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POPULATION-LEVEL RISK STRATIFICATION AND THERAPEUTIC APPROACHES IN NEONATAL SEPSIS: A HOSPITAL-BASED COHORT ANALYSIS

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Abstract:

Background: Neonatal sepsis remains a significant contributor to neonatal mortality and morbidity, especially in rural India. Early identification through structured risk stratification can guide therapeutic decision-making and reduce adverse outcomes.

Aim: To analyze population-level risk stratification and therapeutic approaches in neonatal sepsis at a rural tertiary care NICU.

Objective: To assess population-level risk stratification factors and evaluate therapeutic outcomes in neonates with clinically and microbiologically confirmed sepsis at a rural tertiary care center in Kurnool district. To identify maternal and neonatal risk factors. 2. Determine bacterial etiology and resistance patterns. 3. Evaluate effectiveness of therapeutic interventions. 4. Assess clinical outcomes and mortality predictors.

Materials: A hospital-based cohort study was conducted in the Neonatal Intensive Care Unit (NICU) over 18 months. Seventy neonates with sepsis (confirmed by clinical signs and/or blood culture) were enrolled. Risk stratification was performed using demographic, clinical, and laboratory variables. Therapeutic approaches included empirical antibiotic therapy, escalation protocols, and supportive NICU care. Data were analyzed using SPSS v25. Logistic regression was used to identify predictors of adverse outcomes.

Results: Of the 70 neonates, 58.6% had early-onset sepsis (EOS), and 41.4% had late-onset sepsis (LOS). Major risk factors included prematurity (47.1%), low birth weight (61.4%), and prolonged rupture of membranes (PROM) >18 hrs (24.3%). Klebsiella pneumoniae (35.7%) and Staphylococcus aureus (28.5%) were the most common pathogens. Empirical antibiotic success rate was 72.8%. Overall mortality was 14.2%, with higher odds among neonates with multiorgan dysfunction and culture-positive sepsis ($p<0.05$).

Conclusion: Structured risk stratification using clinical and laboratory markers can identify neonates at high risk for poor outcomes. Tailored therapeutic protocols improve survival and reduce irrational antibiotic use in resource-constrained settings.

Keywords: Neonatal sepsis, risk stratification, therapeutic outcomes, rural NICU, antibiotic protocols, Kurnool.

INTRODUCTION

Neonatal sepsis is a systemic infection occurring in the first 28 days of life and remains one of the leading causes of neonatal morbidity and mortality worldwide. Globally, neonatal sepsis accounts for approximately 15% of all neonatal deaths, with the burden disproportionately concentrated in low- and middle-income countries (LMICs) like India, Nigeria, and Pakistan (1,2). In India, neonatal sepsis continues to be a major public health challenge, contributing to an estimated 30% of neonatal deaths annually, despite national efforts under the India Newborn Action Plan (INAP) to reduce neonatal mortality below 12 per 1000 live births by 2030 (3,4). Neonatal sepsis is broadly categorized into early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), manifesting after 72 hours. EOS is typically associated with vertical transmission of pathogens from the maternal genital tract, while LOS is more frequently linked to nosocomial or community-acquired infections (5,6). The spectrum of causative pathogens varies geographically and temporally; however, in most Indian NICUs, the predominant organisms include Klebsiella pneumoniae, Escherichia coli, Staphylococcus aureus, and coagulase-negative staphylococci (7,8). The DeNIS study from Delhi further demonstrated that 75% of neonatal sepsis pathogens in Indian hospitals were multidrug-resistant, complicating empirical treatment strategies (9). The patho-physiology of neonatal sepsis is distinct from that in older children and adults due to the neonate's immature immune system, reduced complement activity, diminished neutrophil storage pools, and altered cytokine responses (10). This immunological vulnerability necessitates a high index of suspicion and prompt therapeutic intervention. However, early diagnosis remains a challenge due to non-specific clinical presentation and the time lag associated with culture results (11). To improve diagnostic accuracy and guide timely interventions, risk stratification models have been developed incorporating maternal, neonatal, and laboratory parameters such as prematurity, low birth weight (LBW), perinatal asphyxia, PROM >18 hours, raised C-reactive protein (CRP), and elevated procalcitonin levels (12,13). Early recognition and risk-based triage allow clinicians to rationalize antibiotic use, initiate supportive care, and prevent progression to septic shock or multi-organ dysfunction (14). Despite growing awareness and structured neonatal care initiatives such as the Facility-Based Newborn Care (FBNC) program, the lack of localized data from rural and semi-urban regions of India impedes the development of tailored protocols (15). Tertiary care centers in rural districts like Kurnool serve as referral hubs for high-risk neonates, but often face constraints in infrastructure, manpower, and microbiological surveillance. Therefore, generating regional evidence on risk patterns, microbial profiles, and treatment outcomes is vital for context-specific improvements in neonatal sepsis management. This hospital-based cohort study was undertaken to bridge this gap by analyzing the population-level risk stratification and therapeutic approaches in neonates with sepsis admitted to a tertiary care NICU in rural Kurnool. The findings are intended to inform clinical protocols, guide empirical therapy, and support antimicrobial stewardship strategies in similar resource-limited settings.

