



## EPIDEMIOLOGY, CLINICAL SPECTRUM, ANTIMICROBIAL AGENTS OF NEONATAL SEPSIS IN A TERTIARY CARE HOSPITAL

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**ABSTRACT** **Background:** Neonatal sepsis continues to be a leading cause of morbidity and mortality among newborns in low- and middle-income countries. Despite advances in neonatal intensive care, emerging antimicrobial resistance has worsened outcomes. This study aims to determine the incidence, clinical profile, causative organisms, and their antibiotic susceptibility pattern in neonates with sepsis. **Methods:** A prospective observational study was conducted in the NICU of CPR Hospital, Kolhapur, between January 2025 and June 2025. Fifty neonates with clinically suspected sepsis were included. Detailed clinical evaluation, relevant laboratory investigations, and blood culture with antibiotic susceptibility testing were performed. **Results:** Of the 50 neonates, 66% were male and 34% female. Preterm neonates constituted 58%, while term neonates accounted for 42%. Early-onset sepsis (EOS) occurred in 68% of cases, while late-onset sepsis (LOS) was seen in 32%. The most common clinical features were respiratory distress (46%), refusal to feed (44%), and lethargy (36%). Blood culture was positive in 46% of neonates. Gram-negative organisms predominated (71%), with *Klebsiella pneumoniae* being the most common isolate (48%), followed by *Enterococcus* (16%), coagulase-negative *Staphylococcus* (9%), and *Citrobacter* (9%). Among antibiotics, ceftazidime, amikacin, and piperacillin showed higher sensitivity against gram-negative isolates, while vancomycin remained highly effective against gram-positive organisms. The case fatality rate was 23%. **Conclusions:** Neonatal sepsis remains a major cause of morbidity and mortality. Gram-negative organisms, particularly *Klebsiella pneumoniae*, are the predominant pathogens. Rising resistance to commonly used antibiotics such as ampicillin and ceftriaxone emphasizes the need for periodic surveillance of antimicrobial susceptibility patterns and formulation of rational antibiotic policies in NICUs.

**KEYWORDS :** Neonatal sepsis, antimicrobial resistance, *Klebsiella*, antibiotic susceptibility, NICU**INTRODUCTION:**

Neonatal sepsis is a systemic infection occurring in the first 28 days of life and remains one of the most significant contributors to neonatal morbidity and mortality worldwide<sup>(1)</sup>. Recent estimates suggest that sepsis accounts for nearly 20–30% of neonatal deaths in South Asia and sub-Saharan Africa, with case fatality rates ranging from 20% to 40% depending on access to timely and appropriate care. The incidence of neonatal sepsis in India has been reported between 15–30 per 1000 live births, reflecting persistent challenges in perinatal care and antimicrobial resistance<sup>(2)</sup>.

Advances in neonatal intensive care have improved survival, but inappropriate or excessive antibiotic use has accelerated the emergence of multidrug-resistant (MDR) organisms, complicating management strategies<sup>(3)</sup>. Recent studies highlight *Klebsiella pneumoniae*, *Escherichia coli*, and *Staphylococcus aureus* as the most frequent causative organisms, with resistance to commonly prescribed antibiotics such as ampicillin, ceftriaxone, and gentamicin becoming increasingly widespread<sup>(4)</sup>.

Neonatal sepsis is broadly classified into early-onset sepsis (EOS,  $\leq 72$  hours of life) and late-onset sepsis (LOS,  $> 72$  hours). EOS is usually associated with maternal and perinatal risk factors, while LOS is more often related to nosocomial or community-acquired infections. The distinction is crucial since the pathogen profile and antibiotic sensitivity patterns differ in each group<sup>(5)</sup>.

Given the changing epidemiology and rising antibiotic resistance, it is essential to periodically review microbial profiles and antibiotic susceptibility patterns in individual neonatal intensive care units (NICUs). This study was undertaken to determine the clinical spectrum, causative organisms, and antibiotic sensitivity patterns of neonatal sepsis in a tertiary care hospital in Western Maharashtra.

