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Research Article

Drug utilization study of antimicrobial agents in patients of neonatal sepsis in neonatal intensive care unit at a tertiary care hospital in western part of India

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ABSTRACT

Background: Neonatal sepsis is one of the major causes of death and morbidity among neonates in India; however, studies related to neonatal sepsis are somewhat in limited numbers. Furthermore, time to time sensitivity and efficacy of various antimicrobial agents (AMA) change which necessitates studies related to antimicrobial drug utilization in hospitals. The objective of present study was to evaluate the pattern of use of AMAs in neonatal sepsis at the neonatal intensive care unit (NICU) at a tertiary care hospital in western part of India.
Methods: It was a prospective cross-sectional study conducted over a period of 6-month duration in NICU at tertiary care hospital. Data were collected and analyzed.
Results: It has been observed that 57.67% patients were pre-term, 42.32% full term; 23.28% were of normal birth weight, 58.73% low birth weight and 15.34% were very low birth weight. In 48.7% of patients, two different antibiotics were prescribed while in 40.1% of patients three different antibiotics were prescribed. A total number of antibiotics prescribed were 499, per patient 2.78 antibiotics were prescribed. Amikacin was used in 73.01% cases while cefotaxime was used in 64.55% of cases. Piperacilin + tazobactam combination was used in 41.26% cases. In 50.9% cases, antibiotics were prescribed by generic name.
Conclusion: Antibiotic resistance is increasing due to the irrational prescribing habits of physicians, leading to increasing morbidity, mortality and treatment costs. Therefore, the medical professionals as well as government personnel who are related to the health sector need to understand that antibiotics are precious and finite resources. The remedy of this situation requires that regular educational awareness programs should be conducted in hospitals at a regular basis.

Keywords: Antimicrobial agents, Drug utilization, Infections, Neonates

INTRODUCTION

Drug utilization research was defined[1] by the WHO in 1977 as "the marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social and economic consequences."

The principle aim of the drug utilization research is to facilitate rationale use of drugs in populations. For the individual patients, rationale use of a drug implies the prescription of a well-documented drug in an optimal dose for a right indication, with the correct information and at an affordable price.[1]

Without knowledge on how drug are being prescribed and used, it is difficult to initiate discussion on rationale drug use and to suggest measure to change prescribing habits for the better management. Information on the past performance of prescribers is the linchpin of any auditing system.[2]

Drug utilization study is the main component of the drug utilization research.

Drug utilization study may generate hypotheses that set the agenda for further investigations by:

- Comparing drug utilization patterns and costs between

different regions or time periods. Hypotheses can be generated to form the basis for investigations of the reasons for, and health implications of, the differences found. Geographical differences and changes over time in drug use may have medical, social and economic implications both for the individual patient and for society, and are thus important to identify, explain and sometimes to correct

- Comparing observed patterns of drug use with current recommendations/guidelines for the treatment of a certain disease. Hypotheses can then be generated about whether discrepancies represent less than optimal practice, whether pedagogic interventions (education) are required, or whether the guidelines need to be reviewed in the light of actual practice. These considerations should include both underuse and overuse of drugs.

Neonatal sepsis is defined as a clinical syndrome of bacteremia with systemic signs and symptoms of infection in the first 4 weeks of life. When pathogenic bacteria gain access to the bloodstream, they may cause overwhelming infection without much localization (septicemia) or may get predominantly localized to the lung (pneumonia) or the meninges (meningitis).[3]

The incidence of neonatal sepsis[4] according to the National Neonatal Perinatal Database is 30 per 1000 live births. The database 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. Septicemia was the commonest clinical category with an incidence of 23 per 1000 live births while the incidence of meningitis was reported to be 3 per 1000 live births. *Klebsiella pneumoniae* was the most frequent isolated pathogen in intramural setting (32.5%) and extramural setting (27%), followed by *Staphylococcus aureus* (in intramural-13.6% and in extramural - 15%) and *Pseudomonas* in extramural setting (13%).

Neonatal sepsis requires urgent and specific antimicrobial treatment depending upon the causative organism and their sensitivity pattern, however it has been observed that the etiological agents and their sensitivity toward antimicrobial agents (AMA) keep on changing over a period of time, so for optimum management of neonatal sepsis we need data of all these important variables which can be provided by drug utilization studies.

