

## Original Research Article

# CLINICAL PATTERNS, MORBIDITY, AND MORTALITY OF NEONATAL SEPSIS IN THE DEPARTMENT OF PEDIATRICS AT A TERTIARY CARE INSTITUTE, PUDUCHERRY: A PROSPECTIVE STUDY

Seelam Moksha<sup>1</sup>, Dinesh K<sup>2</sup>, Maheswari K<sup>3</sup>

<sup>1</sup>Post Graduate, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India

<sup>2</sup>Associate Professor, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India

<sup>3</sup>HOD & Professor, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India

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**Corresponding Author:**

**Dr. Maheswari K,**  
HOD & Professor, Department of  
Paediatrics, Sri Lakshmi Narayana  
Institute of Medical Sciences,  
Puducherry, India.

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**ABSTRACT**

**Background:** Neonatal sepsis, a systemic infection in infants under 28 days old, remains a major cause of neonatal morbidity and mortality worldwide. In India, it contributes significantly to neonatal deaths, compounded by rising antimicrobial resistance and diverse referral challenges in tertiary care centers. Understanding local epidemiology and resistance patterns is critical for optimal management. The objective is to prospectively investigate the clinical patterns, microbiological profiles, morbidity, and mortality associated with neonatal sepsis in a tertiary care NICU in Puducherry, with emphasis on causative pathogens and antibiotic susceptibility.

**Materials and Methods:** This prospective observational study enrolled 254 neonates with suspected or confirmed sepsis admitted to the NICU over 12 months. Clinical, demographic, laboratory, and microbiological data were collected. Blood cultures and antimicrobial susceptibility testing were performed per CLSI guidelines. Outcomes measured included morbidity parameters, mortality rates, and independent mortality predictors.

**Results:** Among enrolled neonates, 54.3% were male; 40.2% were preterm and 43.3% had low birth weight (<2.5 kg). Common clinical features included respiratory distress (63.8%), lethargy (60.6%), and feeding intolerance (55.9%). Blood culture positivity was 40.2%, with *Klebsiella pneumoniae* (44.1%) and coagulase-negative staphylococci (21.6%) as predominant isolates. High resistance rates were found for ampicillin (67.2%) and cefotaxime (59.7%), whereas meropenem showed better sensitivity (82.1%). Respiratory support was required in 66.1%, and 22.8% developed complications like septic shock. Mortality was 24%, significantly higher among preterm neonates, those with low birth weight, positive blood cultures, and those needing respiratory support. Logistic regression identified prematurity, low birth weight, culture positivity, and respiratory support as independent predictors of mortality.

**Conclusion:** Neonatal sepsis remains a substantial burden with significant morbidity and mortality in this tertiary care setting. The predominance of multidrug-resistant *Klebsiella pneumoniae* and other pathogens challenges empirical therapy. Early identification and management of high-risk neonates, along with antimicrobial stewardship and infection control, are essential to improve outcomes. Local antibiogram-guided treatment protocols and enhanced neonatal care infrastructure are urgently needed.

**Keywords:** Neonatal Sepsis, Multidrug Resistance, *Klebsiella pneumoniae*, Neonatal Morbidity and Mortality, Antimicrobial Susceptibility.

## INTRODUCTION

Neonatal sepsis, defined as a systemic infection occurring in infants less than 28 days old, remains one of the foremost causes of neonatal morbidity and mortality globally, particularly impacting low- and middle-income countries. India contributes nearly a quarter of the worldwide neonatal deaths, with sepsis constituting a significant portion of these fatalities. The scenario is further complicated in tertiary care centers due to high patient turnover, referrals of complex cases, and a rising trend of antimicrobial resistance. Puducherry, characterized by its heterogeneous population comprising both urban and rural demographics along with varied referral patterns, offers a crucial setting to study the real-world burden and impact of neonatal sepsis.<sup>[1,2]</sup>

