

## RESEARCH PAPER

# Immediate Outcomes and Predictors of Mortality in Neonatal Sepsis: A Clinical and Biochemical Risk Profiling Study at a Tertiary Care Centre in Northern Maharashtra

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### Abstract:

#### Background:

Early identification of neonates at high risk of adverse outcomes is crucial for timely intervention in neonatal sepsis. Clinical signs and simple laboratory markers may help in early risk stratification, particularly in resource-limited settings.

#### Aim and Objectives:

To determine the immediate outcomes (recovery or mortality) among neonates with sepsis and to evaluate the association of clinical and biochemical parameters with mortality.

#### Methods:

A retrospective record-based study was conducted among 92 neonates admitted with clinical or culture-proven sepsis. Antenatal, perinatal, clinical, and biochemical variables were analyzed. Their association with immediate outcomes (recovery or death) was assessed using Chi-square or Fisher's exact test, followed by multivariable logistic regression to identify independent predictors of mortality.

#### Results:

Several clinical variables showed significant association with mortality on univariate analysis, including hypoglycemia, hyperglycemia, metabolic acidosis, sclerema, direct hyperbilirubinemia and low gestational age. Hematological and biochemical markers such as leukopenia, thrombocytopenia, low absolute neutrophil count (ANC), and elevated C-reactive protein (CRP) were also significantly associated with mortality. On multivariable logistic regression analysis, presence of sclerema remained an independent predictor of mortality, whereas CRP positivity, although significant on univariate analysis, did not retain independent significance after adjustment.

#### Conclusion:

Simple bedside clinical indicators, particularly the presence of sclerema, may serve as important predictors of mortality in neonatal sepsis. Early recognition of high-risk neonates using clinical signs supported by laboratory parameters may enable timely intervention and potentially improve outcomes.

**Keywords:** Neonatal Sepsis, Neonatal Intensive Care Unit (NICU), Mortality Predictors, Clinical and Biochemical Parameters, Neonatal Outcomes

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### Introduction

Neonatal sepsis remains a major cause of neonatal morbidity and mortality worldwide. Early diagnosis and timely identification of high-risk neonates remain challenging because clinical manifestations are often nonspecific and laboratory markers may lack adequate

sensitivity and specificity. Sepsis in neonates is frequently diagnosed late because of its nonspecific clinical presentation, the variable reliability of biochemical markers, and the low yield of blood cultures. <sup>1</sup> Delayed diagnosis substantially contributes to mortality among affected newborns. <sup>2</sup> The high cost and

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limited availability of certain biochemical investigations further restrict their routine use in many healthcare settings.

Globally, neonatal mortality accounts for nearly 40% of all under-five deaths, with about 25% occurring in South-East Asia and Sub-Saharan Africa.<sup>3</sup> Mortality due to neonatal sepsis is estimated at 3–4% in high-income countries compared with approximately 24% in low- and middle-income settings.<sup>1</sup> Late recognition of sepsis and the increasing prevalence of multidrug-resistant organisms are major contributors to these disparities. Blood culture positivity, the gold standard for diagnosis, is influenced by several factors including timing of sample collection, volume of blood obtained, and prior antibiotic exposure. A range of antenatal and perinatal factors such as gestational age and birth weight, clinical features such as prolonged capillary refill time (CRT) and glucose abnormalities, and biochemical parameters including total leukocyte count (TLC), platelet count, absolute neutrophil count (ANC), C-reactive protein (CRP), and metabolic acidosis have been associated with neonatal sepsis.<sup>4–8</sup> Identification of reliable prognostic indicators is essential for early risk stratification, optimal resource utilization, and improved clinical decision-making. Although several studies have evaluated diagnostic markers of neonatal sepsis, relatively fewer studies have focused on predictors of mortality using both clinical and biochemical parameters. Furthermore, regional data from tertiary care centers in northern Maharashtra are limited. Therefore, the present study was undertaken to determine the immediate outcomes (recovery or mortality) among neonates admitted with clinical or culture-positive sepsis, assess the association between clinical and biochemical parameters and outcomes, and identify independent predictors of mortality among neonates admitted in the neonatal intensive care unit (NICU).

