

A Cross-Sectional Study to Identify the Antibiotic Usage Patterns in Patients Suffering with Neonatal Sepsis Admitted to Neonatal Intensive Care Unit (NICU)

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ABSTRACT

Introduction -Sepsis occurring before 28 days after birth is termed neonatal sepsis. Antibiotic misuse is linked to the emergence and spread of resistant microorganisms. Early identification and rational antibiotic use are critical to reduce antimicrobial resistance and improve outcomes. **Aim** -The aim was to evaluate the antibiotic usage pattern in neonates diagnosed with neonatal sepsis who are admitted to the neonatal intensive care unit. **Methodology**- A cross-sectional and observational study was conducted in the neonatal intensive care unit of a tertiary care Hospital. 50 neonates who met the inclusion criteria over a one-year period were observed. Prior permission was taken from the Institutional Ethics Committee. According to WHO guidelines for drug use studies, information on the use of antimicrobials, including drug choice, number of antibiotics taken, therapeutic class, method of administration, and duration were gathered. The efficacy of the medications was assessed by the treatment outcome and safety/ tolerability by monitoring and recording any adverse events. **Results** - Early-onset newborn sepsis (EONS) affected 68% of the 50 neonates, whereas late-onset neonatal sepsis (LONS) affected 32%. The most often given antibiotics were piperacillin-tazobactam (52%), amikacin (98%), and cefotaxime (72%). Cefotaxime + amikacin was the most seen empirical combination (50%). The most frequently isolated pathogen was *Klebsiella pneumoniae*, and 26% of blood cultures were positive. In 36% of cases, clinical or laboratory results led to a modification in antibiotic treatment. In EONS, the cure rate was 67.6%, while in LONS, it was 93.75%. On average, 2.38 antibiotics were prescribed for every prescription. **Conclusion** -Neonatal sepsis have high clinical heterogeneity and is still without internationally agreed upon diagnostic criteria. This expected heterogeneity may cause significant differences in morbidity and mortality rates.

Keywords: Neonatal sepsis, antibiotic usage pattern, NICU, early-onset sepsis, antimicrobial resistance, empirical therapy.

INTRODUCTION

Sepsis occurring within 28 days after birth is termed neonatal sepsis [1, 2]. There is currently no international consensus on the definition of neonatal sepsis [3, 4]. Most neonatal sepsis criteria used in clinical trials are based on different combinations of clinical and laboratory parameters [4–6].

It includes infections of urinary tract, meningitis, pneumonia, arthritis and osteomyelitis (7). The most frequent cause of newborn mortality, sepsis, accounts for 30 -50% of all neonatal fatalities in underdeveloped nations (8,9). Up to 20% of newborns are thought to suffer sepsis, while only 1% of them pass away from sepsis-related reasons (9).

Early onset neonatal sepsis (EONS) and Late onset neonatal sepsis (LONS) are two forms of neonatal sepsis. While LONS refers to sepsis that manifests after 72 hours but before 90 days of life, EONS refers to sepsis that manifests within 72 hours of life (10).

Neonatal sepsis has a wide range of non-specific signs and symptoms (11). Fever or hypothermia, cyanosis, apnea and respiratory distress, feeding issues, lethargy, irritability, hypotonia, seizures, bulging fontanel, poor perfusion, bleeding issues, abdominal distention, hepatomegaly, unexplained jaundice, or, most importantly, "not looking right" are some of these (12,13).

In neonatal intensive care units (NICU) and new-born wards, antibiotics are the most often prescribed drugs (14). Neonatal sepsis causes serious problems and has vague symptoms. Therefore, even though only 5% of culture findings are positive during hospitalization, doctors frequently provide antibiotics to babies who are at high risk of sepsis (14,15). Antibiotic misuse is linked to the emergence and spread of resistant microorganisms (10,11). Sepsis is caused by multidrug-resistant bacteria, linked to higher mortality, high costs, and treatment difficulties (18). Early identification and prudent antimicrobial agent use can reduce newborn sepsis-related death. Furthermore, extensive support is required (19). Antimicrobial resistance can be significantly reduced by implementation of Infection control and antibiotic stewardship program in the hospital. Also, rational usage of antibiotics must be promoted in clinical practice.

AIMS AND OBJECTIVES

AIM:

To evaluate the antibiotic usage pattern in neonates diagnosed with Neonatal sepsis who are admitted to NICU

OBJECTIVES:

1. To study the pattern of antibiotic utilization in neonates diagnosed with Neonatal sepsis.
2. To study the morbidity and mortality pattern in patients with neonatal sepsis

MATERIALS AND METHODS

In the present study, the pattern of antibiotic usage was evaluated in Neonates with neonatal sepsis admitted to NICU in a tertiary care teaching hospital. The study was conducted after the Institutional Ethics committee's approval. (EC/NEW/INST/2019/397)

Study design: A Cross-sectional observational study.

