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Research Article

# DRUGS UTILIZATION STUDY IN NEONATAL SEPSIS IN TERTIARY CARE HOSPITAL

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**ABSTRACT**

**Objectives:** The present study was taken up to evaluate the drug utilization pattern and adverse drug reactions (ADRs) seen in patients of neonatal sepsis admitted to sick newborn care unit of a tertiary care hospital in Uttarakhand.

**Methods:** This was a prospective observational study. A suitable case record form was designed to collect all the necessary and relevant information. Data of 175 neonatal sepsis matching inclusion criteria were recorded. Pattern of prescription of drug for various diseases in sick newborns was analyzed. Information on ADR were analyzed. ADR was analyzed using Naranjo scale and the WHO causality assessment scale.

**Results:** Blood culture was positive in 137 (78.29%) neonates. *Staphylococcus aureus* (45.26%) was the most common microorganism followed by *Klebsiella pneumoniae* (26.28%) and *Escherichia coli* (14.60%). Out of 137 blood culture-positive neonates, 30.66% were suffering from meningitis. Out of 38 blood culture-negative neonates, 63.16% were suffering from meningitis. Average number of drugs per encounter was 1.71. Percentage of drugs prescribed by generic name was 91%. Parenteral route was the most common route of drug administration. Ampicillin was the most common antimicrobial prescribed. Next common classes of drug used were vasopressor. Out of 10 (5.71%) ADRs identified, 70% were possible and 30% were doubtful as per Naranjo's causality assessment scale. Case fatality rate was 27.42% during the course of study.

**Conclusion:** Parenteral antibiotics (ampicillin plus gentamycin) and vasopressors remain the most commonly prescribed drugs in neonatal sepsis in sick newborn unit. The study concluded that doses and duration, for which drugs were used, were in accordance to AIIMS protocol for neonatal sepsis.

**Keywords:** Neonatal sepsis, Evaluation of drugs, Adverse drug reactions.

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## INTRODUCTION

A neonate is an infant ≤1 month. According to the data from National neonatal-perinatal database (NNPD 2002–2003), the incidence of neonatal sepsis is 30/1000 live births. The NNPD network comprising 18 tertiary care neonatal units across India found sepsis to be one of the most common causes of neonatal mortality contributing to 19% of all neonatal deaths [1]. Neonatal sepsis is a clinical syndrome. It includes signs and symptoms of infection with or without bacteria in blood. Various systemic infections of the newborn such as septicemia, meningitis, pneumonia, arthritis, osteomyelitis, and urinary tract infections are included in sepsis of newborns. Neonatal septicemia is one of the most common causes of neonatal mortality and morbidity throughout the world. It is estimated that 20% of all neonates develop sepsis and is responsible for 30–50% of total neonatal death in the developing countries [2]. Newborns, born out of high-risk pregnancies, premature infants, or those with both risk factors, are at greater risk for medication exposure [2]. Early-onset sepsis (EOS) occurs within 72 h and late-onset sepsis (LOS) occurs after 72 h of life of neonate [3]. The cause is EOS is generally maternally acquired infection whereas in case of LOS, the cause is nosocomial or community acquired [4,5].

Neonatal mortality rate (NMR) is highest in poor and marginalized areas like hilly regions of Uttarakhand that lack medical facilities. The newborns referred from these hilly areas and admitted as extramural neonates contribute to the high NMR of India [6]. Studies based on prescription pattern and drug utilization monitoring can help identify the problems and provide feedback to physicians so as to create awareness about irrational use of drugs that could contribute to reduced mortality of neonates. The present study was taken up to evaluate the drug utilization pattern (using the WHO prescribing indicators) and adverse drug reactions (ADRs) seen in patients of neonatal sepsis admitted to sick newborn care unit (SNCU) of Dr. Susheela Tiwari Hospital attached to Govt. Medical College, Haldwani, Uttarakhand, India.

## METHODS

### Study design

This prospective observational study was carried out September 1, 2017–August 31, 2018, after approval from Departmental Screening Committee of Pharmacology and Institutional Ethics Committee of Government Medical College and Hospital, Haldwani.

### Inclusion criteria

All sick newborn of either sex admitted to SNCU diagnosed by pediatrician according to AIIMS protocol [3] as cases of neonatal sepsis were included in the study.