#### Research methodology:

**Study design and setting:** The present study represents a secondary analysis of data collected during a previously conducted study evaluating the diagnostic utility of clinical and laboratory parameters for early detection of neonatal sepsis. The dataset was retrospectively analyzed to study the association between clinical and biochemical parameters and immediate outcomes (recovery or mortality) among neonates with sepsis. Institutional Ethics Committee approval was obtained prior to conducting the original study. (IEC letter: 1401/SMBT/IMSRC/10/IEC/24/250) Data of 92 neonates with antenatal risk factors, clinical and biochemical signs of sepsis admitted from March 2025 to August 2025 was analyzed to study association with immediate outcome, recovery or death.

**Inclusion criteria:** Neonates admitted to the NICU with clinical suspicion of sepsis and associated risk factors were included in the study.

Risk factors for sepsis present at birth like need for resuscitation at birth, prematurity < 37 weeks of gestational age, low birth weight < 2.5 kg.

Clinical parameters for sepsis that were studied for its association with outcome, mortality or recovery were gestational age, birth weight, presence of hypoglycemia, hyperglycemia, direct hyperbilirubinemia, metabolic acidosis, sclerema and capillary refill time (CRT).

Hematological parameters that were considered were total leukocyte count, platelets count, absolute leukocyte count (ANC) and C-reactive proteins (CRP).

**Exclusion criteria:** Neonates whose clinical records were not complete or not conclusive of sepsis.

**Sample size:** Records of 92 neonates, admitted from March to August 2025, who were admitted for sepsis.

Laboratory diagnostic criteria for definitions used were low total leukocyte count (TLC) <5000/mm<sup>3</sup>, low platelet count <1.5 lakhs/ml, low absolute neutrophil count (ANC) <1800, positive C reactive protein (CRP) 1 mg/L, hypoglycemia (blood glucose <45 mg/dl), acidosis (arterial pH <7.35), hyperglycemia ( blood glucose > 150 mg/dl).

#### Method of data collection:

92 neonates were admitted with antenatal, clinical and biochemical signs of sepsis from March 2025 to August 2025. Data was collected with aim to explore the relationship between Immature to total neutrophil (IT) ratio, clinical features, laboratory findings and blood culture positivity for early diagnosis of neonatal sepsis. Consent was obtained for data collection from relatives. This data was analyzed retrospectively for studying association of clinical and biochemical risk factors with immediate outcome, recovery or death. Data was collected with google form and stored on excel sheet.

**Data analysis:** Data was analyzed with Centre for Disease Control and prevention (CDC) Epi info 7 software. Chi-square test and Fisher's exact test were used to assess association between clinical and biochemical parameters and outcome. A p value <0.05 was considered statistically significant.

Due to the limited number of mortality events (n=24), the number of predictors in the multivariate model was restricted to avoid overfitting in accordance with the event-per-variable principle. Only clinically meaningful and statistically stable variables were included in the final model.

#### Results:

**Baseline characteristics:** A total of 92 neonates with sepsis were enrolled, of whom 24 (26.1%) died and 68 (73.9%) survived. 67 (72.8%) were males and 25 (27.14%) were females. The majority of neonates were low birth weight ( $\leq 2.5$  kg) accounting for 81 cases (88.0%), while 11 (12.0%) weighed more than 2.5 kg. Preterm neonates (<37 weeks) constituted 60 (65.2%) of the study population, whereas 32 (34.8%) were term neonates.

**Gestational age:** Out of 60 preterm neonates 21 (35%) died while 3(9.38%) among term neonates had mortality. This association was statistically significant ( $\chi^2 = 7.11$ ,  $p = 0.0077$ ). Preterm neonates had substantially higher odds of mortality (OR = 5.12; 95% CI: 1.50–23.40) and a markedly elevated risk (RR = 3.73; 95% CI: 1.20–11.57). The risk difference was also significant (+25.6%; 95% CI: +9.9 to +41.4).(Table 1,2)

**Birth weight:** Out of 81 low birth weight <2.5 kg neonates 22 (27.16%) had mortality as compared to 2(18.18%) out of 11 with weight > 2.5 kg. There was no statistically significant association between birth weight and neonatal mortality ( $\chi^2 = 0.40$ ,  $p = 0.52$ ). Effect size estimates (OR = 0.60, RR = 0.67) also indicated no meaningful relationship, with wide confidence intervals. (Table 1,2)