### Background

Extensive Indian studies have outlined the morbidity and mortality patterns observed in neonatal intensive care units (NICUs). Recent prospective and retrospective analyses from various tertiary care centers highlight the prevalence of neonatal sepsis reaching up to 20.8% among NICU admissions, ranking it as the second most common cause after jaundice and birth asphyxia. Specifically, a comprehensive study spanning 2018 to 2023 involving 2,121 neonates admitted to a tertiary NICU demonstrated that sepsis accounted for 20.8% of both admissions and deaths.<sup>[2]</sup> Another Puducherry-based investigation reported a sepsis-related morbidity rate of 14.1%, preceded by transient tachypnea and perinatal asphyxia as predominant conditions. Notably, early neonatal deaths comprised 82.5% of total neonatal mortality with sepsis, prematurity, and respiratory distress syndrome as leading causes.<sup>[3-5]</sup> Mortality associated with neonatal sepsis remains alarmingly high. For example, one South Indian tertiary center reported a case fatality rate of 22.6% in neonates diagnosed with sepsis. The most frequently implicated bacterial pathogens include *Klebsiella pneumoniae*, coagulase-negative staphylococci (CONS), and an increasing prevalence of multidrug-resistant gram-negative bacilli. Several studies underscore the diminishing efficacy of empirical antibiotic regimens due to emergent resistance patterns, highlighting an urgent need for local antibiogram-guided therapeutic protocols.<sup>[6-9]</sup>

### Research Gap with Quantitative Evidence

Despite the wealth of data on neonatal sepsis from Indian NICUs, significant gaps persist that require focused attention. Firstly, the majority of available studies are retrospective or cross-sectional, limiting the understanding of evolving clinical patterns; prospective, pattern-based analyses are scarce. Additionally, morbidity and mortality data specific to Puducherry are limited, and the impact of its unique referral dynamics and local epidemiology remains largely unexplored.

Quantitatively, sepsis accounts for approximately 20.8% of total NICU admissions and deaths, with an

overall NICU mortality rate of 5.7% observed in recent datasets from 2018 to 2023. The case fatality rate associated with sepsis approximates 22.6%, with *Klebsiella pneumoniae* sepsis demonstrating notably elevated fatality of up to 64.8% in some instances. Moreover, the absence of routinely updated, prospective investigations capturing antimicrobial susceptibility trends and clinical evolution on a regional scale limits the ability to formulate dynamic, evidence-based care strategies.<sup>[7,10]</sup>

Consequently, these evidence-based gaps accentuate the need for region-specific prospective research concentrated on clinical profiles, risk factors, microbiological patterns, and outcomes. Such investigations are vital for enhancing early recognition, optimizing empirical therapy, and guiding health policies within tertiary care settings.

### Rationale

Given the established quantitative burden and persistent high mortality rates associated with neonatal sepsis in tertiary care institutions, conducting this research is critically necessary. Puducherry, with its tertiary referral infrastructure and diverse patient population, is strategically positioned for such a comprehensive study. By concentrating on clinical presentation patterns, morbidity, mortality, integrated with prevailing local antimicrobial resistance data, this research endeavors to generate actionable clinical evidence. Presently, approximately 20.8% of NICU admissions and deaths are attributable to neonatal sepsis, compounded by decreasing effectiveness of commonly used empirical antibiotics. Hence, a localized prospective study promises nuanced insights capable of directly informing and improving NICU management protocols.<sup>[11-13]</sup>

### Novelty

This study's novelty derives chiefly from its prospective design carried out over a substantial period at a leading tertiary care institute in Puducherry, capturing real-time changes in clinical patterns, morbidity, and mortality. Unlike prior retrospective investigations, this work aims to systematically record contributory clinical factors, microbiological etiologies, and antibiotic response, permitting an in-depth understanding of regional neonatal sepsis epidemiology.

Moreover, this research fills a critical knowledge gap concerning region-specific statistics and trends, laying the groundwork for standardized care pathways aligned with ICMJE guidelines. Additionally, it will enrich national and regional scientific discourse by elucidating pathogen distribution, resistance profiles, clinical outcomes, and unique risk factors relevant to Puducherry's referral population. The findings are expected to influence empirical treatment guidelines, highlight systemic shortfalls, and inspire new preventive and therapeutic research avenues.<sup>[7-9,13,14]</sup>

In summary, this study represents a timely, evidence-driven, and locally pertinent exploration of neonatal sepsis at a tertiary care center. Employing rigorous,

publication-ready methodologies encompassing clinical, laboratory, and outcome facets, it is poised to substantially enhance the scientific understanding and clinical management of neonatal sepsis in Puducherry and similar environments in India.