**MATERIALS AND METHODS:**

This was a prospective observational study conducted in the Neonatal Intensive Care Unit (NICU) of the Department of Pediatrics, CPR Hospital, Kolhapur, from January 2025 to June 2025. A total of 50 neonates ( $\leq 28$  days old) Neonates presenting with at least two clinical features suggestive of sepsis (fever, poor feeding, lethargy, respiratory distress, apnea, hypothermia, jaundice, convulsions, etc.) and supported by at least two laboratory parameters were included. Neonates with major congenital malformations or superficial localized infections only were excluded.

Maternal and neonatal history was recorded. Clinical examination was performed daily until discharge or death. Blood samples were collected for complete blood count, CRP, micro-ESR, and blood

culture. Identification of bacterial isolates and antimicrobial susceptibility testing was performed according to CLSI guidelines (2023). Data were analyzed using SPSS v25 and expressed as percentages and proportions.

**RESULTS:****Table 1: Distribution Of Neonates By Maturity And Sex:**

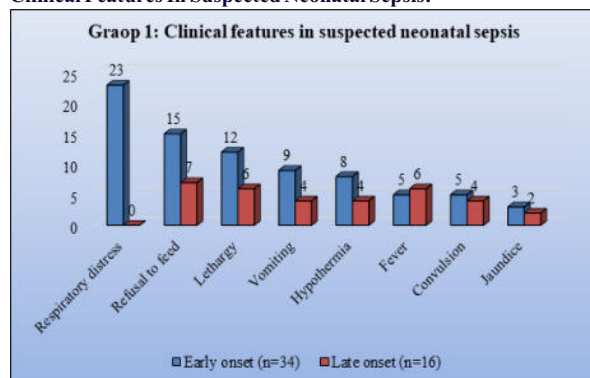
| Maturity | Male       | Female     | Total     |
|----------|------------|------------|-----------|
| Preterm  | 19 (57.6%) | 10 (58.8%) | 29 (58%)  |
| Term     | 14 (42.4%) | 7 (41.2%)  | 21 (42%)  |
| Total    | 33 (100%)  | 17 (100%)  | 50 (100%) |

Among the 50 neonates, 65% were male and 35% female. Preterm neonates accounted for 58% ( $n=29$ ), while term neonates were 42% ( $n=21$ ).

**Table 2: Distribution Of Neonates By Type Of Sepsis:**

| Type of Sepsis     | Frequency | Percent |
|--------------------|-----------|---------|
| Early-onset sepsis | 34        | 68%     |
| Late-onset sepsis  | 16        | 32%     |
| Total              | 50        | 100%    |

Early-onset sepsis was more common (68%,  $n=34$ ) compared to late-onset sepsis (32%,  $n=16$ ).

**Clinical Features In Suspected Neonatal Sepsis:**

The most frequent clinical features were respiratory distress (46%), refusal to feed (45%), and lethargy (36%). Early-onset disease presents with respiratory distress in 67.6% of cases, a symptom completely absent (0%) in late-onset infants. Non-specific signs like refusal to feed (44.1% vs. 43.8%) and lethargy (35.3% vs. 37.5%) are common in both groups. Temperature dysregulation differs, with hypothermia in

23.5% of early cases versus fever in 37.5% of late cases. This pattern suggests early-onset sepsis, contrasting with a later, non-respiratory illness.

**Table 3: Distribution Of Etiological Agents:**

| Organism            | Early onset | Late onset | Total (%)        |
|---------------------|-------------|------------|------------------|
| <i>Klebsiella</i>   | 7           | 4          | 11 (48%)         |
| <i>Enterococcus</i> | 3           | 1          | 4 (16%)          |
| CONS                | 1           | 1          | 2 (9%)           |
| <i>Citrobacter</i>  | 1           | 1          | 2 (9%)           |
| <i>E. coli</i>      | 1           | 0          | 1 (4%)           |
| MRSA                | 0           | 1          | 1 (4%)           |
| <i>Pseudomonas</i>  | 0           | 1          | 1 (2%)           |
| <b>Total</b>        | <b>13</b>   | <b>9</b>   | <b>23 (100%)</b> |