Study site: Neonatal intensive care unit of a tertiary care hospital.

Sample size: A total of 50 Neonates who fit the eligibility criteria during the study period.

Duration of study: one year study period, that is from April 2021 to March 2022.

Study population: Neonates admitted to Neonatal Intensive Care Unit in Paediatric Department.

Inclusion criteria:

- a. Neonates (0 -28 days) admitted in Neonatal intensive care unit who are diagnosed with neonatal sepsis.
- b. Neonates whose parent's written consent is obtained.

Exclusion Criteria:

- a. Neonates who were discharged or expired within 24 hours of Neonatal Intensive Care Unit admission.
- b. Neonates whose parent's consent is not obtained.

METHODOLOGY

This study included a total of 50 cases with positive sepsis screens. Age, sex, birth weight, gestational age and antibiotic use were among the details gathered in a pre-designed case record form. In cases where a culture was positive, the causative pathogen was also documented.

According to WHO guidelines for drug use studies, information on the use of antimicrobials, including drug choice, number of antibiotics taken, therapeutic class, method of administration, and duration, were gathered. Throughout their

hospital stay, the patients were monitored daily to gather information about antibiotic changes as well as treatment outcomes, such as whether they were cured, left against medical advice (LAMA) or passed away.

The efficacy of the medications was assessed by the treatment outcome and safety/tolerability by monitoring and recording any adverse events. The adverse drug reactions were identified actively and passively and by educating the health care professionals to observe and inform if present. The morbidity and mortality was assessed.

Statistical analysis:

Data entry and statistical analysis was performed with Microsoft excel 2010 and SPSS25 (statistical package for the social sciences). The statistical significance level was fixed at $p < 0.05$.

RESULTS

TABLE 1: DISTRIBUTION OF PATIENTS ACCORDING TO GENDER

Category	Number of subjects N=50	Percentage (%)
Male	29	58%
Female	21	42%
Total	50	100%

TABLE 1 - Out of 50 neonates, **58% (n=29) were male**, and 42% (n=21) were female.

TABLE 2: DISTRIBUTION OF PATIENTS ACCORDING TO AGE AT THE TIME OF ADMISSION

Age at admission (Days)	Number of patients (n =50)	Percentage (%)
1 - 7	45	90%
8 - 14	2	4%
15 -21	2	4%
22 - 28	1	2%
Total	50	100%

TABLE 2 -Distribution of PATIENTS according to age at the time of admission out of 50 neonates, the **maximum** number of PATIENTS belong to the age group between **1 to 7 days**, which was 90%

TABLE 3: DISTRIBUTION OF PATIENTS ACCORDING TO PLACE OF BIRTH

Category	Number of patients (n =50)	Percentage (%)
Intramural births	38	76%
Extramural births	12	24%
Total	50	100%

TABLE 3 -Distribution of patients according to place of birth was out of 50 neonates, the **maximum** number of patients were **Inborn**, which was **76%**.

TABLE 4: DISTRIBUTION OF PATIENTS ACCORDING TO GESTATIONAL AGE

Gestational age (weeks)	Category	Number of subjects (n= 50)	Percentage (%)
< 28	extremely preterm	1	2%
28 to 32	very preterm	6	12%
32 to 37	late preterm	11	22%
37 to 42	Term	30	60%
> 42	post term	2	4%
total		50	100%

TABLE 4 - Distribution of PATIENTS according to gestational age out of 50 neonates, the **maximum** number of PATIENTS were **Term neonates**, which were 60%.