### Exclusion criteria

Sick newborns that were discharged or died within 24 h of SNCU admission were excluded from the study. The parents/guardians of the sick newborn who did not give their written consent were excluded from the study. The neonates more than 1 month old and neonates suffering from congenital abnormality, physiological jaundice, road traffic accident, hypoxic-ischemic encephalopathy, and metabolic disorders without sepsis were not included in this study.

### Study procedure

Data of 175 neonatal sepsis matching inclusion criteria were recorded. A suitable case record form was designed to collect all the necessary and relevant information. The gestational age, birth weight, gender, place of delivery, type of delivery, the duration of stay, and discharge status were recorded. The details of medication, that is, number of drugs

used, drug class/category, the dose, route, frequency and duration of administration, the criteria for drug selection, and individualizing the dose were recorded. Pattern of prescription of drug for various diseases in sick newborns was analyzed using AIIMS protocol for neonatal care [3]. Drug use was also analyzed according to the WHO prescribing indicators [7]. Percentage of prescribed essential drugs was analyzed using the WHO Essential Medicine List for Children 2013 [8]. The efficacy of the medications was assessed by the treatment outcome and safety/tolerability by monitoring and recording any adverse events. Any drug interactions among the study medications were also recorded. Information on ADR was analyzed using ADR reporting form provided by CDSCO (now provided by IPC). ADR was analyzed using Naranjo scale and the WHO causality assessment scale [9].

**Statistical analysis**

The data collected were analyzed statistically on SPSS version 21 software using descriptive statistics, namely, mean and standard deviation for quantitative variables and non-parametric tests for qualitative variables. Wherever necessary, the results were depicted in the form of percentages and graphs.

## RESULTS

Demographic data of study population are depicted in Table 1. EOS was more in male neonates (73.44%) in comparison to female neonates (63.83%). LOS was more in female neonates (36.17%) in comparison to male neonates (26.56%). However, differences were not significant. Neonatal sepsis was more common in home delivered neonates (100%) in comparison neonates who were delivered at hospital (69.64%). However, differences were not significant. EOS was more common in normal delivery neonates (75.57%) in comparison to neonates who were delivered by cesarean section (56.82%). LOS was more common in neonates who were delivered by cesarean section (43.18%) and these differences were found significant. EOS was significantly more common in preterm neonates. LOS was significantly more common in very low birth weight neonates.

Out of total 175 neonates, 137 neonates were having blood culture positive. Out of 137 blood culture-positive neonates, 30.66% were suffering from meningitis. Out of 38 blood culture-negative neonates, 63.16% were suffering from meningitis. These differences were found significant (Table 2).

Antimicrobials were the most common drugs used (100%) in the study and vasopressors (dopamine/dobutamine/adrenaline) were used in 50.8% of cases. Antiepileptics (phenobarbitone/phenytoin) were used in 29.14% of neonatal sepsis cases. NSAIDs (paracetamol/diclofenac) were used in 31.42% of cases. Antacids (ranitidine/pantoprazole) were used in 16.57% of cases. Other drugs like micronutrients (Vitamin A/multivitamin syrup) were used for supportive treatment in 8.57% of cases. Vitamin k was used in 4.57% of cases to treat bleeding as liver is immature in neonates (Table 3).

As mentioned in Table 4, a total of seven antimicrobials were cumulatively prescribed. Among them, ampicillin+gentamicin was used in 21.71% sick newborns. Ampicillin+gentamicin+cefotaxime in 33.71% cases of neonatal meningitis. Amikacin+ampicillin was used in 29.14% of LOS cases of neonatal sepsis. The preceding narrative clearly implies that ampicillin and gentamicin were the first-line antimicrobials. Other less commonly used antimicrobials were piperacillin sodium/tazobactam sodium+amikacin in 08.00%, linezolid+amikacin in 2.28, and vancomycin+amikacin in 1.14% of total admitted sick newborns. Less commonly antibiotics were used mainly in cases of LOS and failure to respond to first-line therapy.

*Staphylococcus aureus* (45.26%) was the most common microorganism isolated among different cultures followed by *Klebsiella pneumoniae* (26.28%) and *Escherichia coli* (14.60%). Whereas, in a smaller number of cases, microorganisms such as *Pseudomonas* (8.76%), *Streptococcus pneumoniae* (2.19%), and *Enterococcus* (2.92%) were involved in this condition (Table 5).

