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Original Research Article

Study of drug utilization in intensive care management of neonates at tertiary care hospital

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ABSTRACT

Background: Newborn infants form a highly vulnerable group. Compared to adults they are more prone to adverse drug events. Exposure to multiple drugs is also known to be a leading factor in their well-being. Many advances have been made in this area, yet there is a paucity of information to guide rational prescribing in newborns. This study was conducted to evaluate the drug prescribing trends in a Neonatal Intensive Care Unit (NICU) of a tertiary care hospital in Bidar.
Methods: A prospective study was undertaken, over a period of 3 months at the government teaching hospital, Bidar. Neonates of either sex admitted to NICU were included. Data collection was done by scrutinizing the inpatient case sheets and investigation reports.
Results: A total of 100 neonates were admitted and 11 deaths were noted. Most common cause for admission was septicaemia. The total number of drugs prescribed was 488. The average number of drugs per prescription was 4.9. Antimicrobials were the commonest agents prescribed and intravenous route was the commonest route of drug administration. Most of the drugs were prescribed by generic names.
Conclusions: In our study it was observed that polypharmacy is commonly observed practice in NICU patients. Most of the antibiotics were prescribed empirically. The dose and frequency of administration was mostly as per the standard guidelines.

Keywords: Antimicrobial utilization, Drug utilization, Neonates, Neonatal intensive care unit

INTRODUCTION

Pediatrics is the branch of science that deals with the medical care of children.[1] Among Pediatric age group neonates are the most vulnerable populations susceptible for infectious diseases.[2] The problem is even more compounded in neonates who are critically ill and require intensive care management.

New born infants are unique in their physiology and health problems that they experience. Neonatal period is marked by transition to extra uterine life and rapid growth and development, this phase in life is associated with greatest risk of mortality as well as the potential for long term neurocognitive development.[3] Neonates have a limited repertoire of signs and symptoms to manifest in response to disease entities such as sepsis, congenital heart disease, and intra-abdominal pathology.[4] There is almost half of under-five child deaths occur in the neonatal period. Bacterial infections, manifesting as sepsis and pneumonia are the leading cause of death. Nearly, three fourth deaths occur among the low birth weight newborns. Approximately 40% deaths occur within 72 hours of birth.[3]

Neonatal drug handling is significantly different from that of adults. Such differences are attributed to the rapid physiological changes that take place during the early months of life leading to alterations in various pharmacokinetic and pharmacodynamic variables, which often make the neonates more susceptible to various adverse drug reactions. The recognition of severe drug toxicity following inappropriate drug selection and dosing predominantly in premature neonates and infants is exceedingly important. Secondly, the impact of maternal drug intake on neonatal outcome is also relevant

in this context. Such issues therefore call for a close monitoring of drug prescribing trends in neonates and infants.[5]

While prescribing for children's a number of knowledge-based skills and practical considerations are required.[6]

Medical personnel providing health care for neonates in developing countries are facing a number of challenges during their day-to-day practice of medicine due to inadequate infrastructure, irregular supply of drugs and other health care facilities. Hence, optimal utilization of allocated funds for treatment is exceedingly relevant and important.

Nearly all extremely low birth weight infants (ELBW) infants admitted to a NICU receive an empirical antibiotic treatment in the initial postnatal days, regardless of sterile cultures and low incidence of culture-proven bacterial sepsis in this population.[7,8] The logical use of medications in neonates depends on an appreciation of both physiological immaturity and the developmental maturation that influence neonatal drug disposition and pharmacologic effects. Neonates, especially those of extremely low birth weights, present a pharmacotherapeutic challenge to the clinician. The adaptations of body constitution, weight, size, as well as physiologic and pharmacokinetic parameters that occur with normal growth and maturation during the first few of months of life are greater than at any other time.[9]

Wide spread irrational usage of antimicrobial agents and their shortage in the government hospital, low purchasing capacity of patients and incidence of antimicrobial resistance complicates the outcome of the therapies.Antibiotics are the most commonly used therapeutics in NICU.[10]

Irrational drug use especially of antimicrobials in pediatric patients has become a commonly noted practice. Although the role of antimicrobial agents is vital, its irrational use often leads to emergence and dissemination of drug resistance strains.[5]

Drug utilization was defined by the world health organization (WHO) in 1997 as the marketing, distribution, prescription and use of drugs in our society, with special emphasis on the resulting medical, social and economic consequences.[11]

Drug utilization studies are potent tentative tools. It describes the extent, nature and determinants of drug exposure.[12] They can be used to identify early signs of irrational drug use and to ascertain the role of drugs in the society.[13] As the fundamental goal of drug utilization study is to assess whether the therapy is rational or not.

METHODS

Source of data and study design

The study is done in Neonatal Intensive Care Unit, Bidar Institute of Medical Sciences, Bidar. It is a Prospective Observational Study done over a period of three months.