Most of reported drug utilization studies have been carried out in adults patient with only a few being reported from pediatric and neonatal patients.[5] Furthermore to optimize therapy in accordance to the changing pattern of the causative organisms and their sensitivity toward various AMAs in neonatal sepsis, it is necessary to conduct such studies.

Sepsis-related mortality is largely preventable with rational antimicrobial therapy and aggressive supportive care which can be achieved by measures taken according to data from such kind of studies.

There are various aspects of drug utilization study,[1] however this study was limited to prescribing pattern, culture and sensitivity patterns of causative organisms and outcome of AMAs.

This study will provide us some important data regarding antimicrobial use, its outcome and culture and sensitivity patterns of causative organisms in patients of neonatal sepsis which will help us to intensify or modify the treatment policies if necessary. Furthermore, this study was conducted in a tertiary care hospital in Western India; it may help for conducting large multi-centric studies in future.

METHODS

This study was conducted in the neonatal intensive care unit (NICU) at Sir Sayajirao Gaekwad Hospital, Vadodara, which is tertiary care hospital.

Study design

It was a prospective cross-sectional observational and single center study for 6 months in NICU at SSG Hospital, Vadodara which is a tertiary care hospital located in western part of India.

The setup of NICU in SSG Hospital has been organized as two separate divisions; one is intramural NICU where babies born in SSG Hospital itself are kept while the second extramural NICU where babies referred from other healthcare institutes are kept. Our study included patients of neonatal sepsis from both divisions.

Sample size and study population

The study population included neonates (0-4 weeks) admitted to NICU at SSG Hospital, suspected/diagnosed as having neonatal sepsis.

The study population included was 189 cases of neonatal sepsis.

Data collection

- Period of data collection:
  It was for 6 months, starting from April 1st to September 31st 2013.
- Inclusion criteria:
  a. All patients (0-4 weeks of age) of suspected/diagnosed neonatal sepsis of either sex admitted to NICU after starting date of the study
  b. Only the patients where their parents gave informed consent were enrolled in this study.

- Exclusion criteria:
  a. Where parents of the septic neonates were not willing to participate in the study
  b. Patients aged more than 4 weeks.
- Informed consent: Informed consent was taken from the parents of the neonates having suspected/diagnosed as neonatal sepsis before enrolment.

Study method

Prior permissions were taken from the Head and Professor of the Department of Paediatrics, SSG Hospital, Vadodara and Head of the study unit.

The NICU was visited daily, and it was made sure that appropriate patients were selected and enrolled according to inclusion and exclusion criteria. Patients were followed until discharge from the NICU centers.

Data were collected from indoor case papers as well as directly consulting to the attending pediatrician and parents of neonates, and recorded on a pre-structured case reporting form.

Maternal data were taken from mothers' file whenever available.

Data analysis

Data were recorded on Microsoft excel sheet 2007.

Average number of antimicrobials prescribed per patient and average duration of the hospital stay were calculated by using mean and standard deviation. Other statistical tools were used wherever necessary.

The generic name of the drugs and contents of the formulations were obtained from the Indian Review January-February (Dr. Sanjiv Malik, 2013) and Current Index of Medical Specialities January-April 2013 (Venkatraman, 2013).

Antimicrobial use pattern were analyzed as per following parameters:

- Name and group of the AMAs
- Brand name/generic name of the AMAs
- Dose of the AMAs
- Frequency of the administration
- Route of administration
- Duration of the treatment
- Changes done in the therapy according to culture and sensitivity reports where culture is positive.

RESULTS

In the present study, data of 189 patients of neonatal sepsis admitted to NICU, at Sir Sayajirao General Hospital, Vadodara, a tertiary care teaching hospital attached to Medical College, Vadodara (Baroda) were collected and analyzed as demographic data such as age, gender, and diagnosis including culture reports and antimicrobial sensitivity pattern, antimicrobial therapy including prescribing pattern, duration of NICU stay and outcome.

Among 189 patients recruited, 139 patients (73.93%) were from early neonatal age group while 50 patients (26.45%) were from late neonatal age group, at the time of admission.