The use of drugs in SNCU was analyzed using the WHO prescribing indicators. Average number of drugs per encounter was 1.71. Percentage of drugs prescribed by generic name was 91%. Infections were major cause of admission; therefore, sick newborns were prescribed antibiotics. Oral route is not preferred in neonates; therefore, 175 (100%) sick newborns were given drugs by parenteral route. Percentage of drugs prescribed from essential drugs list or formulary for children (2013) was 73.33**% (**Table 6**).**

Drugs used in newborn may cause various reactions in newborns which are difficult to identify in neonates. Out of 10 ADRs identified, 7 (70%) were possible and 3 (30%) were doubtful as per Naranjo's causality assessment scale. According to the WHO-UMC causality assessment, out of 10 ADRs identified, 4 (40%) were possible and 6 (60%) were unlikely. No attempt was made for rechallenging of the drugs, as it is not entertained in the pediatric patients by the attending pediatrician as the situation could worsen; hence, it became a major limitation for the assessment of the ADRs and to get causal relationship. However, the grade of causality for each ADR remained low due to the presence of coadministered drugs as well as presence of comorbidities in neonates (Table 7)**.**

At the end of the study, it was found that out of 175**,** 119 (68.00%) of the newborns improved with treatment and were successfully discharged. During the course of study, 48 (27.42%) of admitted sick newborns ended up fatally. As per clinician analysis, 5 (4.57%) sick newborns

**Table 1: Demographic characteristics of neonates suffering from neonatal sepsis**

| Demographic characteristics | EOS (n=124), n (%) | LOS (n=51) |
|---|---|---|
| Distribution of neonates according to sex (p=0.215; not significant) | | |
| Male (128) | 94 (73.44) | 34 (26.56) |
| Female (47) | 30 (63.83) | 17 (36.17) |
| Distribution of neonates according to place of delivery (p=0.361; not significant) | | |
| Home (7) | 7 (100.00) | 0 |
| Hospital (168) | 117 (69.64) | 51 (30.36) |
| Distribution of neonates according to mode of delivery (p=0.017; significant) | | |
| Normal delivery (131) | 99 (75.57) | 32 (24.43) |
| Cesarean section (44) | 25 (56.82) | 19 (43.18) |
| Distribution of neonates according to gestational age (p<0.001; significant) | | |
| Preterm (136) | 112 (82.35) | 24 (17.65) |
| Term (39) | 12 (30.74) | 27 (69.23) |
| Distribution of neonates according to birth weight (p<0.0197; significant) | | |
| Very low birth weight (44) | 27 (61.36) | 17 (38.63) |
| Low birth weight (86) | 58 (67.44) | 28 (32.56) |
| Normal birth weight (45) | 39 (86.67) | 6 (13.33) |

EOS: Early-onset sepsis, LOS: Late-onset sepsis

**Table 2: Distribution of neonates according to blood culture positivity and meningitis**

| Blood culture | Meningitis | No meningitis | Total |
|---|---|---|---|
| Blood culture positive | 42 (30.66) | 95 (69.34) | 137 (100.00) |
| Blood culture negative | 24 (63.16) | 14 (36.84) | 38 (100.00) |
| Total | 66 (37.71) | 109 (62.29) | 175 (100.00) |

Figures in parenthesis are percentages. P=0.000524, significant at p≤0.05

**Table 3: Distribution of neonates according to drug use**

| S. No. | Name of drug | n=175, n (%) |
|---|---|---|
| 1 | Antimicrobials | 175 (100.00) |
| 2 | Vasopressor | 89 (50.85) |
| 3 | Antiepileptics | 51 (29.14) |
| 4 | NSAIDs | 55 (31.42) |
| 5 | Antacids | 29 (16.57) |
| 6 | Micronutrients | 15 (8.57) |
| 7 | Vitamin K | 8 (4.57) |

NSAIDs: Nonsteroidal anti-inflammatory drugs

**Table 4: Empirical antibiotic use in neonatal sepsis**

| S. No. | Antimicrobials | n=175, n (%) |
|---|---|---|
| 1 | Ampicillin+gentamicin | 38 (21.71) |
| 2 | Ampicillin+gentamicin+cefotaxime | 66 (33.71) |
| 3 | Ampicillin+amikacin | 51 (29.14) |
| 4 | Piperacillin sodium/tazobactam sodium+amikacin | 14 (8) |
| 5 | Vancomycin+amikacin | 4 (2.28) |
| 6 | Linezolid+amikacin | 2 (1.14) |

