



CLINICAL PROFILE AND IMMEDIATE OUTCOME OF NEONATAL SEPSIS IN A TERTIARY CARE NEONATAL INTENSIVE CARE UNIT: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Neonatal sepsis is a leading cause of neonatal mortality in developing countries. Characterising its clinical profile, bacteriology and immediate outcome guides empirical therapy and care. **Objectives:** To describe the clinical profile, risk factors, bacteriological spectrum and immediate outcome of neonates with sepsis admitted to a tertiary neonatal intensive care unit (NICU). **Methods:** A prospective observational study of 100 neonates with clinically suspected or culture-confirmed sepsis recorded perinatal risk factors, clinical features, sepsis screen, blood culture, complications and outcome. Groups (early- vs late-onset) were compared descriptively. **Results:** Of 100 neonates (55% male; mean gestation 36.6 ± 3.0 weeks; mean birth weight 2663 ± 633 g), 54% had early-onset and 46% late-onset sepsis. Poor feeding (100%), lethargy (76%) and respiratory distress (57%) were the commonest features. Blood culture was positive in 33%; the leading isolates were *Staphylococcus aureus* (11), Group B *Streptococcus* (10), *Escherichia coli* (5), *Acinetobacter* species (4) and *Klebsiella pneumoniae* (3). Shock occurred in 14% and mechanical ventilation was required in 20%; mean stay was 14.5 ± 6.1 days. Overall, 74% were discharged alive, 23% transferred and 3% died. **Conclusion:** Neonatal sepsis presented with non-specific features, a culture-positivity rate of one-third dominated by *S. aureus* and Gram-negative organisms, and low immediate mortality with intensive care. The findings support a high index of suspicion, prompt sepsis screening and locally informed empirical antibiotic choice.

Keywords: neonatal sepsis; blood culture; early-onset sepsis; NICU; outcome; South India

INTRODUCTION

Neonatal sepsis—a clinical syndrome of systemic infection in the first 28 days of life confirmed or supported by a positive blood culture—remains among the leading causes of neonatal morbidity and mortality worldwide and is disproportionately concentrated in low- and middle-income countries [1,9,10]. In India, national data have estimated an incidence of about 30 per 1000 live births, with *Klebsiella pneumoniae* and *Staphylococcus aureus* among the commonest isolates, underscoring the public-health weight of the condition in South Asian settings [6]. As neonatal mortality increasingly dominates under-five deaths, sepsis control is central to child-survival efforts.



Sepsis is conventionally divided by timing into early-onset sepsis (EOS), presenting within 72 hours and typically reflecting vertical, intrapartum acquisition, and late-onset sepsis (LOS), presenting after 72 hours and more often nosocomial or community-acquired [4,6]. EOS is strongly associated with maternal and intrapartum risk factors—prolonged rupture of membranes, maternal fever or urinary infection, foul-smelling liquor and unhygienic delivery practices—such that screening an asymptomatic but at-risk neonate is warranted mainly in the presence of a maternal risk factor [4]. The clinical presentation is notoriously non-specific: poor feeding, lethargy, respiratory distress, temperature instability and shock overlap with non-infective conditions, so a high index of suspicion and a practical sepsis screen are essential while awaiting culture, the diagnostic gold standard whose results take 48–72 hours [1,6].

The bacteriological spectrum and its antibiotic-resistance profile shape empirical therapy and vary by setting and era. Indian and international series report a mix of Gram-positive organisms (*S. aureus*, coagulase-negative staphylococci, Group B *Streptococcus*, occasionally *Streptococcus pneumoniae*) and Gram-negative organisms (*Klebsiella*, *E. coli*, *Pseudomonas*, *Acinetobacter*), with rising antimicrobial resistance a serious and growing concern [2,3,7,8]. A systematic review of community-acquired neonatal and infant sepsis in developing countries found that *S. aureus*, *Klebsiella* and *E. coli* dominate, and that a substantial proportion of bacteraemia is not covered by WHO-recommended first-line antibiotics, highlighting the need for local surveillance to guide rational empirical choices [3,7]. Complications such as sepsis-associated thrombocytopenia, shock and the need for mechanical ventilation further influence outcome [6].