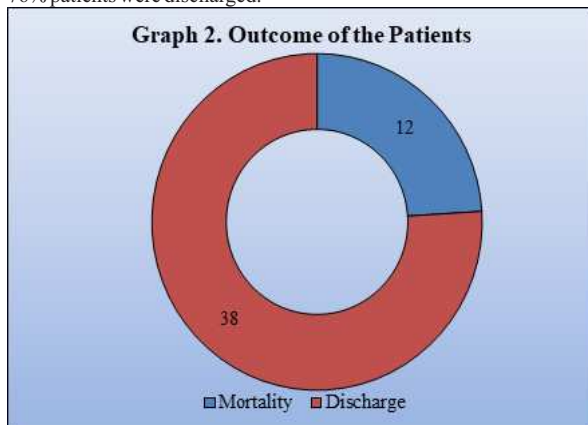
Blood culture was positive in 46% (n=23). Gram-negative organisms predominated (71%, n=16), with *Klebsiella pneumoniae* being the most common isolate (48%, n=11).

**Table 4: Antibiotic Sensitivity Pattern Of Isolates:**

| Organism                  | Sensitive antibiotics                           | Resistant antibiotics   | MDR (%) |
|---------------------------|-------------------------------------------------|-------------------------|---------|
| <i>Klebsiella</i> (n=11)  | Ceftazidime, cefotaxime, amikacin, piperacillin | Ampicillin, ceftriaxone | 22%     |
| <i>Enterococcus</i> (n=4) | Vancomycin, linezolid                           | Ampicillin              | 0%      |
| CONS (n=2)                | Vancomycin, linezolid                           | Erythromycin            | 0%      |
| <i>Citrobacter</i> (n=2)  | Cefotaxime                                      | Ampicillin              | 0%      |
| <i>E. coli</i> (n=1)      | Ceftazidime, amikacin                           | Ampicillin              | 0%      |
| MRSA (n=1)                | Vancomycin, linezolid                           | Beta-lactams            | 0%      |
| <i>Pseudomonas</i> (n=1)  | Ceftazidime                                     | Ampicillin              | 0%      |

#### Outcome Of The Patients:

In the present study, the overall case fatality rate was 24% (n=12) and 76% patients were discharged.



#### DISCUSSION:

This study highlights that neonatal sepsis continues to be a major concern in tertiary care hospitals in India. The predominance of gram-negative organisms, especially *Klebsiella pneumoniae*, is consistent with reports from by study of Sharma et al. (2023)<sup>(6)</sup> and Patel et al. (2022)<sup>(7)</sup>.

The overall culture positivity rate (45%) in our series was comparable to recent studies, ranging between 40–50%. Similar to other reports, early-onset sepsis was more common than late-onset sepsis, underscoring the importance of maternal and perinatal risk factors mentioned in report by WHO (2023) on Neonatal sepsis<sup>(8)</sup>.

Antibiotic susceptibility patterns in our study indicate poor sensitivity to ampicillin and ceftriaxone, antibiotics still widely used in empirical therapy. Instead, ceftazidime, cefotaxime, and amikacin showed better sensitivity against gram-negative organisms. Vancomycin and linezolid remained effective against gram-positive organisms. These findings are in line with the study by Deshmukh et al., (2024)<sup>(9)</sup> about antimicrobial resistance and highlight the importance of rationalizing antibiotic use.

The mortality rate of 23% is similar to recent Indian study by Kumar et al., (2022)<sup>(10)</sup>, where case fatality rates ranged from 20–30%. Higher mortality among culture-positive neonates reinforces the need for early diagnosis and timely initiation of effective antibiotics.

#### CONCLUSION:

Neonatal sepsis remains a leading cause of morbidity and mortality, particularly among preterm infants. Gram-negative organisms, especially *Klebsiella pneumoniae*, predominate, with significant resistance to first-line antibiotics. Periodic review of pathogen distribution and resistance patterns is crucial for guiding empirical therapy. Implementation of strict infection control measures, judicious antibiotic use, and strengthening of perinatal care can help reduce sepsis burden.

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