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Assessment Of Medication Use Patterns For Managing Neonatal Sepsis At A Tertiary Care Hospital

D. Saranya Shanmugapriya[*], R.D. Sathyasuba[**], G. Sathyaprabha[1], R. Sathish Kumar[2], Shreedevi Rajendran[2], Karthickraja Marimuthu[2], S. Krishnaprasath[3], Shenbagam Esakkimuthu[3], J. Dhinagar[3]

[*]Associate Professor

[**] Assistant professor & Research Scholar,

[1]Professor,

[2]Assistant Professor,

[3]Pharm D Interns

RVS College of Pharmaceutical Sciences, RVS college of Arts and Sciences, Sulur, Coimbatore, Tamil Nadu, India-641402

Corresponding Author :

Email ID: saranyaragupharmacy@gmail.com

ORCID ID: 0009-0004-3441-4938

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ABSTRACT

Background: Neonatal sepsis remains a critical health Challenge in developing countries, contributing heavily to infant illness and death. Effective management on the judicious use of medications, particularly antibiotics, and strict adherence to antimicrobial stewardship principles are critical for improving outcomes. This study investigates how medications are utilized, identifies adverse drug reactions (ADRs), and evaluates clinical results in neonates diagnosed with sepsis at a tertiary care hospital in Coimbatore, Tamil Nadu.

Methods: Study was prospective and observational review of patients record in the hospital.400 neonates admitted to the NICU. Cases were categorized into early-onset (EOS) and late-onset sepsis (LOS). Prescribing trends were reviewed using WHO indicators, and ADRs were assessed using the WHO-UMC causality scale and the Naranjo algorithm.

Results: Males comprised 53.75% of the study group, with an 85.25% survival rate. EOS was prevalent among preterm and home-born neonates. A total of 1,428 drugs were prescribed, averaging 3.57 medications per neonate. Antibiotics were administered in 60.3–100% of cases, most commonly ampicillin, gentamicin, and cefotaxime. Injectable drugs accounted for 86.97% of prescriptions. Between 71.2–73.33% of drugs were from the Essential Medicines List, and 78–91% were prescribed generically. ADRs were recorded in 2.5% of cases, most categorized as "possible." The most frequently isolated microorganism was Staphylococcus aureus.

Conclusion: Initial antibiotic prescribing was generally appropriate, though the findings point to the necessity for more consistent prescribing practices, better ADR documentation, and stricter adherence to essential medicine guidelines.

Keywords: *Neonatal sepsis, drug usage analysis, antibiotics, WHO indicators, NICU, antimicrobial resistance, ADRs.*

1. INTRODUCTION

A neonate refers to an infant aged 28 days or younger. Sepsis during this period remains one of the leading causes of infant morbidity and mortality, especially in resource-limited regions. According to NNPD (2002–2003), the rate of neonatal sepsis stood at 30 per 1,000 live births, contributing to nearly one-fifth of neonatal deaths in 18 tertiary care centers across India. Globally, sepsis affects approximately 20% of neonates, contributing to up to half of neonatal deaths in lower-income nations.

Neonatal sepsis represents a systemic inflammatory response due to infection, and includes manifestations like pneumonia, meningitis, and urinary tract infections. Sepsis is generally classified based on the timing of onset: EOS (within 72 hours of birth) is often due to maternal transmission, whereas LOS (after 72 hours) commonly arises from hospital or community-acquired infections.

High-risk groups include preterm neonates and those undergoing invasive interventions in NICUs. The neonatal mortality rate remains high in underserved regions due to delayed medical care and limited facilities.

Judicious medication use is vital in improving sepsis outcomes and avoiding unnecessary toxicity or resistance. Drug utilization research helps identify current practices and highlights areas for rationalizing treatment. This study aims to explore medication trends and ADR occurrences in neonates with sepsis at a tertiary care hospital in Coimbatore.

2. METHODS

2.1 Study Design

A prospective observational study was carried out at KG Hospital and Research Centre, Coimbatore, from January to December 2024, with ethical approval obtained prior to initiation.

2.2 Inclusion Criteria

- Neonates ≤28 days of age with clinically diagnosed sepsis (EOS or LOS).
- Confirmed or suspected sepsis cases admitted to NICU.