Figure 1 - DISTRIBUTION OF PATIENTS ACCORDING TO BIRTH WEIGHT

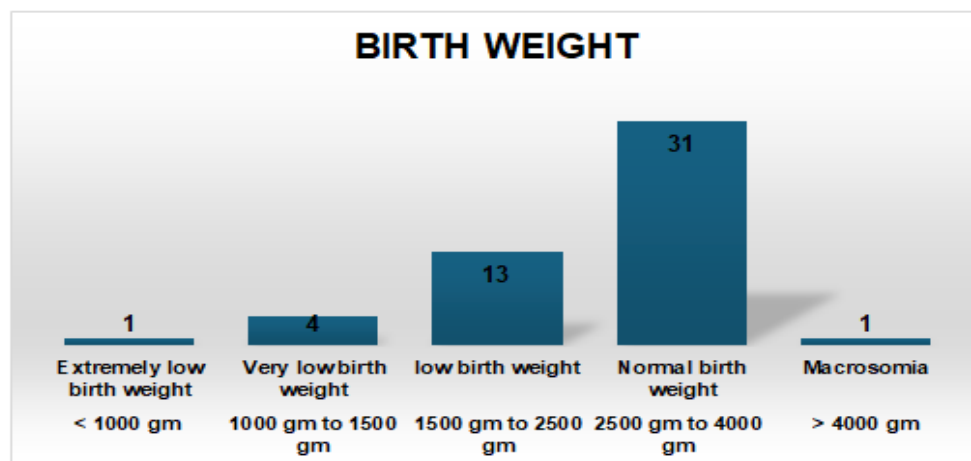


Figure 1-Distribution of patients according to birth weight out of 50 neonates, the **maximum** number of PATIENTS were of **normal birth weight**.

Figure 2 -DISTRIBUTION OF PATIENTS ACCORDING TO MODE OF DELIVERY

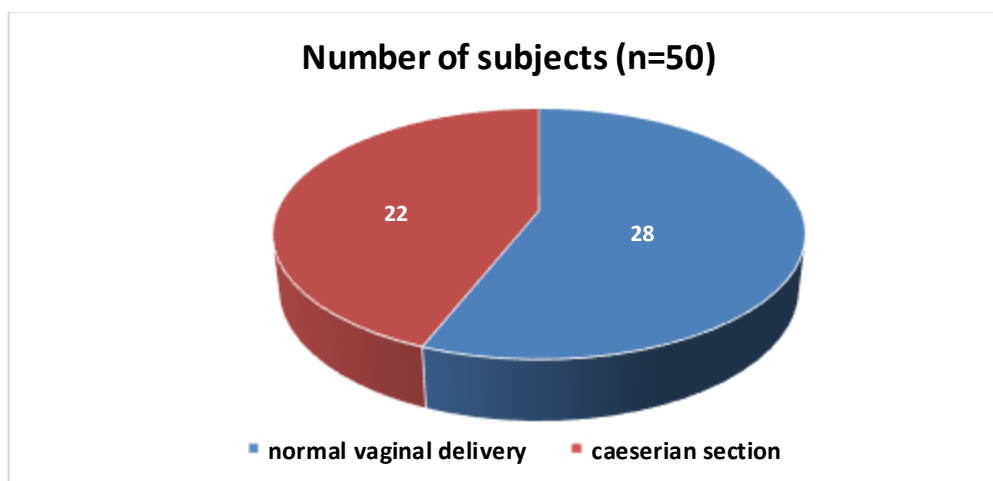


Figure 2 -Distribution of PATIENTS according to mode of delivery out of 50 neonates, the **maximum** number of PATIENTS were delivered by **Normal vaginal delivery**, which was 56%.

TABLE 5: DISTRIBUTION OF PATIENTS ACCORDING TO DURATION OF STAY

Duration of stay (days)	Number of subjects (n= 50)	Percentage (%)
1 to 4	12	24%
5 to 8	16	32%
9 to 12	15	30%
13 to 16	3	6%
17 to 20	3	6%
> 21	1	2%
Total	50	100%

TABLE 5: Distribution of patients according to duration of stay out of 50 neonates, the **maximum** number of patients were admitted for the duration of **5 to 8 days**, which were 32%.

TABLE 6: DISTRIBUTION OF PATIENTS ACCORDING TO TYPE OF SEPSIS

Category	Number of patients (n= 50)	Percentage (%)
Early onset Neonatal sepsis	34	68%
Late onset Neonatal sepsis	16	32%
Total	50	100%

TABLE 6: Distribution of patients according to type of sepsis out of 50 neonates, the **maximum** number of patients were suffering from **Early onset neonatal sepsis**, which were 68%

TABLE 7: BLOOD CULTURE REPORT PATTERN

Pathogen	Number of samples (n = 50)	Percentage (%)
no growth	37	74%
Klebsiella pneumoniae	7	14%
Pseudomonas aeruginosa	3	6%
Escherichia coli	2	4%
Acinetobacter baumannii	1	2%
Total	50	100%

TABLE 7: Distribution of patients according to result of blood culture out of 50 samples, the **maximum number** of samples showed no growth, which was 74%, and among culture positive samples the most common pathogen found was **Klebsiella pneumoniae**.