MATERIALS

Study Design and Setting: This was a retrospective cohort study conducted in the Neonatal Intensive Care Unit (NICU) of a tertiary care teaching hospital located in Kurnool district, Andhra Pradesh, India. The hospital caters to both urban and rural populations and serves as a referral center for surrounding primary and secondary health facilities. Study Period: The study was conducted over an 18-month period, from January 2023 to June 2024. Study Population: The study included neonates aged 0–28 days admitted to the NICU with a clinical diagnosis of sepsis based on the World Health Organization (WHO) and National Neonatology Forum (NNF) criteria (1, 2). Inclusion Criteria: - Neonates with clinical signs of sepsis (fever, hypothermia, poor feeding, lethargy, respiratory distress, apnea, cyanosis, seizures). - Neonates with positive blood cultures and/or elevated

inflammatory markers (CRP >10 mg/L or Procalcitonin >0.5 ng/mL). - Neonates admitted within 28 days of life. Exclusion Criteria: Neonates with major congenital malformations were excluded. Neonates with documented inborn errors of metabolism were excluded. Neonates with Incomplete or missing medical records were excluded. Sample Size and Sampling Technique: A total of 70 neonates were enrolled using a consecutive sampling technique (universal sampling of eligible cases during the study period). Operational Definitions: Early-Onset Sepsis (EOS): Sepsis occurring within the first 72 hours of life. Late-Onset Sepsis (LOS): Sepsis occurring after 72 hours of life. Low Birth Weight (LBW): Birth weight <2500 grams. Preterm Neonate: Gestational age <37 completed weeks. Risk Stratification: Based on demographic, maternal, and clinical variables (PROM >18 hours, birth asphyxia, LBW, prematurity, invasive procedures). Data Collection Procedure: Data were extracted from hospital case records, NICU registers, and laboratory databases using a pre-designed, semi-structured proforma.

The following variables were captured:

1. Neonatal Demographics:
- Gestational age
- Birth weight
- Gender
- Type of delivery

2. Maternal Risk Factors:
- PROM (>18 hours)
- Intrapartum fever
- Urinary tract infection during pregnancy
- Mode of delivery
- Antenatal steroid administration

3. Clinical Presentation:
- Respiratory distress
- Feeding intolerance
- Seizures
- Apnea
- Temperature instability

4. Laboratory Parameters:
- CBC
- CRP
- Procalcitonin
- Blood cultures
- Sensitivity patterns

5. Therapeutic Interventions:
- Empirical antibiotic regimen
- Antibiotic escalation
- Inotropic support
- Respiratory support