2.3 Exclusion Criteria

- Neonates discharged or deceased within 24 hours of admission.
- Infants older than 28 days.
- Cases with congenital abnormalities, metabolic disorders, or non-sepsis conditions.
- Lack of informed parental or guardian consent.

2.4 Data Collection and Analysis

Demographic and clinical details were recorded in a structured format. Medication details (name, dosage, frequency, route, duration) were captured. WHO prescribing indicators were used for evaluation. ADRs were categorized using standard scales (WHO-UMC, Naranjo). Data were analyzed using SPSS v26 or higher, with descriptive statistics and appropriate tests (Chi-square/Fisher's exact test).

3. RESULTS

3.1 Patient Demographics and Morbidity Patterns

Out of 400 neonates, 215 were male (53.75%), and 185 females (46.25%). Sepsis accounted for 37.9% of NICU admissions. Survival was seen in 85.25% of neonates; the remainder succumbed to sepsis, birth asphyxia, or respiratory distress.

Most neonates were term (70%), with the remainder categorized as preterm (28.5%) or extremely preterm (1.25%). Birth weights were distributed as follows: >2.5 kg (45.58%), 2–2.5 kg (23.17%), 1.5–2 kg (16.8%), 1–1.5 kg (8.6%), and <1 kg (5.7%).

3.2 Sepsis Onset and Delivery Method

Among 175 neonates:

- EOS was more common in males (73.44%) and vaginal deliveries (75.57%).
- LOS was frequently seen in C-section births and low birth weight infants.
- EOS correlated significantly with prematurity.
- All home-delivered neonates developed sepsis compared to 69.64% of hospital births.

3.3 Drug Use Overview

A total of 1,428 medications were prescribed (average: 3.57 drugs/neonate). Antibiotics dominated prescribing patterns.

3.3.1 Antimicrobials were the most frequently prescribed class

Table:1

Antimicrobial Usage	Frequency (%)
Ampicillin + Gentamicin	21.71%
Ampicillin + Gentamicin + Cefotaxime	33.71%

Ampicillin + Amikacin	29.14%
Piperacillin-Tazobactam + Amikacin	9.28%
Linezolid + Amikacin	2.14%

3.3.2 The most common prescribed antibiotics were

Table:2

Drug	% of Prescriptions
Ampicillin	71.02%
Gentamycin	42.5%
Cefotaxime	19.2%
Amikacin	18.2%
Ciprofloxacin	15.5%
Piperacillin-tazobactam	9.5%
Meropenem	7.7%

3.3.3 According to WHO-ATC classification

Table:3

Drug Category	% Usage
Anti-infectives for systemic use	60.36%
Nervous system drugs	7.84%
Alimentary tract	4.83%
Respiratory system	3.15%
Cardiovascular system	2.8%

3.4 Microbial Profile

3.4.1 Among 137 culture-positive neonates

Table:4

Pathogen	% Isolated
Staphylococcus aureus	45.26%
Klebsiella pneumoniae	26.28%
Escherichia coli	14.60%
Pseudomonas aeruginosa	8.76%

3.5 WHO Core Drug Use Indicators

Table:5

Indicator	Value
Average drugs per encounter	1.71–3.57%
Antibiotics per prescription	60.3–100%

Parenteral drug use	86.97–100%
Generic prescribing	78–91%
EML (Essential Medicine List) adherence	71.2–73.33%

3.6 Adverse Drug Reactions (ADRs)

Out of 10 ADRs:

- 70% were classified as possible (Naranjo scale).
- 40% were possible and *60% unlikely (WHO-UMC scale).
- No drug rechallenge were done due to ethical concerns in neonates.

3.7 Clinical Outcomes

Out of 175 neonates evaluated closely:

- 119 (68.00%) improved and were discharged.
- 48 (27.42%) expired during treatment.
- 5 (4.57%) left against medical advice (LAMA).

4. DISCUSSION

Neonatal sepsis continues to be a major contributor to neonatal morbidity and mortality, especially in developing countries. This study combined two independent datasets from tertiary care hospitals to analyse the demographic patterns, drug utilization trends, and clinical outcomes of neonatal sepsis cases.

Demographic Characteristics and Morbidity Patterns

Out of the total neonates admitted, neonatal sepsis accounted for 37.9%, making it the most common reason for NICU admission. The condition was more prevalent among males (53.75%) than females (46.25%), although the gender difference was not statistically significant.