**Hypoglycemia** had significant association with neonatal mortality ( $\chi^2 = 26.33$ ,  $p < 0.000001$ ; Fisher's exact  $p < 0.000001$ ). Mortality was markedly higher among neonates with hypoglycemia (51.2%) compared to those without (4.1%). The odds of mortality were 96% lower in neonates without hypoglycemia (OR = 0.041, 95% CI: 0.009–0.189), and the risk of mortality was reduced by 92% in the absence of hypoglycemia (RR = 0.080, 95% CI: 0.020–0.320). (Table 1,2)

**Hyperglycemia** and neonatal mortality had significant association ( $\chi^2 = 18.19$ ,  $p = 0.00002$ ; Fisher's exact  $p = 0.00019$ ). All neonates with hyperglycemia in this cohort died (100% mortality), compared with a mortality rate of 20.9% among those without hyperglycemia. The odds ratio approached zero due to the absence of survivors in the hyperglycemia group (MLE OR = 0.000, 95% CI: 0.000–0.192), indicating an extremely strong association. Mortality risk was reduced by 79% in neonates without hyperglycemia (RR = 0.21, 95% CI: 0.14–0.32). (Table 1,2)

**Direct hyperbilirubinemia** was strongly associated with increased mortality. Mortality was significantly higher in neonates with direct hyperbilirubinemia compared to those without (39.6% vs 7.7%,  $p < 0.001$ ). The odds of mortality were nearly eight-fold higher in neonates with direct hyperbilirubinemia. (Table 1,2)

**Capillary refill time:** CRT was studied as < 2 sec normal and > 2 sec prolonged. Prolonged capillary refill time ( $\geq 2$  seconds) was associated with higher odds of mortality (OR 2.23; 95% CI 0.25–19.7); however, this association was not statistically significant ( $p = 0.19$ ). (Table 1,2)

**Metabolic acidosis** was strongly associated with mortality ( $\chi^2 = 20.07$ ,  $p < 0.001$ ). Mortality was significantly higher among neonates with metabolic acidosis (65%) compared to those without acidosis (15.3%). The presence of metabolic acidosis increased

the risk of death by more than four times, making it one of the strongest clinical predictors of mortality in neonatal sepsis. (Table 1,2)

**Sclerema** showed a very strong association with mortality. Mortality was substantially higher among neonates with sclerema (67.7%) compared with those without sclerema (4.9%). The odds of death were 40.6 times higher in neonates with sclerema, while the relative risk of death was 13.8 times higher. The presence of sclerema increased absolute mortality risk by 62.8%. This association was highly significant ( $\chi^2 = 42.1$ ,  $p < 0.0001$ ; Fisher's exact  $p < 0.0001$ ). (Table 1,2)

#### Biochemical parameters

Low **absolute neutrophil count** (ANC <1800) was associated with a higher proportion of mortality (28.6%) compared to neonates with ANC  $\geq 1800$  (18.2%).(Table 1,2)

Although the odds of death were 1.8 times higher in the low ANC group (OR 1.80; 95% CI 0.54–5.98), this association was not statistically significant ( $p = 0.33$ )

**Elevated CRP** (>1 mg/dL) was significantly associated with higher mortality. Among neonates with raised CRP, 37.1% died compared to only 3.3% among those with CRP  $\leq 1$  mg/dL. The odds of mortality were significantly higher in the elevated CRP group (OR 17.10; 95% CI 2.18–134.06). The relative risk was 11.13 (95% CI 1.58–78.55), with an absolute risk difference of 33.8%. Chi-square and Fisher's exact tests confirmed a strong association ( $\chi^2 = 11.95$ ,  $p < 0.001$ ; Fisher's exact  $p = 0.0003$ ). (Table 1,2)

**Platelets count:** Thrombocytopenia was found significantly associated with mortality in neonatal sepsis ( $\chi^2 = 17.23$ ,  $p < 0.0001$ ; Fisher exact  $p = 0.00003$ ). Mortality was markedly higher in neonates with platelet count <1.5 lakh/mm<sup>3</sup> (44.7%) compared with those with platelet count  $\geq 1.5$  lakh/mm<sup>3</sup> (6.7%). Thrombocytopenia was associated with a substantially increased risk of death (RR = 6.70, 95% CI: 2.15–20.93) and a more than elevenfold increase in odds of mortality (OR = 11.31, 95% CI: 3.07–41.69). (Table 1,2)