**Table 5: Distribution of culture-positive cases in neonatal sepsis**

| Serial number | Type of microorganism | Number of cases (n=137), n (%) |
|---|---|---|
| 1 | *Staphylococcus aureus* | 62 (45.26) |
| 2 | *Klebsiella pneumoniae* | 36 (26.28) |
| 3 | *Escherichia coli* | 20 (14.60) |
| 4 | *Enterococcus* | 4 (2.92) |
| 5 | *Streptococcus pneumoniae* | 3 (2.19) |
| 6 | *Pseudomonas aeruginosa* | 12 (8.76) |

were very sick and not in condition to be discharged, they were taken by their parents against the medical advice of the doctor (LAMA) (Table 8).

## DISCUSSION

Our study showed that 70.85% of sick newborns were <72 h old while 29.15% were more 72 h old. Our findings were similar to the study conducted by Kayange *et al*. in a tertiary hospital, Mwanza-Tanzania [10]. In a study at Bengaluru, Karnataka, by Anitha *et al*., 86.6% of neonates were in the age group of 1–7 days [11]. In our study, mean age of sick newborn was 5.6 days±1.8 days. The mean age of neonates was 3.44±2.47 days in a study in NICU at Bengaluru, Karnataka, by Anitha *et al*. [11]. More males (73.14%) were affected by neonatal sepsis as compared to females (26.86%). This was consistent with the observations in other studies carried out in neonates at Haldwani, Uttarakhand, by Rakholia *et al*. [6] and Bengaluru, Karnataka, by Anitha *et al*. [11]. In our study, sepsis was more common in home and normal delivery. Our finding was consistent with a study of neonatal sepsis cases admitted at a district-level SNCU at district hospital of Birbhum, West Bengal, by Viswanathan *et al*., [12] where 86.57% of neonates were from normal delivery and 13.43% were from cesarean section. Term neonates were less affected as compared to preterm neonates. In a study of antibiotic prescribing pattern in a tertiary level neonatal intensive care unit at Pune (Maharashtra) by Suryawanshi *et al*., 46.6% were term and 53.4% were preterm [13]. In another study on drug utilization pattern in NICU at Bellary, South India, Sharanappa *et al*. [14], 51% of neonates were full term and 49% were preterm. These preterm to term variations vary from studies to studies. Neonatal sepsis is more common in very low birth weight and low birth weight neonates [2,3]. Female genital tract is a source of infection in early neonatal sepsis which is postulated by researchers in some studies [15].

**Table 6: Analysis of prescription using the WHO prescribing indicators**

| Serial number | WHO prescribing indicator | Number/ percentage |
|---|---|---|
| 1 | Average number of drugs per encounter | 1.71 |
| 2 | Percentage of drugs prescribed by generic name | 91.0 |
| 3 | Percentage of encounters with antibiotics prescribed | 100 |
| 4 | Percentage of encounters with injections prescribed | 100 |
| 5 | Percentage of drugs prescribed from essential drugs list or formulary | 73.33 |

**Table 7: Causality assessment of reported adverse drug reaction**

| Serial number | Adverse drug reaction | WHO-UMC causality | Naranjo's |
|---|---|---|---|
| 1 | Sedation | Possible (*n*=2) | Possible (*n*=2) |
| 2 | Urticaria | Unlikely (*n*=3) | Possible (*n*=2) Doubtful (*n*=1) |
| 3 | Vomiting | Unlikely (*n*=2) | Possible (*n*=1) Doubtful (*n*=1) |
| 4 | Rashes | Possible (*n*=2) Unlikely (*n*=1) | Possible (*n*=2) Doubtful (*n*=1) |
| | Total | 10 | 10 |

UMC: Uppsala monitoring center

**Table 8: Treatment outcome of neonatal sepsis**

| Outcome | EOS | LOS | Total |
|---|---|---|---|
| Cured and discharged | 95 (79.83) | 24 (20.17) | 119 (100.00) |
| LAMA | 3 (37.5) | 5 (62.5) | 8 (100.00) |
| Died | 26 (54.16) | 22 (45.84) | 48 (100.00) |
| Total | 124 (70.86) | 51 (29.14) | 175 (100.00) |