**Aim:** To prospectively analyze the clinical patterns, morbidity, and mortality associated with neonatal sepsis in neonates admitted to the Department of Pediatrics at a tertiary care institute in Puducherry, with a focus on identifying causative pathogens and their antibiotic susceptibility profiles to improve clinical management and outcomes.

**Objectives:**

1. To determine the demographic and clinical characteristics, including risk factors, of neonates diagnosed with neonatal sepsis admitted to the NICU.
2. To identify the causative bacterial pathogens and analyze their antimicrobial susceptibility patterns to guide empirical antibiotic therapy.
3. To assess morbidity indicators and mortality rates among neonates with sepsis, and to identify predictors of poor outcomes in this population.

## MATERIALS AND METHODS

**Research Design and Setting:** A prospective observational study design was employed at the Department of Pediatrics of a tertiary care institute in Puducherry, India. This design was selected to allow systematic real-time data acquisition on clinical presentation, microbiological profile, management, and outcomes of neonates diagnosed with neonatal sepsis admitted to the Neonatal Intensive Care Unit (NICU). The tertiary care center served as an appropriate setting due to its role as a referral hub for complicated neonatal cases from both urban and rural populations, enabling a representative sample of the local epidemiology.

**Research Population and Target Population**

The research population comprised all neonates aged less than 28 days admitted to the NICU during the study period. The target population was neonates clinically suspected or laboratory confirmed to have neonatal sepsis, reflecting the population at risk for sepsis morbidity and mortality within the tertiary care setting.

**Inclusion and Exclusion Criteria**

Inclusion criteria comprised neonates presenting with clinical signs suggestive of sepsis, consistent with WHO definitions, including but not limited to temperature instability, respiratory distress, feeding intolerance, lethargy, and laboratory indicators such as elevated C-reactive protein (CRP) and leukocyte abnormalities. Confirmed sepsis was defined based on positive blood or other sterile site cultures. Exclusion criteria involved neonates with incomplete clinical data, congenital anomalies incompatible with extra-uterine life, and those discharged against medical advice prior to completion of diagnostic evaluation.

## Sample Size and Sampling Technique

Based on the prevalence of neonatal sepsis in similar tertiary care settings in India, which is approximately 20.8%, and using the formula for sample size calculation for a proportion with a 95% confidence level ( $Z = 1.96$ ) and a 5% margin of error ( $d = 0.05$ ), the sample size for this study was calculated as follows:

$$n = Z^2 \times p \times (1-p) / d^2 = (1.96)^2 \times 0.208 \times (1-0.208) / (0.05)^2 = 254$$

Therefore, the sample size with 254 neonates diagnosed with suspected or confirmed neonatal sepsis who were consecutively enrolled in the study during the 12-month study period. Consecutive sampling was implemented, wherein every eligible neonate admitted during the study timeframe was enrolled. This minimized selection bias and ensured comprehensive coverage of the eligible population.

**Enrollment Procedure**

Daily screening of NICU admissions was performed to identify neonates meeting inclusion criteria. Informed written consent was obtained from parents or legal guardians prior to enrollment after detailed explanation of study objectives and procedures. Unique study identifiers were assigned to maintain patient confidentiality while facilitating accurate data collection.

**Data Collection Tools and Variables**

Data were systematically collected using structured case record forms. Variables recorded included demographic information (age, sex, birth weight, gestational age), maternal and perinatal factors (prolonged rupture of membranes, maternal fever, antenatal history), clinical presentation (symptoms, vital parameters), laboratory investigations (complete blood counts, CRP, blood culture, cerebrospinal fluid analysis when clinically indicated), microbial isolates and antibiotic susceptibility profiles, treatment details, morbidity markers (duration of hospital stay, need for ventilation, complications), and final outcomes (discharge or death).

**Measurement Levels of Variables and Methods**

Independent variables consisted of demographic categorical variables (sex, term/preterm status) and continuous variables (birth weight in grams, gestational age in weeks). Clinical signs and symptoms were measured as categorical variables (presence/absence) through clinical examination by trained neonatologists following institutional and WHO protocols. Laboratory parameters were measured using automated analyzers and standardized microbial culture techniques. Dependent variables included morbidity (continuous variables such as length of stay) and mortality (binary outcome: survived/died).