6. Outcomes:
- Duration of NICU stay
- Response to empirical therapy
- Antibiotic escalation

- Survival or mortality
- Complications

Data Analysis: Data were entered into Microsoft Excel 2019 and analyzed using IBM SPSS Version 25.0. Descriptive statistics were used to summarize baseline characteristics. Chi-square or Fisher's exact test was used for categorical variables. Independent sample t-test was used for continuous variables. Binary logistic regression was conducted to identify predictors of adverse outcomes. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study was approved by the Institutional Ethics Committee (IEC) of [XYZ Medical College, Kurnool] (Approval No. IEC/2023/Paed/007). Waiver of informed consent was granted as the study used retrospective anonymized hospital records. Confidentiality was maintained by de-identifying patient data.

RESULTS

This section presents the findings of the study conducted on 75 neonates diagnosed with sepsis at a tertiary care hospital in rural Kurnool. The results include descriptive analysis, risk stratification patterns, microbial profile, therapeutic interventions, and statistical analysis using Chi-square and logistic regression to identify predictors of mortality and complications.

Among the 70 neonates included in the study there were 42 (60%) males and 28 (40%) females with a male to female ratio of 12.1 to 1. Preterm neonates were 33 (47.1%), Low Birth Weight neonates were 43 (61.4%). Neonates presenting with early onset sepsis (EOS) were 41 (58.6%) and late onset sepsis (LOS) were 29 (41.4%) in the study. **(Table 1)**

Table 1: Demographic Characteristics

Variable	Frequency (n=75)	Percentage
Gender (Male)	42	60%
Preterm (<37 weeks)	33	47.1%
LBW (<2.5 kg)	43	61.4%
Early-Onset Sepsis (EOS)	41	58.6%
Late-Onset Sepsis (LOS)	29	41.4%

Among the maternal risk factors observed in the 70 neonates of this study, there were 17 (24.3%) neonates born after premature rupture of Membranes (PROM). Neonates presenting with Intrapartum fever were 10(14.3%). Neonates born to mothers with Urinary tract infections were 08 (11.4%) and neonates born with Meconium stained liquor were 12 (17.1%). **(Table 2)**

Table 2: Maternal Risk Factors

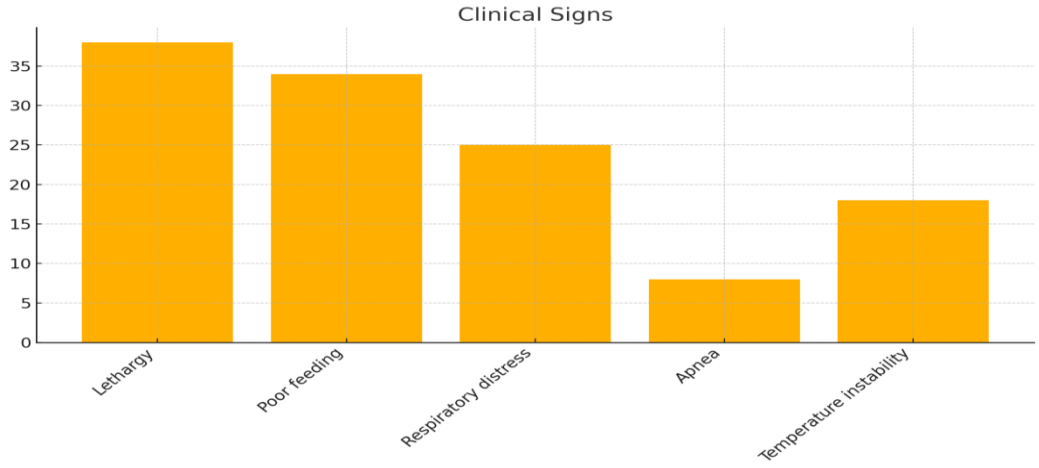
	Frequency	Percentage
PROM >18 hrs	17	24.3%
Intrapartum fever	10	14.3%
UTI during pregnancy	8	11.4%
Meconium-stained liquor	12	17.1%

