates (8.6%), the association did not reach statistical significance. However, multiple studies corroborate the trend. Salem et al. (2006) demonstrated that low gestational age independently predicted sepsis development and associated mortality in neonates ≤ 1500 g (10).

Early-Onset vs Late-Onset Sepsis

One of the most critical findings in our study was the significant association between early-onset sepsis (EOS) and mortality (35.6%) compared to late-onset sepsis (LOS, 5%). This is strongly supported by Jumah et al. (2007), who reported a 62.9% mortality in EOS versus 36.5% in LOS, underscoring the aggressive nature of infections acquired perinatally (11).

Oxygen Support and Resuscitation

The requirement of advanced oxygen support, such as mechanical ventilation and CPAP, correlated with higher mortality rates in our study. Mechanical ventilation showed a striking 48.4% mortality, reinforcing its role as a marker of severity. Similarly, the need for neonatal resuscitation was highly predictive of poor outcomes (46.9% mortality), echoing the findings from Gupta et al. (2024), who identified resuscitation at birth as a strong independent predictor of mortality in VLBW neonates (12). Interestingly, HFNC showed no associated mortality in our cohort, suggesting that it may be a safer modality when appropriate. This was also noted by Wilar & Lestari (2022), who found better outcomes in neonates requiring less invasive respiratory support (13).

Maternal and Obstetric Influences

Eclampsia emerged as the most significant maternal predictor of neonatal mortality (90% death rate, $p < 0.00001$), aligning with Meshram et al. (2019), who found maternal hypertension as a critical risk

factor in outborn neonates with sepsis (14). Similarly, the presence of meconium-stained liquor, PROM, and fever had trends toward worse outcomes, although they were not statistically significant in our data.

Blood Culture Findings

Acinetobacter and coagulase-negative Staphylococci were the most prevalent pathogens, consistent with findings from the German Neonatal Network, which also identified *E. coli* and CONS as common causes of neonatal sepsis in VLBW infants (15). However, in our study, Klebsiella showed a significant association with mortality (75% mortality, $p = 0.036$), reinforcing concerns raised by Jumah et al. (2007), who found high mortality in Klebsiella and Pseudomonas infections (11).

Laboratory Predictors

Positive CRP and PCT levels between 0.5–2.0 ng/mL were associated with improved survival, while higher PCT values (>2.0) predicted increased mortality. These findings complement those of Bhat & Kumar (2009), who found that although CRP had low sensitivity on its own, when combined with clinical parameters, it could guide prognosis more effectively (9).

Comparison with Global Mortality Rates

Our overall mortality rate of 17.6% is within the range reported in similar tertiary care studies, such as Shobowale et al. (2015) who observed a mortality of 15.7% among neonates with sepsis in Lagos (16). Notably, our discharge rate of 79.6% reflects successful outcomes in the majority, attributable to robust NICU protocols and early intervention strategies.

Conclusion

This study highlights several key predictors of mortality in neonates with culture-proven septicemia, including low birth weight, small for gestational age status, early-onset sepsis, need for resuscitation at birth, and specific pathogens like Klebsiella pneumoniae. These findings emphasize the importance of early risk stratification and aggressive supportive care in high-risk neonates. Strengthening perinatal care, timely initiation of empirical antibiotics, and continuous monitoring in well-equipped SNCUs are essential strategies to reduce sepsis-related mortality. Future research should focus on rapid diagnostics and antimicrobial resistance patterns to further enhance outcomes in resource-limited settings.

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