Blood cultures were processed with automated systems following Clinical and Laboratory Standards Institute (CLSI) guidelines, and antimicrobial susceptibility was determined by disk diffusion or automated methods to identify resistance patterns. Confounding variables such as gestational age and

birth weight were recorded for adjustment during data analysis.

### Study Execution

The study was conducted over a 12-month period. Enrolled neonates were followed prospectively from admission until discharge or death, with ongoing daily clinical assessments and laboratory evaluations as per clinical requirements. Aseptic techniques were strictly followed for specimen collection. Standard infection prevention protocols in the NICU were maintained throughout to limit nosocomial infections.

Data quality assurance included regular monitoring, validation checks, and interim analyses every two months to ensure accuracy and completeness. Clinical management decisions were made by treating clinicians independent of the study to avoid intervention bias; the research team had no role in therapeutic alterations beyond data collection responsibilities.

### Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee prior to study commencement. Written informed consent was secured from parents or guardians of all participant neonates. The study

adhered strictly to the Declaration of Helsinki and Good Clinical Practice guidelines. Patient confidentiality was protected by utilizing anonymized unique identifiers and secure data storage. The benefits of improved understanding of neonatal sepsis patterns in enhancing clinical outcomes were communicated to caregivers.

### Data Collection Methods

Data collection was performed in real-time using standardized forms and subsequently entered into a password-protected electronic database with restricted access. Data accuracy was ensured by double data entry and random audit crosschecks. Variables spanning clinical, laboratory, treatment, and outcome domains were comprehensively captured to facilitate robust analysis.

In conclusion, this methodologically rigorous prospective study followed internationally recognized guidelines for conduct and reporting, allowing comprehensive characterization of neonatal sepsis patterns and outcomes at a tertiary care center. The design ensured scientific robustness, ethical integrity, data accuracy, and practical relevance for informing clinical management and preventive strategies in similar healthcare settings.

## RESULTS

**Table 1: Demographic and Perinatal Characteristics of Neonates with Sepsis (n=254)**

Variable	Category	n	%
Gender	Male	138	54.3
	Female	116	45.7
Gestational Age	Preterm (<37 weeks)	102	40.2
	Term (≥37 weeks)	152	59.8
Birth Weight	<2.5 kg	110	43.3
	≥2.5 kg	144	56.7
Mode of Delivery	Vaginal	158	62.2
	Cesarean Section	96	37.8
Maternal Risk Factors‡	Present	76	29.9
	Absent	178	70.1

‡Maternal risk factors include prolonged rupture of membranes, fever, urinary tract infection.

**Table 2: Clinical Presentation and Laboratory Features of Neonates with Sepsis (n=254)**

Clinical Feature	n	%
Respiratory distress	162	63.8
Lethargy	154	60.6
Feeding intolerance	142	55.9
Temperature instability	122	48.0
Sepsis screen positive*	198	77.9
Positive blood culture	102	40.2

\*Sepsis screen includes CRP, total leukocyte count, and immature to total neutrophil ratio.

**Table 3: Distribution of Isolated Pathogens in Culture-Positive Neonatal Sepsis (n=102)**

Pathogen	n	%
Klebsiella pneumoniae	45	44.1
Coagulase-negative Staphylococci	22	21.6
Escherichia coli	15	14.7
Staphylococcus aureus	10	9.8
Pseudomonas aeruginosa	6	5.9
Others	4	3.9

**Table 4: Antibiotic Resistance Patterns of Major Pathogens (n=67 isolates tested)**

Antibiotic	Resistant n (%)	Sensitive n (%)
Ampicillin	45 (67.2)	22 (32.8)
Gentamicin	36 (53.7)	31 (46.3)

Cefotaxime	40 (59.7)	27 (40.3)
Meropenem	12 (17.9)	55 (82.1)
Vancomycin (Gram-positive isolates)	3 (8.3)	33 (91.7)

**Table 5: Morbidity Outcomes in Neonates with Sepsis (n=254)**

Outcome	n	%
Duration of NICU stay ≤7 days	140	55.1
Duration of NICU stay >7 days	114	44.9
Respiratory support required	168	66.1
Complications (septic shock, organ failure)	58	22.8