Data collection

The data is collection is done by scrutinizing case sheets for 3 months including the following parameters:

- Demographic data.
- Number of drugs used;
- Drug class / category,
- The dose, route, frequency and
- Duration of administration, the criteria for drug selection and individualizing the dose will be recorded.
- The efficacy of the medications will be assessed by the treatment outcome, and
- Safety/tolerability by monitoring and recording any adverse events. Any drug interactions among the study medications will also be recorded. Fluids and electrolyte solutions, parenteral nutrition, nutritional supplements, prophylactic vitamin K, oxygen administration, immunizations, phototherapy and prophylactic ophthalmic treatment, will not be considered for data analysis. In addition any medications received by breast feeding mothers will also be recorded.
- Clinical diagnosis, comorbid conditions and laboratory data.
- Adverse drug reactions, Interactions and its outcome.

Inclusion criteria

- All neonates admitted to NICU, receiving one or more antibiotic.
- Willingness of parents / legal representatives to give written informed consent.

Exclusion criteria

- Neonates not receiving any antibiotic.
- Neonates who are discharged or die within 24hrs of NICU admission.
- Neonates whose parents/guardians are not willing to give consent.
- Neonates who are HIV or HbsAg positive.
- Where sufficient data is not available.

In total 100 neonates are analysed from admitting to discharged and results are expressed as mean ± SD while categorical data are presented as percentage. WHO essential medicine list is referred to check the adherence of drugs used in the NICU.

RESULTS

Total 100 patients are included in the study out of which 55% are male neonates and rest 45% are female babies as shown in Figure 1 and majority of the neonates are less than 2.5 kg as depicted in Figure 2.

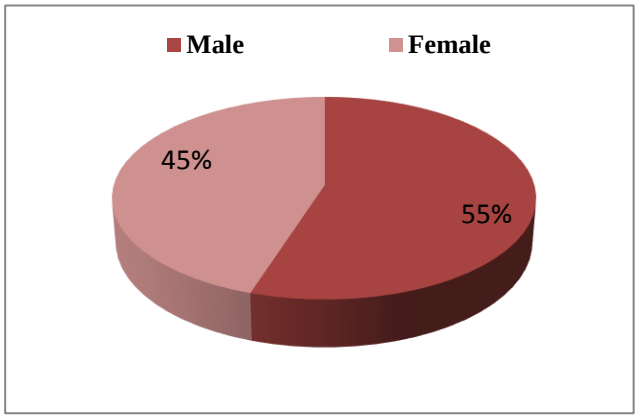

Figure 1: Gender wise distribution.

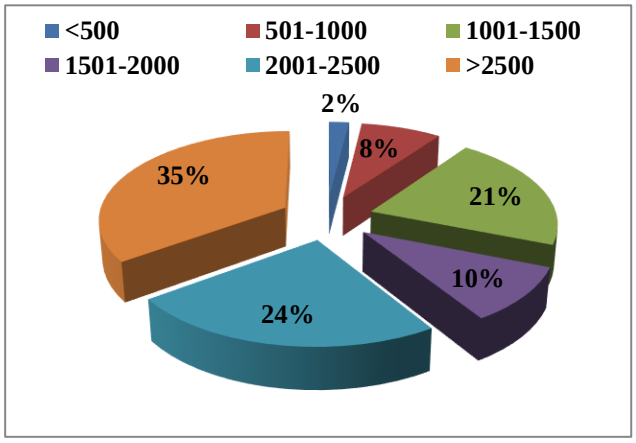

Figure 2: Percentage of neonates according to birth weight.

Table 1: Common drugs used in NICU.

Name	Total
Amikacin	80
Meropenem	50
Metronidazole	56
Piptaz	66
T. Bact ointment	4
Cefixime	101
Ranitidine	10
Aminophylline	10
Calcium gluconate	66
Dopamine	10
Phenytoin	15
Phenobarbital	20

Table 1 shows the drugs used in NICU. The antibiotic cefixime is commonly prescribed.

The reasons for admission of neonates has been depicted in the Table 2. Majority of the neonates were admitted to NICU for septicemia, followed by low birth weight, birth Aaphyxia and meconium aspiration syndrome.

Table 2: Reasons for admission in NICU.

Diagnosis	No. of neonates
Septicemia	52
Birth asphyxia (BA)	18
Meconium aspiration syndrome	20
Others*	10

*Neonatal hyperbiluribinemia, neonatal convulsion

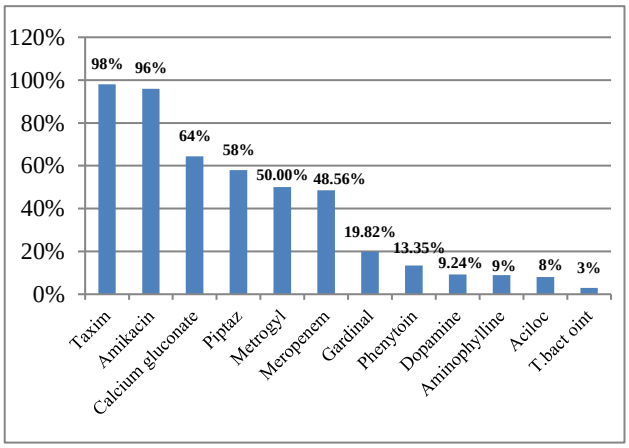

Figure 3: Exposure rates of neonates to drugs.