EOS: Early-onset sepsis, LOS: Late-onset sepsis, LAMA: Leave against medical advice

Ampicillin and gentamicin were the most prescribed antimicrobials in hospitalized neonates. Our studies were consistent with the study done by Chatterjee *et al*. [16] and Brijal *et al*. [17]. In an attempt to identify the causative organism for neonatal sepsis blood culture was done as a part of routine investigations in accordance with AIIMS protocol [3]. Our results were consistent with a study conducted by Sharma *et al*. [18] where the causative organisms in cases of neonatal sepsis were *S. aureus* (49%), *K. pneumoniae* (27%), and *E. coli* (11%) followed by *Enterococcus*, *S. pneumoniae,* and *Pseudomonas aeruginosa*. However, result was different from other study report done by Viswanathan *et al*. [12] who showed that *K. pneumoniae* is predominant microorganism followed by *E. coli* and *Enterobacter*. The study concluded that doses and duration, for which drugs were used, were in accordance to AIIMS PROTOCOL for neonatal sepsis. The choice of antibiotic and change in antibiotic based on culture sensitivity were in accordance with AIIMS PROTOCOL for the management of neonatal sepsis [2].

Evaluation of prevalent drugs prescribing practices was analyzed using the WHO drug prescribing indicators. Average number of drugs per

encounter was 1.71. Percentage of drugs prescribed by generic name was 91%. About 100% of sick newborns were prescribed antibiotics. About 97% of sick newborns were given injections. Percentage of drugs prescribed from the WHO Essential Medicine List (EML 2013) [8] for children was 100%.

In the present study, 48 cases out of 175 died; therefore, case fatality rate observed was 27.42%. In a study mortality pattern of neonates in NICU at Rohtas District, Bihar, by Kumar *et al.* [19], the overall NICU mortality rate was 13.6%. The case fatality rate was high in our study when other similar studies were compared. This may be because extramural neonates were admitted more as compared to intramural neonates. Therefore, due to lack of transportation facilities, timely intervention would have not been possible.

A total of 10 (5.71%) ADRs were found in sick newborns during the study period. Out of 10 ADRs, sedation was reported in two cases, urticaria was reported in three cases, vomiting was reported in two cases, and rashes were reported in three cases. Evaluation of ADR was done using the WHO and Naranjo scale. According to the WHO-UMC scale, 40% were possible cases and 60% were unlikely. Evaluation using Naranjo scale showed that 60% were possible and 40% were doubtful cases. In a prospective drug utilization study in neonatal intensive care unit at tertiary care hospital, Rajkot, Gujarat, by Brijal *et al.* [17], only two ADRs (mild rash by ampicillin and fever by hepatitis B vaccine) were reported during the study period. The causality for both ADRs was "possible" according to the WHO-UMC scale. They were mild in severity and preventable in nature. In a prospective study of prescribing pattern of drugs in NICU at Basaveshwar Teaching and General Hospital, Gulbarga, Karnataka, by Gayathri *et al.* [20], one neonate had IUGR (intrauterine growth retardation) as an adverse effect of maternal intake of prednisolone. One neonate had acute renal failure due to maternal amikacin (aminoglycoside antibiotic) intake. Four neonates had generalized rash due to phototherapy. Different studies have shown that detection as well as assessment of adverse drug reaction are difficult in neonates. This is mainly due to lack of awareness as well as difficulty in assessing the reactions in newborns.

## CONCLUSION

The study concludes that there was male predominance of sick newborns indicating gender discrimination. Newborns were admitted mainly during early neonatal period (<72 h). Sick newborns were mainly admitted with infections as a major cause which may be acquired during intrapartum or postpartum period. Therefore, antimicrobials were the most common drugs used. Faster onset of action is needed in newborns; therefore, parenteral route was the most common route of drug administration used for sick newborns. Ampicillin was the most common antimicrobial prescribed. Next common classes of drug used were vasopressor. Antiepileptic drug prescribed most commonly was phenobarbitone.

## ACKNOWLEDGMENT

Nil.

## CONFLICTS OF INTEREST

Nil.

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