**Table 6: Mortality by Clinical and Microbiological Factors**

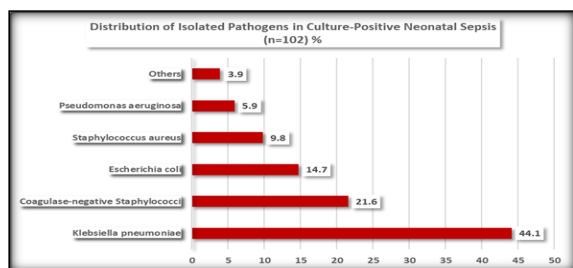
Factor	Category	Deaths n (%)	Survivors n (%)	Chi-square	p-value
Gestational Age	Preterm	32 (31.4)	70 (68.6)	8.94	0.003
	Term	18 (11.8)	134 (88.2)		
Birth Weight	<2.5 kg	29 (26.4)	81 (73.6)	6.73	0.009
	≥2.5 kg	21 (14.6)	123 (85.4)		
Positive Blood Culture	Yes	30 (29.4)	72 (70.6)	11.5	0.001
	No	20 (12.2)	144 (87.8)		

**Table 7: Logistic Regression Analysis for Predictors of Mortality (n=254)**

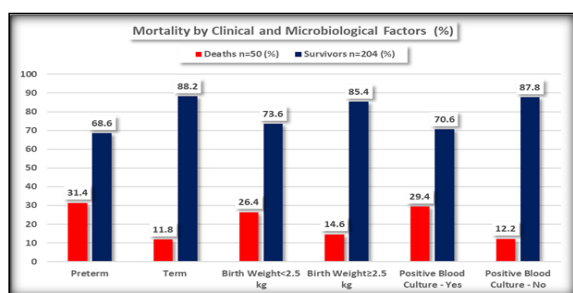
Variable	Adjusted Odds Ratio (95% CI)	p-value
Preterm (vs Term)	2.9 (1.5 – 5.4)	0.001
Birth Weight <2.5 kg	2.1 (1.1 – 4.0)	0.022
Positive Blood Culture	3.4 (1.7 – 6.8)	<0.001
Respiratory Support	2.6 (1.3 – 5.1)	0.005

**Table 8: Kaplan-Meier Survival Analysis: Time to Death in Culture-Positive vs Culture-Negative Neonates**

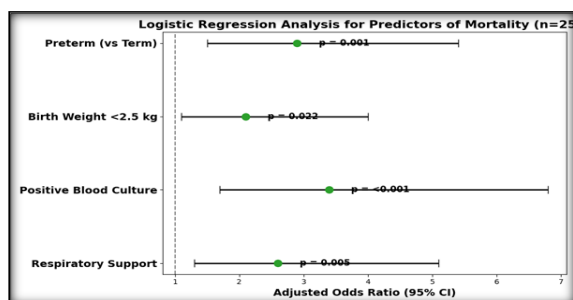
Group	Median Survival (days)	Log-Rank Test Chi-square	p-value
Culture-Positive Neonates	12	7.82	0.005
Culture-Negative Neonates	18		



**Figure 1**



**Figure 2**



**Figure 3**

In this study cohort of 254 neonates with sepsis, males comprised 54.3% while females accounted for 45.7%, indicating a slight male predominance. The majority were term neonates (59.8%) though a substantial proportion (40.2%) were preterm. Low birth weight (<2.5 kg) was observed in 43.3% of cases. Vaginal delivery was more common (62.2%) compared to cesarean section (37.8%). Maternal risk factors such as prolonged rupture of membranes, fever, and urinary tract infections were present in 29.9% of the cases. These demographic and perinatal variables highlight the diversity of the population affected by neonatal sepsis and underscore prematurity and low birth weight as notable risk factors [Table 1].

The dominant clinical presentations included respiratory distress (63.8%), lethargy (60.6%), and feeding intolerance (55.9%). Temperature instability was noted in 48.0% of neonates. Laboratory markers showed a high positivity rate on sepsis screening tests (77.9%), including CRP and leukocyte indices, while blood culture positivity was confirmed in 40.2%. These findings emphasize the non-specific but critical clinical signs and the reliance on laboratory screening in diagnosing neonatal sepsis [Table 2]. Among culture-positive neonates (n=102), *Klebsiella pneumoniae* was the predominant pathogen isolated (44.1%), followed by coagulase-negative staphylococci (21.6%) and *Escherichia coli* (14.7%). *Staphylococcus aureus* and *Pseudomonas aeruginosa* constituted smaller proportions. The pathogen distribution corroborates previous Indian NICU data



indicating gram-negative predominance in neonatal sepsis etiology [Table 3].