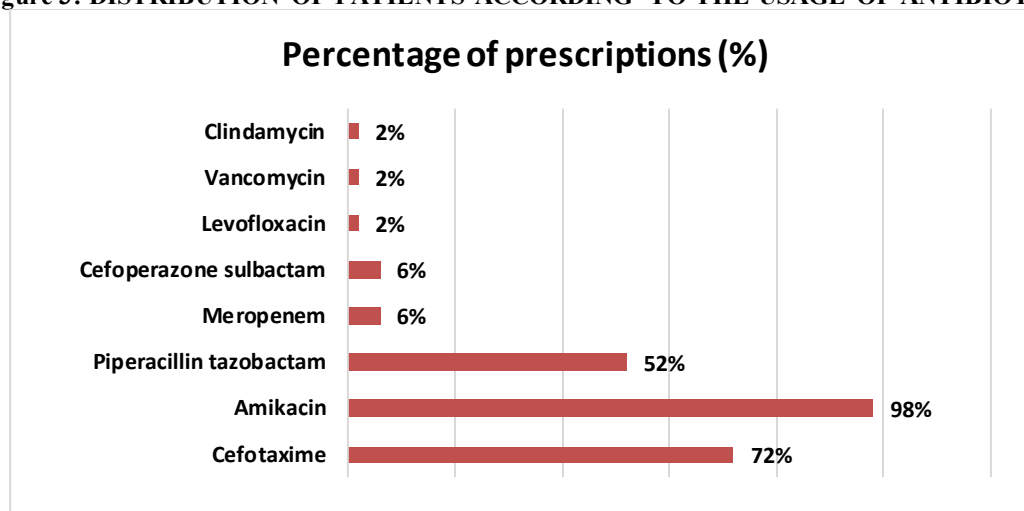
Figure 3: DISTRIBUTION OF PATIENTS ACCORDING TO THE USAGE OF ANTIBIOTICS

Figure 3: Among all the antibiotics prescribed **amikacin** was **most prescribed** followed by cefotaxime and piperacillin tazobactam.

TABLE 8: DISTRIBUTION OF PATIENTS ACCORDING TO CHOICE OF EMPIRICAL ANTIBIOTICS

Antibiotics	Number of prescriptions	Percentage (%)
Cefotaxime	1	2%
Cefotaxime+ Amikacin	25	50%
Piperacillin Tazobactam+ Amikacin	14	28%
Cefotaxime+ Piperacillin Tazobactam+ Amikacin	10	20%

TABLE 8: Most common choice of empirical antibiotic combination was cefotaxime + amikacin followed by piperacillin tazobactam + amikacin

TABLE 9: PATIENTS BASED ON INDICATION FOR THE CHANGE OF ANTIBIOTICS

Indication	Number of cases (n=50)	Percentage (%)
Clinical deterioration	5	10%
Based on Laboratory report	13	26%
No change of Antibiotic	32	64%

TABLE 9: The most common indication for change of antibiotics was based on laboratory reports, **maximum percentage** of neonates there **was no change of antibiotics**.

TABLE 10: ANTIBIOTICS USED PATTERN PER SUBJECT

Number of antibiotics	Number of subjects	Percentage (%)
1	1	2%
2	32	64%
3	15	30%
4	1	2%
5	1	2%
Total	50	100%

TABLE 10: In majority of neonates two antibiotics were prescribed followed by three antibiotics

TABLE 11: TREATMENT OUTCOME OF EARLY ONSET NEONATAL SEPSIS

Outcome	Number of subjects (n=34)	Percentage (%)
Cured and discharged	23	67.64%
Expired	9	26.47%
left against medical advice	2	5.80%
Total	34	100%

TABLE 11: Maximum number of neonates got cured and discharged in EONS whereas 26.47% of neonates expired which is higher percentage than LONS

TABLE 12: TREATMENT OUTCOME OF LATE ONSET NEONATAL SEPSIS

Outcome	Number of PATIENTS(n=16)	Percentage (%)
cured and discharged	15	93.75%
Expired	1	6.25%
left against medical advice	Nil	0%
Total	16	100%

TABLE 12: The maximum number of neonates got cured and discharged in LONS whereas 6.25% of neonates expired.

DISCUSSION

The most common cause of mortality and morbidity in the NICU is neonatal sepsis. Usually in clinical practice to start empiric antibiotic therapy in suspected instances following prompt sepsis screening while awaiting the findings of investigations to prevent death from neonatal sepsis, which can be fatal very rapidly (20). Such empirical antibiotics are typically chosen based on the culture sensitivity and local antibiogram and antibiotic susceptibility found in the specific region. The most frequent bacteria identified in our investigation were *Klebsiella pneumonia* (14%), which was followed by *Pseudomonas* (6%), *E. coli* (4%) and *Acinetobacter baumannii* (2%).