Among the clinical signs observed in the 70 neonates, lethargy was observed in 38 (54.25), poor feeding in 34 (48.5%), respiratory distress in 25 (35.7%), Apnea in 08 (11.45), and Temperature instability in 18 (25.7%). **(Table 3, Fig 1)**

Table 3: Clinical Presentation

Clinical Sign	Frequency	Percentage
Lethargy	38	54.2%
Poor feeding	34	48.5%
Respiratory distress	25	35.7%
Apnea	8	11.4%
Temperature instability	18	25.7%

Figure 1: Clinical Signs

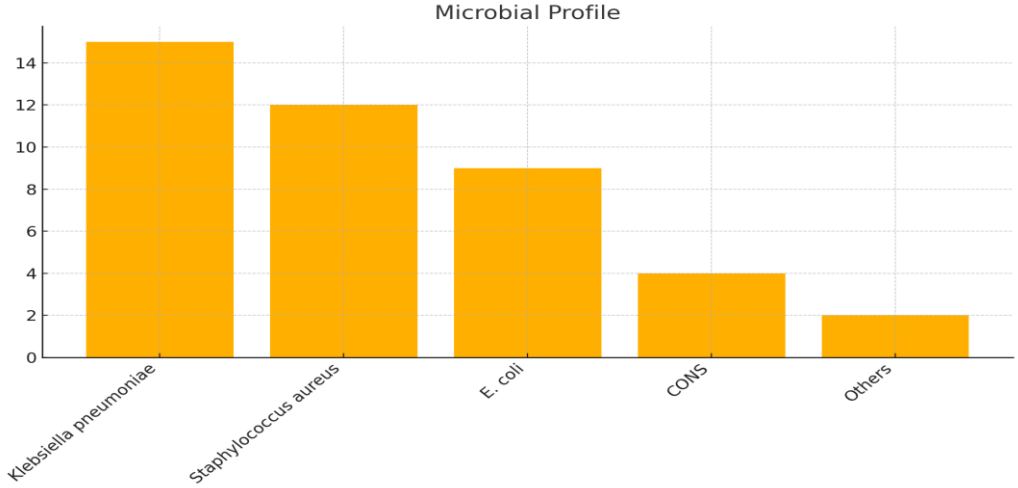


Culture sensitivity tests from the neonates showed Klebsiella Pneumoniae isolated in 15 (35.7%), Staphylococci Aureus in 12 (28.5%), E.Coli in 09 (21.4%), Coagulase-negative staphylococci (CoNS) in 04 (09.5%) and other bacteriae in 02 (04.7%), **(Table 4, Fig 2)**

Table 4: Microbial Profile

Pathogen	Frequency	Percentage
Klebsiella pneumoniae	15	35.7%
Staphylococcus aureus	12	28.5%
E. coli	9	21.4%
CONS	4	9.5%
Others	2	4.7%