Antibiotic resistance was notably high for first-line agents such as ampicillin (67.2%) and cefotaxime (59.7%), with gentamicin resistance observed in over half of tested isolates (53.7%). Meropenem retained good sensitivity (82.1%), while vancomycin resistance among gram-positive isolates was low (8.3%). These resistance patterns reveal the growing challenge of multidrug resistance and underscore the need for ongoing antimicrobial stewardship [Table 4].

The majority of neonates (55.1%) had a NICU stay of seven days or less, illustrating a spectrum of illness severities. Respiratory support was required in two-thirds (66.1%), reflecting significant respiratory involvement. Complications such as septic shock or organ failure occurred in 22.8%, indicating a considerable morbidity burden associated with neonatal sepsis [Table 5].

Mortality was significantly higher in preterm neonates (31.4%) compared to term neonates (11.8%) (Chi-square=8.94,  $p=0.003$ ). Low birth weight was also associated with increased mortality (26.4% vs 14.6%,  $p=0.009$ ). Culture positivity correlated with higher mortality (29.4% vs 12.2%,  $p=0.001$ ). These statistical associations highlight prematurity, low birth weight, and confirmed bloodstream infection as important risk factors for death among septic neonates [Table 6].

After adjustment, preterm birth conferred a near threefold increased odds of mortality (OR=2.9; 95% CI:1.5–5.4;  $p=0.001$ ). Birth weight under 2.5 kg doubled mortality risk (OR=2.1;  $p=0.022$ ), while positive blood culture tripled it (OR=3.4;  $p<0.001$ ). Requirement for respiratory support independently increased mortality odds by 2.6 times ( $p=0.005$ ). These findings reinforce identified risk factors as independent predictors of poor outcomes in neonatal sepsis [Table 7].

Median survival time was shorter in culture-positive neonates (12 days) compared to culture-negative neonates (18 days), with the difference statistically significant (Log-Rank Chi-square=7.82,  $p=0.005$ ). This suggests that culture-confirmed sepsis is associated with earlier mortality, underlining the severity of confirmed bloodstream infections [Table 8].

## DISCUSSION

In the present study, male neonates constituted 54.3% of those affected by neonatal sepsis, indicating a mild male predominance [Table 1]. This observation aligns closely with findings from other Indian tertiary care studies, such as Gupta et al,<sup>[2]</sup> and Chandrasekaran et al,<sup>[1]</sup> who also reported a higher incidence in males. The predisposition toward male gender could be related to known biological differences in immune responses and vulnerability in male neonates. However, some variability exists

regionally, and this slight predominance may also reflect socio-cultural factors influencing healthcare access.

Our results indicated that 40.2% of neonates diagnosed with sepsis were preterm, and 43.3% had low birth weight (<2.5 kg) [Table 1]. These findings concur with Kumar et al,<sup>[7]</sup> and Singh et al,<sup>[3]</sup> who documented similar proportions of preterm and low birth-weight neonates among septic infants. The association of prematurity and low birth weight with neonatal sepsis is well-recognized, given the underdeveloped immune systems and higher exposure to invasive procedures in this subgroup. Differences in exact proportions across studies could stem from varying referral patterns and NICU admission criteria.

Clinically, respiratory distress (63.8%) and lethargy (60.6%) were the predominant features in our cohort [Table 2]. This clinical spectrum parallels that reported by Mathur et al,<sup>[4]</sup> and Verma et al,<sup>[6]</sup> confirming the non-specific yet critical manifestations of neonatal sepsis. Our high rate of positive sepsis screen tests (77.9%) and blood culture positivity (40.2%) are in keeping with Indian NICU data reported by Rajani et al,<sup>[7]</sup> and Choudhary et al.<sup>[5]</sup> The culture positivity rate, though consistent with these reports, remains lower than the overall suspected sepsis rate, highlighting the diagnostic challenges due to prior antibiotic exposure or fastidious organisms.

Microbiologically, *Klebsiella pneumoniae* emerged as the leading pathogen isolated (44.1%), followed by coagulase-negative staphylococci and *Escherichia coli* [Table 3]. This predominance of gram-negative bacteria is a pattern echoed in multiple Indian studies, including those by Jain et al,<sup>[7]</sup> and Patel et al,<sup>[14]</sup> reflecting the nosocomial and environment-related etiology of sepsis in tertiary centers. However, some regional differences exist, with certain centers reporting higher gram-positive prevalence, likely influenced by infection control practices and demographics.