**Total leukocyte count** and mortality were significantly associated in neonatal sepsis ( $\chi^2 = 23.77$ ,  $p < 0.00001$ ; Fisher exact  $p < 0.00002$ ). Neonates with leukopenia (TLC < 5,000/mm<sup>3</sup>) had markedly higher mortality, with 90% of infants in this group dying, compared to 18.3% mortality among those with TLC  $\geq 5,000$ /mm<sup>3</sup>. The odds of mortality were 40.2 times higher in neonates with leukopenia (95% CI: 4.73–341.86). (Table 1,2)

#### Multivariable Logistic Regression for Clinical Parameters and outcome

Although several clinical and biochemical variables including lower gestational age, hypoglycemia, hyperglycemia, metabolic acidosis, direct

hyperbilirubinemia and abnormal leukocyte parameters showed significant association with mortality on univariate analysis, these were not included in the final multivariate model. This decision was based on (1) the limited number of mortality events (n=24), necessitating restriction of predictors to avoid overfitting as per the event-per-variable principle; (2) the presence of interrelated severity markers which could introduce multicollinearity and unstable coefficient estimates; and (3) complete or quasi-complete separation observed for certain variables (e.g., hyperglycemia), precluding reliable estimation in standard logistic regression. Therefore, the final model was restricted to two clinically meaningful and statistically stable predictors—sclerema and CRP positivity.

On multivariate logistic regression analysis, sclerema remained independently associated with mortality (Adjusted OR 0.03, 95% CI 0.006–0.16,  $p < 0.001$ ). Although CRP positivity was significantly associated with mortality on univariate analysis, it did not retain statistical significance after adjustment (Adjusted OR 1.99, 95% CI 0.17–23.20,  $p = 0.58$ ). (Table 3)

#### Discussion

Among clinical parameters direct hyperbilirubinemia, low gestational age, hyperglycemia, hypoglycemia, presence of metabolic acidosis and presence of sclerema had significant association with mortality. Metabolic abnormalities such as hypoglycemia and hyperglycemia may reflect severe systemic infection and stress response. Hyperglycemia has been associated with increased inflammatory cytokine release and poor outcomes in critically ill neonates. In the present study, prematurity showed a significant association with mortality, whereas low birth weight did not demonstrate a statistically significant association, possibly due to the small number of neonates with birth weight  $> 2.5$  kg in the cohort. Jovicic et al reported low birth weight and extreme prematurity association with mortality. (12) While Meshram et al reported low admission weight, gestational age and prolonged CRT to be associated with mortality.---(13) Prematurity, low birthweight and hyperglycemia association was reported by Gosai et al. (3) This study found statistically significant association between low absolute neutrophil count, raised C-reactive protein, low total leukocyte count, thrombocytopenia and neonatal mortality. Leukopenia may indicate bone marrow suppression or overwhelming infection, both of which are associated with severe sepsis and poor prognosis. Thrombocytopenia is frequently observed in neonatal sepsis due to platelet consumption, disseminated intravascular coagulation and inflammatory cytokine-mediated suppression of platelet production. Gosai et al found association of CRP and thrombocytopenia with neonatal mortality. (3) While Asif et al found thrombocytopenia, leucopenia and raised CRP significantly associated with mortality. (14)

Ahmed et al found low birth weight and neutropenia as independent predictor of mortality. (14) Meshram et al

found admission weight and age, gestational age, duration of admission and prolonged CRT as predictor of mortality in neonates.---(13) Multivariate regression: In the present study, presence of sclerema was independently associated with mortality (adjusted OR 33.3 for mortality when coded inversely). Sclerema reflects severe systemic inflammation, circulatory compromise, and advanced septic state, which likely explains its strong association with adverse outcomes. Although CRP positivity demonstrated significant association with mortality on univariate analysis, it did not retain independent significance after adjustment. This may be attributed to the dominant effect of clinical severity markers such as sclerema and the limited number of mortality events in the cohort. These findings highlight the importance of bedside clinical assessment in prognostication of neonatal sepsis. The present study provides a comprehensive evaluation of both clinical and biochemical predictors of mortality in neonatal sepsis in a tertiary care setting in northern Maharashtra. Unlike many studies focusing primarily on laboratory markers, this study highlights the prognostic value of bedside clinical indicators such as sclerema along with commonly used biochemical parameters. The findings emphasize that simple clinical signs may serve as important predictors of mortality, particularly in resource-limited settings where advanced investigations may not always be readily available. The present study highlights simple bedside clinical assessment along with basic laboratory tests while evaluating neonatal sepsis. Clinical and biochemical parameters like sclerema, metabolic disturbances, poor perfusion, leukopenia, thrombocytopenia and elevated CRP were linked to adverse outcomes.