Total 80 patients (42.32%) were pre-terms while 109 patients (57.67%) were full terms meaning that they were born before 37 weeks and after 37 weeks of pregnancy, respectively. Out of 189 patients, 119 (62.96%) were males; while 70 (37.03%) were females. In 119 male patients and considering it as 100%, 49 patients (41.18%) were born pre-term while 70 (58.82%) patients were born full term. In 70 female patients recruited and considering it as 100%, 31 (44.29%) were delivered pre-term, and 39 (55.71%) were delivered full term.

Among the septic neonates, birth weight and maturity wise distribution were observed which have been shown in Table 1.

Average weight of patient was 2068.2±559 g.

Table 2 shows sepsis and maturity wise distribution.

Table 1: Birth weight and maturity wise distribution.

Category	Number of neonates	Percentage
Normal (>2500 g)	44 (pre-term - 0) (full term - 44)	23.28 (pre-term - 0) (full term - 23.28)
Low birth weight (1500-2499 g)	111 (pre-term - 46) (full term - 65)	58.73 (pre-term - 24.33) (full term - 34.39)
Very low birth weight (1000-1499 g)	29 (pre-term - 29) (full term - 0)	15.34 (pre-term-15.34) (full term-0)
Extreme low birth weight (<1000 g)	1 (pre-term - 1)	0.5 (pre-term - 0.5)
Weight not known	4	1.59
Total	189	100

Table 2: Pattern of sepsis and maturity wise distribution.

Sepsis	Maturity (n (%))		Total n (%)
	Pre-term	Full term	
Early onset sepsis	67 (55.37)	54 (44.63)	121 (64.02)
Late onset sepsis	13 (19.12)	55 (80.88)	68 (35.98)
Total	70	109	189

Among all the patients included in the study, it was evident that among all the patients included in the study, the most frequent observed comorbidity was prematurity in 80 patients (42.30%) and others followed. These data have been shown in Table 3 and Figure 1.

Number of antimicrobials prescribed to a patient during the course of the therapy ranged from 2 to 5, highest number of patients, i.e. 92 (48.67%) received 2 antimicrobials, which was followed by 77 patients (40.07%) receiving 3 antimicrobials, 17 patients (8.99%) receiving 4 antimicrobials and 3 patients (1.5%) receiving 5 antimicrobials during the course of therapy (Table 4 and Figure 2).

In 189 patients, 499 times antimicrobials were prescribe and the mean of antimicrobial prescribed was 2.78.

Out of total 499 times antimicrobials were prescribed, 254 times (50.9%) antimicrobials were prescribed by generic name and remaining (49.1%) were prescribed by brand name.

Results showed that for neonatal sepsis, most frequent prescribed antimicrobials were amikacin, cefotaxime, and piperacillin + tazobactam combination. Least prescribed antimicrobials were levofloxacin and metronidazole (Figure 3).

This study showed that most number (%) of the neonates were exposed to amikacin, cefotaxime, and piperacilllin + tazobactam combination; while least percentage of neonates were exposed to levofloxacin in 2 patients (1.1%) and metronidazole in 1 patient (0.53%) (Table 5 and Figure 4).

In this study, duration of hospital stay per patient was recorded to be 12.07±7.26 days.

In the study, it was observed that percentage of antimicrobials prescribed from national list of essential medicine was 36.87%.

In this study, we observed that all the antimicrobials during this study were given at 12 hourly and via intravenous route.

However in this study, no drug was able to reach the DU 90% parameter.

During the course of therapy, in 53.44% of patients it was seen that antimicrobials were either changed or new antimicrobials

Table 3: Pattern of comorbid condition.

Co-morbidity	Number of times observed	Percentage of total patients (189 patients)
Prematurity	80	42.30
RDS	26	13.76
Birth asphyxia	18	9.52
Neonatal jaundice	11	5.82
Congenital anomaly	10	5.29
MAS	7	3.70
HIE	4	2.11
HMD	2	1.06
Multiple gestation	2	1.06
Convulsions	1	0.5
Total	161	

RDS: Respiratory distress syndrome, HMD: Hyaline membrane disease, MAS: Meconium aspiration syndrome, HIE: Hypoxic ischemic encephalopathy

Table 4: Number of antimicrobials prescribed.