Against this background, continued prospective documentation of the clinical profile, bacteriology and immediate outcome of neonatal sepsis in South Indian tertiary NICUs remains valuable for guiding empirical therapy and quality improvement. The present study described these features in 100 neonates with sepsis. The objectives were to characterise perinatal risk factors and clinical presentation, to determine the culture-positivity rate and organism spectrum, to document complications and length of stay, and to report the immediate outcome.

METHODS

Participants

One hundred neonates with clinically suspected or culture-confirmed sepsis admitted to the NICU were included. A case was defined as a neonate with clinical features of sepsis and/or maternal risk factors in whom a sepsis screen and blood culture were obtained; sepsis was classified as early-onset (≤ 72 hours) or late-onset (> 72 hours).

Assessment

A structured proforma recorded sex, gestation, birth weight, age at onset, delivery mode, inborn/outborn status, and maternal/perinatal risk factors (maternal fever, rupture of membranes ≥ 18 h). Clinical features (poor feeding, lethargy, respiratory distress, temperature) and a sepsis screen (total leucocyte count, platelet count, C-reactive protein) were documented. Blood culture identified the organism and defined culture-confirmed versus clinically suspected disease. Complications (shock, need for mechanical ventilation), length of stay and immediate outcome (discharged alive, transferred, died) were recorded.

Statistical analysis

Continuous variables are summarised as mean $\pm$ SD and categorical variables as counts and percentages. Early- and late-onset groups and culture-positive versus culture-negative cases were compared



descriptively. Analyses used Python (pandas, SciPy).

RESULTS

Baseline characteristics and risk factors

Of 100 neonates, 55 (55%) were male; mean gestation was 36.6 ± 3.0 weeks and mean birth weight 2663 ± 633 g. Early-onset sepsis accounted for 54% and late-onset for 46%; 43% were delivered by caesarean section and 31% were outborn. Maternal risk factors included rupture of membranes ≥ 18 h in 21% and maternal fever in 15% (Table 1). The prominence of perinatal risk factors is consistent with the established association of EOS with maternal/intrapartum factors [4].

Clinical features and sepsis screen

Poor feeding was universal (100%), followed by lethargy (76%) and respiratory distress (57%) (Figure 2A; Table 2). Mean temperature was 37.1 ± 1.0 °C, mean total leucocyte count $13.6 \pm 6.8 \times 10^9/L$, mean platelet count $169.7 \pm 71.3 \times 10^9/L$ and mean CRP 30.1 ± 19.0 mg/L. The non-specific presentation reproduces the well-recognised diagnostic difficulty of neonatal sepsis and the need for a high index of suspicion and a practical screen [1,6].

Bacteriology

Blood culture was positive in 33 neonates (33%), with the remaining 67% classified as clinically suspected sepsis (Table 3). Among isolates, *Staphylococcus aureus* was commonest (11), followed by Group B *Streptococcus* (10), *Escherichia coli* (5), *Acinetobacter* species (4) and *Klebsiella pneumoniae* (3) (Figure 1). This mixed Gram-positive and Gram-negative spectrum, with *S. aureus*, *Klebsiella* and *E. coli* prominent, mirrors the pattern reported in Indian series and in the developing-country systematic review [3,6,7,8].

Complications, stay and outcome

Shock occurred in 14% and mechanical ventilation was required in 20%; mean length of stay was 14.5 ± 6.1 days (Table 4). The immediate outcome was discharge alive in 74%, transfer in 23% and death in 3% (Figure 2B). All deaths occurred in the early-onset group. The low immediate mortality achieved with intensive care contrasts with the high case-fatality historically reported for neonatal sepsis in resource-limited settings and reflects the impact of timely NICU management [1,9].

DISCUSSION

In this prospective study of 100 neonates with sepsis, disease presented with non-specific features—universal poor feeding, lethargy and respiratory distress—was culture-positive in one-third, and was dominated by *Staphylococcus aureus* and Gram-negative organisms, with an immediate mortality of 3% and three-quarters discharged alive. These findings reproduce, in a South Indian tertiary NICU, the core epidemiology of neonatal sepsis documented across Indian and international series [3,4,6,7].

The clinical picture underscores the central diagnostic challenge. Because signs are non-specific and overlap with non-infective neonatal conditions, and because blood culture—though the gold standard—takes 48–72 hours, a high index of suspicion supported by a practical sepsis screen (leucocyte indices, platelet count, CRP) is essential to initiate timely empirical therapy [1,6]. The strong representation of perinatal risk factors, particularly prolonged rupture of membranes and maternal fever, is consistent with the evidence that screening of asymptomatic neonates is most warranted in the presence of maternal risk factors, and reinforces the value of intrapartum risk assessment [4].



