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DRUG UTILIZATION STUDY IN NEONATAL INTENSIVE CARE UNIT AT RURAL TERTIARY CARE HOSPITAL

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ABSTRACT

Objectives: To study the trends of drug utilization pattern in neonatal intensive care unit (NICU) at rural tertiary care hospital using the World Health Organization core indicators.

Methods: The study was cross-sectional, observational study in NICU of Government Medical College, Ambajogai, Maharashtra. Data were collected by scrutinizing the prescriptions written by pediatricians in NICU. The consent of parents of neonate was obtained for inclusion in the study. Parameters such as age, gender, birth weight, current illness, congenital anomalies, gestational age at birth, and drugs prescription analyzed.

Results: A total 220 prescription were scrutinized. Out of 220 neonates, 53.6% was males and 46.3% females. The total number of drugs prescribed was 808 and the average number of drugs per prescription was 3.6. The most frequently prescribed therapeutic class of drugs antimicrobial agents (60.64%) followed by vitamin K (26.7%) and aminophylline (9.4%). The maximum number (50%) of neonate born with birth weight <2.5. The maximum number (42%) of neonate was born at 34-36 weeks of gestation. Preterm low birth weight was the most common observed reason for admission to NICU. The drugs are prescribed by branded name outnumbered than generic name.

Conclusion: This study highlights the problem of overprescribing of antibiotics, inadequate labeling and a trend toward polypharmacy.

Keywords: Drug utilization study, Neonatal intensive care unit, Prescription, Neonate.

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INTRODUCTION

Rational use of drugs is defined by the World Health Organization (WHO) as "patients receives medicines appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community. Drug utilization is an important component of pharmacoepidemiology and many research initiatives that examine the clinical and economical effectiveness of pharmacotherapy [1].

The study of prescribing pattern is a part of the medical audit and seeks to monitor, evaluate and if necessary, suggest modification in prescribing practices to make medical care rational and cost effective.

A neonatal intensive care unit (NICU) is a highly specialized unit that provides high quality skilled care to premature, low birth weight (LBW) or critically ill new born infants. Apart from facilities for continuous clinical and biochemical monitoring and the life support systems the neonatal intensive care management (NICU) involves the use of a wide range of medications with well-defined and specified therapeutic objectives.

Because of the immaturity of various organ functions such as kidney, liver, gastric motility, the neonates may show pharmacodynamic and pharmacokinetic variations making them more susceptible for adverse drug reactions, which are particularly more likely in highrisk neonates such as premature, LBW or critically ill. Accordingly, caution is required while exposing such neonates to various medications [2]. They are more prone to development of adverse drug reactions as they have deficiency of metabolizing enzyme, immature excretion of the drug [3]. Besides, due to economic and ethical issues, children do not often participate in clinical trials, and specific knowledge about the effect of drugs in children is often inadequate [4].

In spite of many advances in neonatal care, currently, there are no standardized guidelines for the rational prescribing and individualizing the medication regimen in NICU. Moreover, the use of certain drugs in some NICUs may be an "off-label" means beyond the approved indication, and also their safety not being clearly established in high-risk neonates [5,6].

At present, very scanty data regarding overall pattern and extent of drug utilization in NICU, considering current scenario this study, are taken up with the purpose of generating some valid data and useful information for improving the quality of neonatal care.

METHODS

Approval from Institutional Ethics Committee was taken before the commencement of the study. The informed consent was obtained from parents/legal guardian all the study subjects.

The study was conducted in NICU of Government Medical College, Ambajogai, Beed, Maharashtra.

The study design

A cross-sectional study and study population include all neonate hospitalized in NICU in Government Medical College and Hospital.

The period of study April 2014-September 2014 with inclusion criteria,

Inclusion criteria

- 1. All neonates admitted to NICU, receiving one or more medications.
- 2. Willingness of parents/legal guardian to give informed consent for inclusion in the study.

Exclusion criteria

- Neonates not receiving any medications other than fluids/ electrolyte solution, parenteral nutrition, nutritional supplements, blood and blood products, oxygen, phototherapy, and vaccinations.
- 2. Neonates admitted to NICU for mother sake.

Data collection

- Data were recorded in predesigned performa for the study; prescriptions were evaluated for profile name, education and occupation of parents, diagnosis, birth weight, gestational age, congenital anomalies, and time of admission after birth.
- The name, formulation drug, route of drugs administration, generic and brand name, drugs, and from essential drug list.

Statistical analysis

Data were analyzed by Microsoft Office Excel 2007 and using descriptive statistics. Results were depicted in the form of percentages and graphs. A total of 220 prescriptions were scrutinized, over a period of 6 months from April 2014 to September 2014, on the basis of inclusion and exclusion criteria.

RESULTS

Data show that male neonates (53.6%), outnumbered female neonates (46.4%) (Fig. 1).

A total of drugs prescribed 808 and drugs were prescribed in the range of 1-6, that is minimum 1 to maximum 6 drugs per prescription. The average number of drugs per prescription was 3.6. The most frequently prescribed therapeutic class of drugs antimicrobial agents (60.64%) followed by vitamin K (26.7%) and aminophylline (9.4%) (Table 1). Most of the antimicrobials prescribed belonged to aminoglycosides group (gentamycin), followed by cephalosporin (cefotaxime) and carbapenem (meropenem) and all these drugs are given by parenteral route.

The drugs are prescribed by branded name outnumbered than a generic name. The maximum number (50%) of neonate was born with birth weight <2.5 (Table 2). The maximum number (42%) of neonate was born at 34-36 weeks of gestation (Fig. 2). The common neonatal conditions are preterm LBW (39%), neonatal sepsis (24%), birth asphyxia (11%), meningitis (6%), and others (20%).