Number of antimicrobials	Number of encounters in neonates	Percentage
0	0	0
1	0	0
2	92	48.67
3	77	40.07
4	17	8.99
5	3	1.5

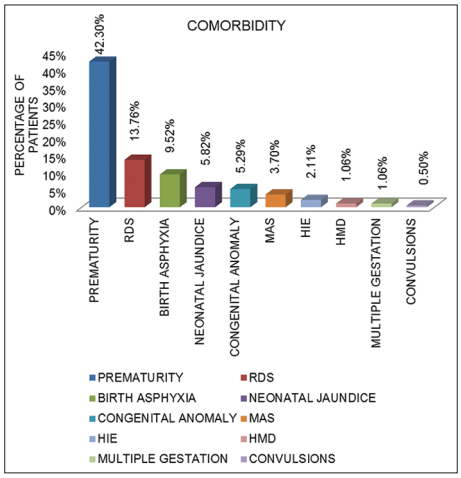

Figure 1: Pattern of comorbid condition.

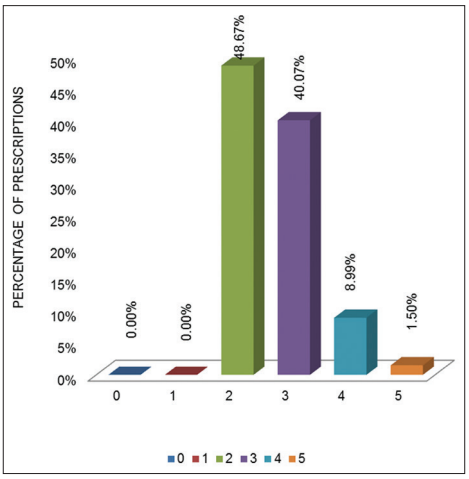

Figure 2: Number of antimicrobials prescribed.

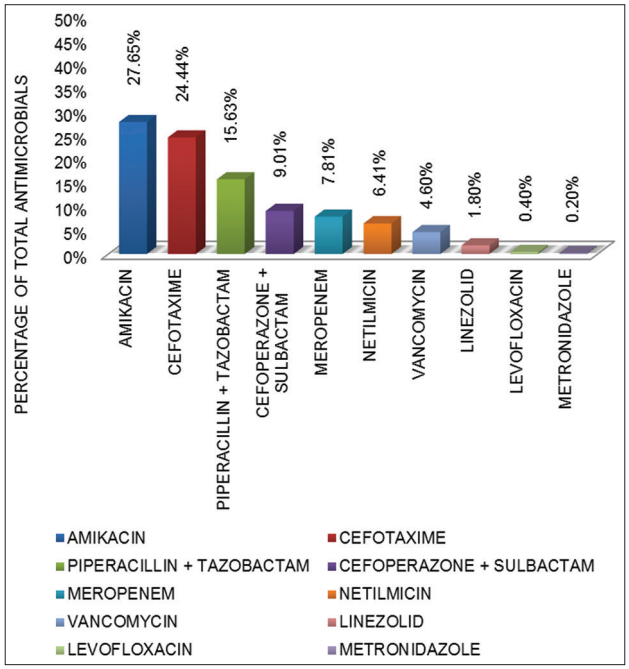

Figure 3: Frequency of individual antimicrobial prescribed.

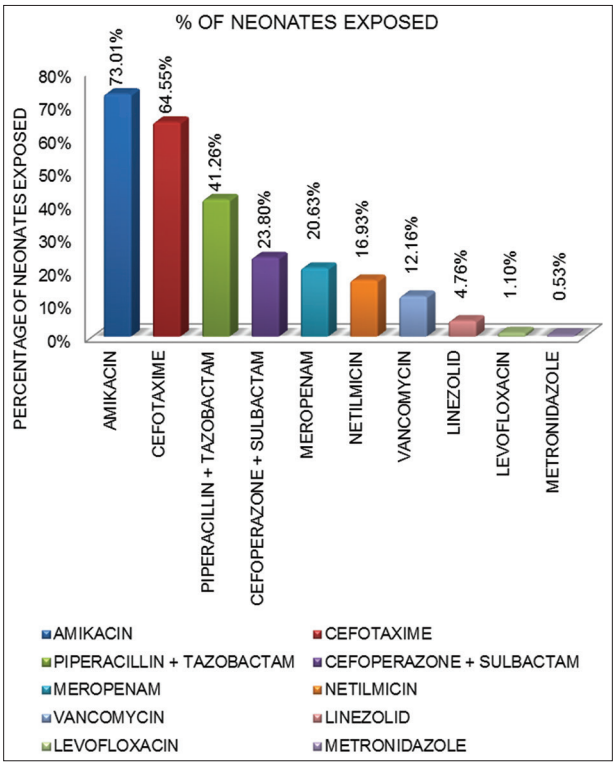

Figure 4: Percentage of neonates exposed to the individual antimicrobial.