Early-onset sepsis (EOS) was more common in preterm and low birth weight neonates, particularly those delivered vaginally and born at home. Notably, home-delivered neonates had a 100% incidence of neonatal sepsis, highlighting poor aseptic conditions and lack of medical care during delivery.

Clinical Outcomes

The overall survival rate was relatively high in both datasets, with 85.25% in one and 68% in the other being successfully discharged after treatment. However, mortality ranged between 14.75% and 27.42%, with significant fatalities attributed to severe birth asphyxia, respiratory distress syndrome, and sepsis. A small proportion (4.57%) of neonates were taken against medical advice in critical condition (LAMA), further contributing to poor outcomes.

Drug Utilization Patterns

A total of 1428 medications were prescribed to 400 neonates, with an average of 3.57 drugs per patient, indicating polypharmacy, which is often inevitable in intensive care.

1. Antibiotic Usage

Antimicrobials were universally prescribed (100%), with ampicillin and gentamicin being the most frequently used empirical therapy, consistent with national and WHO recommendations. The most commonly used antibiotic combinations were: Ampicillin + Gentamicin (21.71%), Ampicillin + Gentamicin + Cefotaxime (33.71%), especially in meningitis, Ampicillin + Amikacin (29.14%) in LOS cases. Other higher-end antibiotics like piperacillin-tazobactam, vancomycin, linezolid, meropenem, and colistin were reserved for resistant or culture-positive LOS cases. This reflects a rational stepwise approach in antimicrobial stewardship, escalating therapy only when needed.

2. Other Drug Classes

Besides antibiotics: Vasopressors (50.8%) were used for hemodynamic support, Antiepileptics (29.14%) such as phenobarbitone and phenytoin were common in convulsing neonates, NSAIDs (31.42%), antacids (16.57%), and micronutrients (8.57%) were also part of supportive therapy, Vitamin K (4.57%) was given to address coagulopathy due to immature liver function

The WHO-ATC classification revealed that 60.36% of total drugs prescribed were anti-infectives, underscoring the dominance of infections as a clinical issue in ADR reporting in neonates is inherently challenging. Out of 10 ADRs identified:

70% were possible per Naranjo's scale, 60% were classified as unlikely per WHO-UMC criteria. The inability to rechallenge drugs, polypharmacy, and comorbidities reduce the reliability of causality assessments. Yet, this highlights the need for vigilant ADR monitoring in NICU settings.

NICUs.

Microbiological Profile

Staphylococcus aureus (45.26%) emerged as the most commonly isolated pathogen, followed by Klebsiella pneumoniae (26.28%) and Escherichia coli (14.60%). The presence of Pseudomonas, Enterococcus, and Streptococcus pneumoniae highlights the diversity of pathogens involved in neonatal sepsis, many of which are potentially drug-resistant.

Adverse Drug Reactions (ADRs)

The evaluation of WHO core prescribing indicators revealed that the average number of drugs prescribed per neonate was 3.57, indicating a moderate level of polypharmacy, which is often necessary in the management of critically ill neonates. Antibiotics were prescribed in 60.3% of the cases, reflecting the high prevalence of infectious conditions such as sepsis in the neonatal intensive care unit.

A high proportion of drugs (86.97%) were administered via injection, which is justifiable given the limited options for oral administration in neonates due to immature gastrointestinal function and the severity of illness. However, it was observed that only 78% to 91% of drugs were prescribed by their generic names, suggesting room for improvement in promoting generic prescribing practices. Additionally, 71.2% to 73.33% of the drugs were from the Essential Drug List, indicating a fair but suboptimal level of adherence to national essential medicine guidelines.

While the high use of injectables is appropriate in this clinical context, there is a need to enhance prescribing practices by increasing the use of generic names and aligning more closely with the Essential Drug List, in order to promote rational and cost-effective drug use in neonatal care.

5. CONCLUSION

This study reveals:

- A substantial burden of neonatal sepsis
- Predominant reliance on empirical antibiotics, often adjusted by culture results
- Frequent isolation of drug-resistant organisms like *Staphylococcus aureus*
- Opportunities for enhancing ADR surveillance and rational prescribing practices

The findings may inform future antimicrobial policies, help optimize NICU treatment protocols, and encourage better training in neonatal pharmacotherapy.

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