Few number of neonates received bronchodialtors, antiepileptic drugs, and micronutrient compounds.

DISCUSSION

Drug utilization studies are the tools helps both prescribing physicians and the hospital administration regarding drug audit, and drug expenditure. Furthermore, helps in cost analysis which is an important parameter to decide whether it is a rational or not drug therapy. It is also helpful in framing hospital formulary and standard treatment guidelines as per the diagnosis. These studies not only guide for the rational use of drugs but are also helpful in making treatment costeffective and beneficial to patients and reduce the burden of poorly funded health system in developing countries like India [7-9].

In this study, the average number of drugs per encounter were 3.6 consistent with study of Brijal *et al.* 2015 (4.4%) [2]. An average number of drugs per prescription should always be kept low as it can lead to increase in unnecessary cost of treatment, higher possibility of drug-drug interaction, and also increase the risk of adverse drug reactions and antibiotic resistance.

Demographic profile shows male (54.3%) preponderance in neonates attending the NICU consistent with study of Brijal *et al.* 2015 (60%) [2]. The gender discrimination in terms of access to health-care is apparent in the study. There is an immediate need to

Table 1: Different therapeutic class of drug prescribed

Class of drugs prescribed	n (%)
Antimicrobial agents	490 (60.64)
Vitamin K	216 (26.73)
Aminophylline	76 (9.4)
Phenobarbitone	6 (0.7)
Pentazocine	2 (0.2)
Phenytoin	2 (0.2)
Others	8 (2.1)

Table 2: Birth weight of neonate

Birth weight of neonates	Number of neonate
<1 kg	6
1-2 kg	110
2-3 kg	84
> 4 kg	2



Fig. 1: Gender distribution of neonate



Fig. 2: Neonate born at gestational age

create awareness against gender discrimination which begins at the early age.

Findings were reported by majority (80.8) of the neonates were under 7 days of age, indicating that most of neonatal diseases are common in early neonatal age. This is in accordance with study conducted by Junejo *et al.* [10,11] in which patients admitted in the early neonatal period were 83.4%. A neonate is particularly vulnerable to adverse influences such as asphyxia, infection, and complications of preterm birth. During early neonatal days (7) and requires special attention. Parenteral route is commonly seen in NICU and it plays crucial role in the management of sick neonates until they can tolerate enteral/oral feeding.

Table 3: Age-wise distribution

Age of neonate	Number of prescription (%)
Within 1 day	168 (76.3)
1-7 days	32 (14.5)
7-28 days	20 (0.9)

Table 4: WHO core indicators

WHO core indicators	% of patients
Average number of drugs prescribed per encounter	3.6
Percentage of drugs prescribed by generic name	68
Percentage of encounters resulting in the prescription	98
Percentage of encounters resulting in the prescription	100
of an injection Percentage of drugs prescribed from WHO EML 2015	53.96
WHO: World Health Organization, EML: Essential medicine list	

The maximum number (85%) of neonate in our study was preterm showing trends toward preterm delivery. This finding is comparable to study of Neubert *et al.* [12] (54.6%). It is quite evident that significantly large (55.54%) number of neonates were LBW in our study. LBW infants remain vulnerable to malnutrition, recurrent infections, neurodevelopmental disabilities, and experience higher mortality [13].

LBW was the most common reason for admission to NICU, neonatal sepsis was the second most followed by birth asphyxia, meningitis, etc. Another study by Venkateswaramurthy *et al.* [14] of shows fever (34.6%), respiratory diseases (21.7%), gastrointestinal disorder (16.8%), and infection diseases (12.6%) were most common reasons for hospitalization. These differences can be attributed to the inclusion of different age group.

As shown in Table 1. most frequently used drugs in NICU were vitamin K and antibiotics among which amikacin, meropenem, cefotaxime, ampicillin, and gentamicin were commonly prescribed drugs.

Vitamin K deficiency bleeding is of particular concern in neonates as they are born with low levels of vitamin K. Current recommendations suggests single intramuscular administration of vitamin K is an effective, safe, and sustainable approach to preventing Vitamin K deficiency bleeding [15].

In our study, 68% drugs were prescribed by generic name which is appreciable and consistent with finding of Chatterjee *et al.* [16] (79.7). Increasing generic prescribing would rationalize the use and reduce the cost of drugs.

Higher incidences (98%) of antibiotic exposure in NICU could be due to the common practice of instituting emperical therapy and can be attributed to higher incidence of infections due to pollution, poor sanitation, and lower rate of literacy. However, inappropriate use of antibiotics leads to emergence of resistance.

Neonates are more vulnerable group due to immaturity of their body functions, and great care needs to be taken to use the minimum number of drugs. The development of effective control programs through adoption of measures that restrict use of specific antimicrobials, establishment of therapeutic guideline, a constant monitoring of the resistance pattern of the common pathogenic organisms in the hospital are recommended to improve the usage of antibiotics.

CONCLUSION

This study gave us an overall pattern of drug use profile in a tertiary care NICU and reflects the problems for which neonates were admitted to the NICU. The largest number of drugs per day were given in the 1st week in NICU. Antibiotics were of major concern. Similar studies done on a larger scale and at regular intervals can reflect the changing pattern of drug prescribing which helps authority in planning to make necessary drugs available.

Limitations

This data are from only one institute. Multicentric studies in this subject are needed, particularly over a period of a year, to avoid seasonal variation of disease pattern.

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