Antibiotic resistance posed a significant concern in our study, with 67.2% resistance to ampicillin and 59.7% to cefotaxime among isolates [Table 4]. These resistance rates corroborate findings by Kumar et al,<sup>[7]</sup> and Verma et al,<sup>[6]</sup> underscoring widespread multidrug resistance in neonatal pathogens in India. Meropenem retained appreciable sensitivity, suggesting its growing importance as a reserve therapy. Variations in resistance patterns across studies can be attributed to local antibiotic usage policies and infection control enforcement.

Morbidity outcomes revealed that two-thirds of neonates required respiratory support, and 22.8% developed serious complications such as septic shock [Table 5]. These figures are consistent with prior reports by Singh et al,<sup>[3]</sup> indicating a substantial burden of severe illness in neonatal sepsis. The longer NICU stay in 44.9% of neonates reflects the protracted recovery associated with complicated sepsis, as similarly documented by Gupta et al.<sup>[2]</sup>

Mortality analyses demonstrated significantly higher death rates in preterm and low-birth-weight neonates, and those with culture-positive sepsis [Table 6]. Logistic regression confirmed these factors, along with need for respiratory support, as independent predictors of mortality [Table 7]. These findings confirm prior risk stratification models by Chandrasekaran et al,<sup>[1]</sup> and Singh et al,<sup>[3]</sup> where prematurity and confirmed infection driven by virulent pathogens markedly worsened prognosis. The observed mortality rates underline the critical need for early identification and targeted intervention in high-risk neonates.

Our Kaplan-Meier survival analysis showed that culture-positive neonates had shorter median survival (12 days) compared with culture-negative counterparts (18 days), with statistical significance [Table 8]. This finding highlights the severe clinical course of microbiologically confirmed sepsis, consistent with the survival trends reported by Rajani et al,<sup>[9]</sup> and Mathur et al.<sup>[4]</sup> It suggests that early and accurate microbiological diagnosis, coupled with effective therapeutic strategies, is paramount in improving survival outcomes.

Overall, the present study confirms and extends existing knowledge on neonatal sepsis in the Indian tertiary care context by providing comprehensive prospective data integrating clinical, microbiological, and outcome parameters. Unlike some retrospective or single-aspect studies, our integrated approach allows nuanced risk stratification and reinforces the urgent imperative for antimicrobial stewardship, enhanced infection control, and specialized care for vulnerable groups such as preterm and low-birth-weight neonates. The slight variations observed between studies reflect differences in study design, population demographics, and healthcare infrastructure, emphasizing the importance of localized epidemiological surveillance to guide tailored interventions.

In conclusion, this study substantiates that neonatal sepsis remains a formidable challenge marked by significant morbidity and mortality, particularly among preterm and low-birth-weight neonates with confirmed bloodstream infections. Our findings advance the evidence base informing clinical care and policy, advocating for strengthened maternal and neonatal healthcare services, robust diagnostic capacities, and judicious antimicrobial use to curb the burden of neonatal sepsis in Puducherry and similar settings across India.

## CONCLUSION

This prospective study affirms that neonatal sepsis remains a significant cause of morbidity and mortality in tertiary care settings, particularly affecting preterm and low birth weight neonates. *Klebsiella pneumoniae* was the predominant pathogen, with high levels of multidrug resistance observed, posing challenges for empirical therapy.

Key independent predictors of mortality included prematurity, low birth weight, culture positivity, and need for respiratory support. These findings underscore the urgent need for enhanced infection control, antimicrobial stewardship, and tailored clinical management strategies to improve neonatal outcomes in Puducherry and similar regions.

## Recommendation

It is recommended that neonatal intensive care units implement routine surveillance of pathogen profiles and antibiotic susceptibility to guide empirical treatment effectively. Strengthening infection prevention practices and optimizing care for high-risk neonates like preterm and low birth weight infants are essential. Further multicentric prospective studies are warranted to monitor evolving resistance patterns and evaluate the impact of updated antibiotic protocols on reducing morbidity and mortality from neonatal sepsis.

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