#### Conclusion:

Sclerema was identified as an independent predictor of mortality in neonates with sepsis. Although CRP positivity showed significant association on univariate analysis, it did not independently predict mortality after adjustment. Early recognition of high-risk neonates using simple clinical indicators such as sclerema, along with supportive laboratory markers, may facilitate timely intervention and improved outcomes in neonatal sepsis.

#### Limitations:

The study was conducted at a single tertiary care center, which may limit the generalizability of the findings. The sample size was relatively small, and the number of mortality events was limited, restricting the number of predictors that could be included in multivariate analysis. Certain clinical severity markers such as ventilatory and inotropic support were not included in the final regression model due to statistical constraints. The retrospective record-based design may introduce information bias. Larger multicenter prospective studies are required to validate these findings and develop robust mortality prediction models. Blood culture positivity and organism-specific outcomes were not analyzed in relation to mortality in the present study.

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Variable	Death n (%)	Survived n (%)	Odds Ratio (95% CI)	Relative Risk (95% CI)	p value
Gestational age <37 weeks	21 (35%)	39 (65%)	5.12 (1.42–19.13)	3.73 (1.20–11.57)	0.0077
Birth weight <2.5 kg	22 (27.2%)	59 (72.8%)	1.68(0.34-8.42)	1.49(0.40-5.48)	0.47
Hypoglycemia	Higher mortality (51.2%)	4.1%	24.6(5.3 – 114.9)	12.53(3.13-50.30)	<0.001
Hyperglycemia	100%	0%	Not estimable	—	<0.001
Direct hyperbilirubinemia	39.6%	7.7%	7.88(2.15-28.90)	5.15(1.65-16.05)	<0.001
Prolonged CRT (>2 sec)	27.06%	72.94%	OR 2.23; (0.25–19.7)	1.89; (0.30–11.94)	0.19
Metabolic acidosis	65%	15.3%	10.30(3.36-31.55)	4.25(2.26-8.01)	<0.001
Sclerema	67.7%	4.9%	40.6(10.2-161.3)	13.8(4.45-42.55)	<0.0001
ANC <1800	28.6%	18.2%	1.80 (0.54–5.98)	1.57(0.60-4.11)	0.33
CRP >1 mg/dL	37.1%	3.3%	17.10 (2.18–134.06)	11.13 (1.58–78.55)	<0.001
Platelet <1.5 lakh/mm <sup>3</sup>	44.7%	6.7%	11.31 (3.07–41.69)	6.70 (2.15–20.93)	<0.001
TLC <5000/mm <sup>3</sup>	90%	10%	40.2 (4.73–341.86)	4.92(2.98-8.13)	<0.001

**Table 2 Diagnostic performance of clinical and biochemical parameters with mortality in neonatal sepsis**

Parameter	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC	Interpretation
Gestational age	87.5	42.6	35.9	90.62	0.65	Moderate predictor
Birth weight	91.6	13.23	27.1	81.8	0.52	Poor predictor
Sclerema	87.5	85.3	67.7	95.1	0.86	Excellent predictor
Hypoglycemia	91.7	69.1	51.2	95.9	0.80	Good predictor
Hyperglycemia	25.0	100	100	79.1	0.63	Highly specific
CRT	95.8	8.82	27.06	85.7	0.52	Poor predictor
Metabolic acidosis	54.2	89.7	65.0	84.7	0.72	Moderate predictor
Platelet <1.5 lakh	87.5	61.8	44.7	93.3	0.75	Moderate predictor
CRP positive	95.8	42.6	37.1	96.7	0.69	Screening marker
Direct hyperbilirubinemia	87.5	52.9	39.6	92.3	0.70	Moderate predictor
Leukopenia	37.5	98.5	90.0	81.7	0.68	Highly specific marker
Low ANC	16.7	73.5	18.2	71.4	0.45	Not useful

**Table 3: Multivariable logistic regression analysis for predictors of mortality**

Term	Odds Ratio	95%	C.I.	Coefficient	S.E.	Z-Statistic	P-Value
SCLEREMA CODE (Yes/No)	0.0328	0.0065	0.1657	-3.4161	0.8259	-4.1362	0.0000
CRP 2 (Yes/No)	1.9956	0.1716	23.2039	0.6910	1.2517	0.5520	0.5809
CONSTANT	*	*	*	2.6741	0.7311	3.6578	0.0003