Table 3: Mean characteristics of neonates.

Characteristics	Value
Mean birth weight	2.2
Mean gestational age	33.4
Mean length stay	10.4

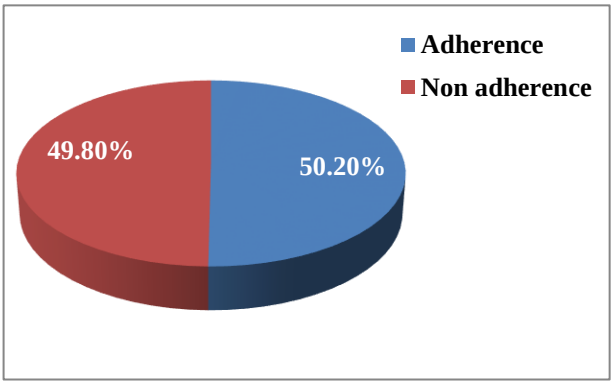

Figure 4: Adherence to WHO EML.

Figure 4 shows the adherence of prescription for EML.

DISCUSSION

The present study is done in neonates admitted to the NICU in BRIMS, Bidar. Total 100 neonates are included

in the study and the results shows male preponderance with 55% male babies and 45% female babies. This study of ours is in accordance with male preponderance in the study conducted by A Afsharapiman et al, and Subhash et al.[14,15]

Table 4: Analysis of prescription.

Particular	Number
Total number of drugs used	488
Percentage of drugs per prescription	4.9%
Drugs prescribed under generic name	44.26%
Drugs prescribed under brand name	55.73%
Fixed dose combinations used	13.2%

But our current study result for gender was found different from Sharanappa et al, where female preponderance (57%) was found.[16]

On observing reasons for admission in NICU, it was noted that septicemia (28%) was the common condition followed by infants with low birth weight (52%). The less common condition was 10% which included neonatal convulsions, neonatal hyperbiluribinemia, refusal to feed and others.

This results are similar to the study conducted by Patel et al, where septicemia is most common cause of admission and in another study conducted by Chryssoula et al, sepsis is found most common reason for admission.[17,18]

But it is not in accordance to study conducted by Sharanappa et al, where common cause for admission is perinatal asphyxia with 48%, followed by 20% of admission due to MAS and 8% of admissions are due to sepsis which is least.[16] It can be explained due to referred cases from outside. Whereas study done in Nepal showed jaundice being the commonest cause followed by sepsis and perinatal asphyxia.[19]

The high rate of antibiotic exposure in our study is similar to studies published in thepast and is probably due to the standard practice of administering antibiotics pending bacterial culture results in sick neonates and is not a true reflection of the incidence of bacterial infection.[19]

In our current study it shows that inj. cefixime is commonly prescribed antibiotic followed by amikacin ijection.

49.80 % of prescribed drugs are listed in WHO essential drug lists.

The selection of antimicrobial agents is rational in about 57% cases of septicaemia. Secondly, in 2 cases alteration of the antibiotic had to be done since the initially prescribed antibiotics were found to be resistant.

Limitations

The limitation of our study was:

1. That data regarding maternal antibiotic management are available in only 20% of the cases and this may have attributed to our inability to evaluate the true impact of exposure to maternal antibiotics.
2. Not all cases get the culture and sensitivity reports.
3. 3 The neonates are not closely observed for any adverse drug reactions.

The usage of intravenous fluids, vitamins and calcium supplementation was also high in this study and all neonates in the NICU were administered vitamin K to prevent haemorrhagic disease of the newborn.

CONCLUSION

In our study most common antibiotic used is inj. cefixime to neonates admitted to NICU. This is evident from the fact that a large proportion of the neonates in this setting were treated due to high risk of sepsis or high index of clinical suspicion without documented bacteriologic evidence of sepsis.

This may reflect the wide variation in the incidence of invasive disease, lack of guidelines supporting a role for prophylaxis and concerns related to the emergence of resistant strains of microorganisms. Furthermore, there is insufficient evidence from randomized trials to support or refute the use of prophylactic antibiotics in neonatal sepsis. In these neonates, in addition to routine microbiological culture, molecular methods used in the diagnosis of microorganism will provide rapid and reliable diagnosis. As a result, the disease must be diagnosed quickly and the routine use of antibiotics would be in place, but microbiological cultures must be the gold standard methods to rule out infection in newborn infants with neonatal sepsis and for the decision whether the use of antibiotics will be continued.

Prescription audit studies can be repeatedly carried out to find out overuse of antimicrobials and nutritional products and to find out causes for over consumption of drugs that are outside the WHO/ National Essential drug list as both the list.

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