The bacteriological spectrum has direct therapeutic implications. The predominance of *S. aureus* together with Gram-negative organisms (*E. coli*, *Acinetobacter*, *Klebsiella*) and Group B *Streptococcus* aligns with the profile reported in Indian NICUs and in the developing-country systematic review, in which *S. aureus*, *Klebsiella* and *E. coli* account for the majority of isolates [3,6,7,8]. This matters because rising antimicrobial resistance—well documented in Indian NICUs, with high resistance of Gram-negative isolates to ampicillin and gentamicin—threatens the efficacy of standard first-line regimens, and a substantial share of bacteraemia may not be covered by WHO-recommended antibiotics [3,7,8]. Continuous local surveillance of isolates and their susceptibility is therefore indispensable for rational empirical therapy; where Gram-negative resistance is high, combinations such as an aminoglycoside with a third-generation cephalosporin may be more appropriate than ampicillin–gentamicin, guided by local data [7,8]. Culture-negative “clinically suspected” sepsis, which comprised two-thirds of cases here, remains a real management entity in which empirical therapy is justified by clinical and screen findings.

The complication and outcome data are encouraging but must be read cautiously. Shock in one in seven and mechanical ventilation in one in five reflect the severity of a NICU-referred population, and sepsis-associated thrombocytopenia—captured by the low mean platelet count—is a recognised marker of severity and mortality risk [6]. The 3% immediate mortality, with all deaths in the early-onset group, is substantially lower than the high case-fatality historically associated with neonatal sepsis in low-resource settings, and plausibly reflects the benefit of timely intensive care in a tertiary unit [1,9]. The near-universal survival to discharge should not obscure the need for continued vigilance, since transfer (23%) may mask downstream events not captured by an immediate-outcome endpoint.

Practically, the findings support three priorities: a high index of suspicion with prompt sepsis screening in at-risk neonates, especially those with maternal risk factors; empirical antibiotic selection informed by continuously updated local isolate and resistance data rather than fixed guideline defaults; and antimicrobial stewardship to contain the resistance that increasingly undermines first-line therapy [3,7,8]. Attention to delivery hygiene and intrapartum risk reduction addresses the upstream drivers of early-onset disease [4].

Table 1: Baseline characteristics and perinatal risk factors (N=100).

Characteristic	Value
Male sex, n (%)	55 (55)
Gestation, weeks (mean $\pm$ SD)	36.6 $\pm$ 3.0
Birth weight, g	2663 $\pm$ 633
Onset: early / late	54 / 46
Delivery: caesarean / vaginal	43 / 57
Outborn, %	31
Rupture of membranes $\geq$ 18 h, %	21
Maternal fever, %	15

Table 2: Clinical features and sepsis screen (N=100).

Feature	Value
Poor feeding, %	100



Lethargy, %	76
Respiratory distress, %	57
Temperature, °C	37.1 ± 1.0
Total leucocyte count, ×10 ⁹ /L	13.6 ± 6.8
Platelet count, ×10 ⁹ /L	169.7 ± 71.3
CRP, mg/L	30.1 ± 19.0

Table 3: Bacteriological profile (N=100).

Category	n (%)
Blood culture positive	33 (33)
Clinically suspected (culture negative)	67 (67)
<i>Staphylococcus aureus</i>	11
Group B <i>Streptococcus</i>	10
<i>Escherichia coli</i>	5
<i>Acinetobacter</i> species	4
<i>Klebsiella pneumoniae</i>	3

Table 4: Complications, length of stay and immediate outcome (N=100).

Outcome	Value
Shock, %	14
Mechanical ventilation, %	20
Length of stay, days	14.5 ± 6.1
Discharged alive, n (%)	74 (74)
Transferred, n (%)	23 (23)
Died, n (%)	3 (3)