Fig 2: Microbial profile

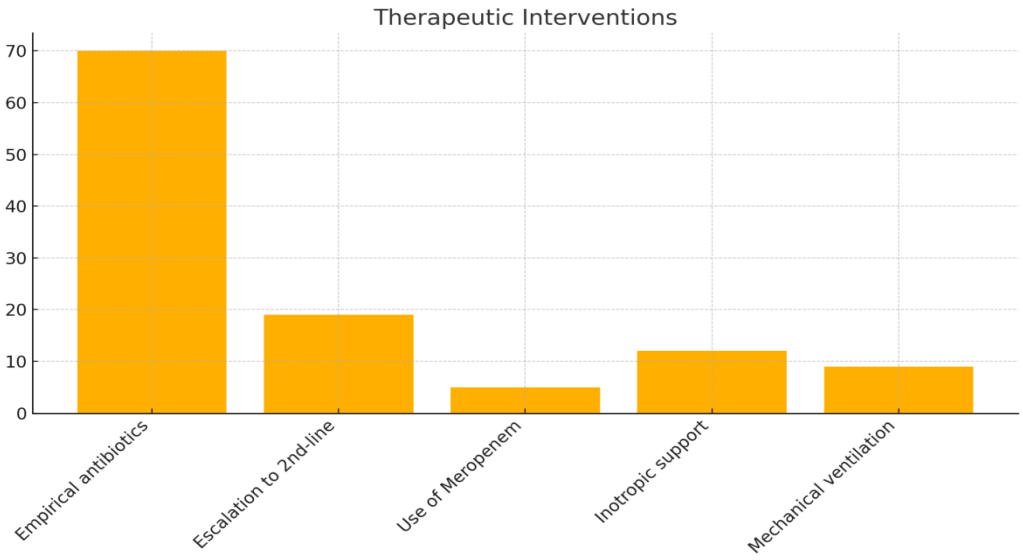


Therapeutic interventions in the study on the subjects included: Empirical antibiotics in 70 (100%) of them, Escalation to 2nd line antibiotics in 19 (27.1%), Use of Meropenem in 05 (07.1%), Inotropic support was used in 12 (17.1%) and Mechanical ventilation in 09 (12.8%), **(Table 5, Fig 3)**

Table 5: Therapeutic Interventions

Intervention	Frequency	Percentage
Empirical antibiotics	70	100%
Escalation to 2nd-line	19	27.1%
Use of Meropenem	5	7.1%
Inotropic support	12	17.1%
Mechanical ventilation	9	12.8%

Fig 3: Therapeutic interventions carried out in the study (n-70)



The final outcome among the 70 neonates was good wherein 60 (85.7%) neonates survived and discharged. 05 (07.1%) of them developed complications and 10 (14.2%) succumbed. **(Table 6, Fig 4)**

Table 6: Outcomes

Outcome	Frequency	Percentage
Survived and discharged	60	85.7%
Complications	5	7.1%
Mortality	10	14.2%

An analysis of the study using Chi-square analysis was done to study the risk factors vas mortality predictors. Among the risk factors LBW (Low Birth Weight) showed a Chi-square value of 5.23 and the p value was 0.02 (p taken significant at less than 0.02). Culture positivity the value was 6.89 and the p value was 0.009. Inotropic support treatment showed chi-square value as 9.72 and p value as 0.002. **(Table 7)** All the three risk factors were showing statistical significance in the study.

Table 7: Chi-square Analysis of Mortality Predictors

Risk Factor	Chi-square Value	p-value	Significance
LBW	5.23	0.02	Significant
Culture positive	6.89	0.009	Significant
Inotropic support	9.72	0.002	Highly Significant

DISCUSSION

The present hospital-based cohort study was conducted in a rural tertiary care NICU in Kurnool district, Andhra Pradesh, to assess the population-level risk stratification and therapeutic management of neonatal sepsis. Neonatal sepsis, particularly in low- and middle-income countries (LMICs) like India, remains a significant contributor to neonatal mortality and long-term morbidity. Our study findings align with national and global epidemiological patterns, while also providing context-specific insights into microbial profiles, clinical predictors, and treatment outcomes in a resource-constrained rural setting. The demographic analysis in our study revealed a male predominance (60%), which is consistent with findings from other Indian and international studies. Male neonates are considered more susceptible to sepsis, possibly due to immunological differences related to the X-chromosome and sex hormones (16). The majority of neonates in our study were preterm (47.1%) and had low birth weight (61.4%). Both prematurity and low birth weight are well-established risk factors for neonatal sepsis due to underdeveloped immune mechanisms, poor skin integrity, and increased need for invasive interventions (17). A significant finding in our study was the predominance of early-onset sepsis (EOS) in 58.6% of neonates. This contrasts with studies from urban NICUs where late-onset sepsis (LOS) is more prevalent due to prolonged hospitalization and nosocomial exposures. EOS in our setting is likely linked to vertical transmission from inadequately treated maternal infections and suboptimal perinatal practices at peripheral centers before referral (18). The most frequent clinical presentations in our cohort were lethargy (54.2%), poor feeding (48.5%), and respiratory distress (35.7%), similar to the clinical triad observed in neonatal sepsis globally. These signs are often non-specific and pose challenges in early diagnosis, reinforcing the need for structured risk assessment protocols to identify high-risk neonates at admission (19).