In our study, we discovered that males (58%) were admitted to the NICU at a higher rate than females. This result was consistent with research done in Kenya and Nepal by Tank et al. and Pokhrel et al (21,22). In a study done in Nigeria by Olukemi et al., more males than females were admitted to the NICU (23).

In our study, we discovered that individuals with early-onset sepsis were admitted to the NICU more frequently than those with late-onset sepsis. This result was consistent with the research done in Nepal by Pokhrel et al. Neonates who were born prematurely (74%) and with low birth weight (62%) had a higher incidence of neonatal sepsis. This finding has been supported by other studies (25,26).

Neonatal sepsis was more common in situations of normal vaginal birth (56%) than the caesarean section (44%). Similar results were obtained in a study by Behera N. et al. (7) in India, where it was discovered that caesarean sections were less likely to result in infant sepsis than of normal vaginal birth cases which were 79%.

The most often prescribed antimicrobial agents (AMAs) were Amikacin (98%) Cefotaxime (72%) and Piperacillin tazobactam (52%). Numerous Indian studies, including Patel et al and Choudhary et al. have validated the widespread use of cefotaxime and amikacin. Similar conclusions were reached in a study by Singh et al. (27) This data contrasts with those of research by Prusakov et al. (14) and A.P. Pasaribu et al. (20) which found that cefotaxime (71.60%) and Gentamycin (72.22%) were the two most often administered antibiotics in NICUs. The various empiric antibiotic options were determined by the pathogen distributions in specific hospitals.

This conclusion is consistent with the study done by Raj SC et al. (28) that *Klebsiella pneumonia* is the most common bacterium, followed by *E. coli* and *Pseudomonas*. Similar results were found in research by A.P. Pasaribu et al. (26) in which *Klebsiella pneumoniae* was the most frequently isolated pathogen.

Both in EONS and LONS, cefotaxime plus amikacin was the recommended option for empirical antibiotic therapy. In both EONS and LONS, Piperacillin tazobactam+ Amikacin was the other frequently utilized antibiotic regimen. Only 20% of instances required the use of three antibiotic combinations, such as (29) cefotaxime + piperacillin + amikacin, which were only used for certain illnesses including meningitis.

According to a study by Vaniya et al., the average amount of antibiotics prescribed per prescription was (3.74) which was in accordance with our study 2.38 (30). Most of the newborns received 2 (64%) to 3 (30%) antibiotic prescriptions. Similar conclusions were reached from a study carried out by Behera N et al. (7) in India.

In our study, a decision was taken about the course of antibiotics after obtaining the culture and sensitivity reports, i.e., whether to stick with the current regimen (due to the patient's improved condition) or choose a regimen as advised by the sensitivity report. Both EONS (67.64%) and LONS (93.75%) had a much higher cure percentage and (4%) in EONS had left against medical advice. However, EONS had a substantially higher death percentage (26.47%) than LONS (6.25%). The delay in seeking medical care or referrals from other institutions could have contributed to the death. Similar results were discovered in a study carried out by Behera N et al. (7) in India, where there was a considerably higher percentage of cured patients in both EONS (68%) and LONS (80%) separately. However, the death rate was much higher (20%) for EONS than LONS.

Drug resistance is a result of the indiscriminate and overlapping spectrum usage of antibiotics, which leads to the creation of resistant strains. It is important to remember that antibiotics should only be used when necessary. To alter the patterns of resistance, Antibiotic policy should be strictly adhered in switching to the higher Antibiotics. It is best to avoid administering potent antibiotics for prevention and mild illnesses.

With a case fatality rate of 24-69%, sepsis causes one-fourth to almost half of newborn fatalities in India. In our investigation, the fatality rate related to neonatal sepsis was 20%. In our experience, early-onset septicemia had a higher fatality rate (26.47%), but late-onset septicemia had a lower mortality rate (6.25%).

CONCLUSION

Neonatal sepsis has high clinical heterogeneity and is still without internationally agreed upon diagnostic criteria. This expected heterogeneity may cause significant differences in morbidity and mortality rates. In the face of the ongoing changes of microbial prevalence and resistance, local treatment protocol should be reviewed and assessed periodically to combat neonatal sepsis in NICU.

Ethics approval and informed consent -The study was started after the approval from the Institutional Ethics Committee. The written consent from parents or guardians was obtained.

Limitations of the study: It was conducted only on the population admitted in one hospital of Andhra Pradesh, India. It is a time-bound single-center study conducted on a small sample size. However, additional studies with larger sample sizes and with different ethnic population groups are needed to further validate our study findings.

Conflicts of Interest - none declared

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Authors' contributions: All the authors equally contributed to the work.

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