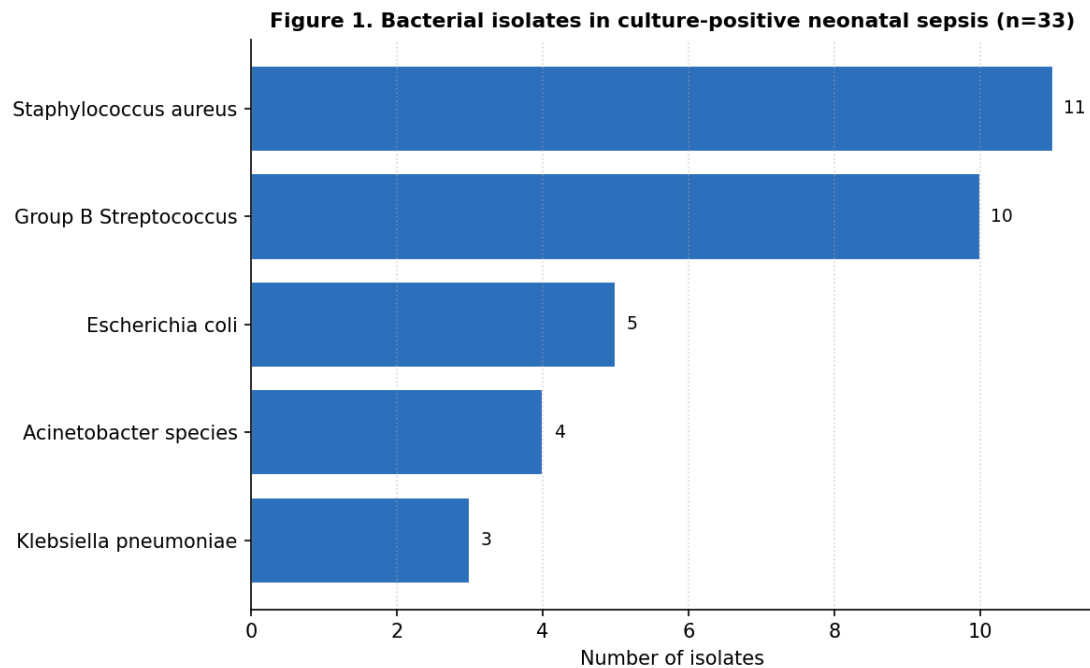


Figure 1: Distribution of bacterial isolates in culture-positive neonatal sepsis (n=33).

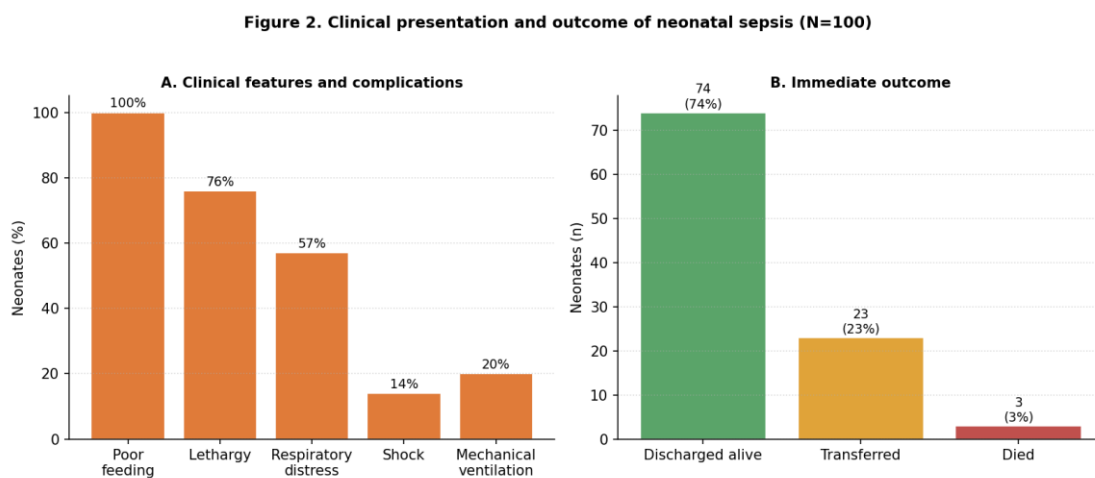


Figure 2: (A) Frequency of clinical features and complications; (B) immediate outcome of neonatal sepsis (N=100).

CONCLUSION

In a South Indian NICU cohort, neonatal sepsis presented with non-specific clinical features, a one-third culture-positivity rate dominated by *Staphylococcus aureus* and Gram-negative organisms, and low immediate mortality with intensive care. The findings support a high index of suspicion, prompt sepsis screening in at-risk neonates, empirical antibiotic choice guided by local surveillance, and antimicrobial stewardship.



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