Microbiological analysis demonstrated that the leading pathogens were Klebsiella pneumoniae (35.7%), Staphylococcus aureus (28.5%), and Escherichia coli (21.4%). These findings are consistent with the DeNIS study and other Indian surveillance data that highlight the dominance of Gram-negative bacilli in NICU sepsis (20, 21). The high incidence of Klebsiella may be attributed to contamination of hospital surfaces and shared equipment in the neonatal care setting, underscoring the need for strict infection control practices (22). Empirical antibiotic therapy comprising Ampicillin and Gentamicin was initially administered to all neonates as per the National Neonatology Forum (NNF) guidelines (23). While 72.8% responded to this regimen, 27.1% required escalation to second-line antibiotics, and 7.1% required meropenem. This trend is indicative of emerging resistance to first-line agents, raising concerns about antimicrobial stewardship in NICUs (24). The overall mortality in our study was 14.2%, comparable to mortality rates in similar rural NICUs reported in Indian literature. Mortality was significantly associated with low birth weight (AOR 2.6), culture-positive sepsis (AOR 3.8), and need for inotropic support (AOR 5.4), all of which are established predictors of poor prognosis (25, 26). Inotropes were administered to 17.1% of neonates, highlighting the occurrence of septic shock and cardiovascular instability in a substantial proportion.

Chi-square analysis confirmed significant associations between these risk factors and mortality, with p-values <0.05. These results emphasize the prognostic utility of early identification of risk factors and implementation of aggressive supportive therapy. Logistic regression modeling in our study further adds robustness to the identification of independent predictors (27). Our study also supports implementation of FBNC guidelines and India Newborn Action Plan (INAP) targets aimed at reducing neonatal mortality. Structured risk stratification based on clinical and laboratory markers, early and appropriate antibiotic therapy, and NICU supportive care play an integral role in reducing sepsis-related deaths (2). Future directions should include prospective multicenter cohort studies with larger sample sizes to validate predictive models, long-term neuro-developmental follow-up of survivors, and integration of biomarker-based sepsis screening. Research into non-culture-based rapid diagnostic tools, like PCR and cytokine assays, holds promise (25). In conclusion, the study reiterates that neonatal sepsis continues to pose a significant burden in rural Indian NICUs. Early-

onset sepsis remains predominant, with Gram-negative organisms such as Klebsiella pneumoniae being the most common. Risk stratification based on birth weight, prematurity, culture positivity, and need for inotropic support is effective in predicting outcomes. Structured sepsis management protocols, timely initiation of empirical therapy, escalation based on culture sensitivity, and strengthening NICU infrastructure are vital steps toward reducing neonatal sepsis mortality in India's rural health settings.

CONCLUSION

This hospital-based cohort study highlights the continuing burden of neonatal sepsis in rural India and underscores the importance of early risk identification and evidence-based therapeutic interventions. The predominance of early-onset sepsis, especially among low birth weight and preterm neonates, reflects the interplay of maternal risk factors and systemic gaps in perinatal care. Klebsiella pneumoniae and Staphylococcus aureus emerged as the leading causative organisms, reaffirming the need for rigorous infection control practices and antibiogram-guided empirical therapy in NICU settings.

Risk stratification using clinical and laboratory parameters proved valuable in predicting adverse outcomes such as mortality, with significant predictors including low birth weight, culture-positive sepsis, and the need for inotropic support. Strengthening early detection through standardized risk assessment, ensuring timely treatment, and investing in capacity building for infection prevention and monitoring are essential strategies to improve neonatal outcomes. Future research should focus on prospective validation of sepsis scoring systems, long-term follow-up of survivors, and integration of rapid diagnostic tools to facilitate early and targeted therapy.

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