were added to the prescription. In 74 prescriptions (39.15%) antimicrobials were changed according to culture sensitivity reports while in 27 prescriptions (14.29%), changes were done without any culture positive reports.

The outcomes of treatment of the condition have been mentioned in Table 6 and Figure 5.

Table 5: Frequency of individual antimicrobial prescribed percentage of neonates exposed to individual antimicrobials.

AMA	Number of times prescribed	Percentage of total antimicrobials	Percentage of neonates exposed
Amikacin	138	27.65	73.01
Cefotaxime	122	24.44	64.55
Piperacillin+ tazobactam	78	15.63	41.26
Cefoperazone+ sulbactam	45	9.01	23.80
Netilmicin	42	8.41	16.93
Meropenem	39	7.81	20.63
Vancomycin	23	4.60	12.16
Linezolid	9	1.80	4.76
Levofloxacin	2	0.40	1.1
Metronidazole	1	0.20	0.53
Total	499	100 (n=499)	(n=189)

AMA: Antimicrobial agents

Table 6: Outcome of antimicrobial therapy.

Outcome	Number of neonates	Percentage
Discharged	110	58.20
Referred	0	0
DAMA	33	17.46
Absconded	12	6.34
Death	43	22.75
Not known	1	0.5
Total	189	100

DAMA: Discharge against medical advice

DISCUSSION

Septicemia is one the major causes of morbidity and mortality in the neonatal period, and it often has a rapid and fulminant course. The database comprising 18 tertiary care neonatal units across India found sepsis to be one of the commonest causes of neonatal mortality contributing to 19% of all neonatal deaths.[4]

Neonatal sepsis requires urgent and specific antimicrobial treatment depending on the causative organism and their sensitivity pattern, however it has been observed that the etiological agents and their sensitivity towards AMAs keep on changing over a period of time, so for optimum management of neonatal sepsis we need data of all these important variables, which can be provided via drug utilization study.

In the present study, we collected data of 189 neonates admitted to NICU, at Sir Sayajirao General Hospital, a tertiary care teaching hospital attached to Medical College, Baroda (Vadodara). Data of the neonates such as age, gender,

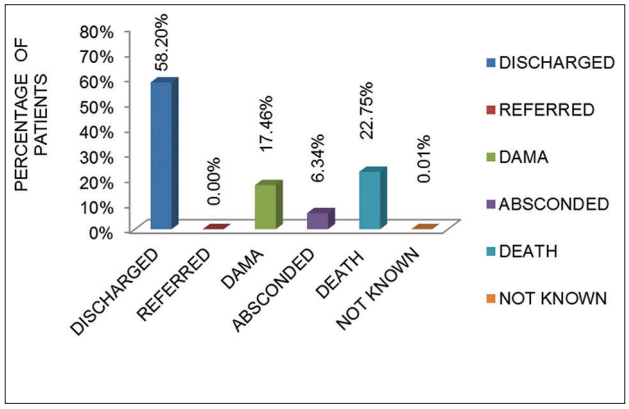

Figure 5: Outcome of antimicrobial therapy.

diagnosis including culture reports, and antimicrobial sensitivity pattern, drug therapy, duration of NICU stay and outcome of patients were collected and analyzed.

In this study, among the 189 patients of neonatal sepsis 73.93% of patients admitted were from early neonatal age group while 26.45% were of late neonatal age group.

In present study, among the patients, 119 (62.96%) were males while 70 (37.03%) were females. This is in contrast to the studies of Kumar et al.[6] and Neubert et al.[7] who reported 57% and 55.7% of admission of male neonates, respectively.

This study showed that out of 189 patients admitted, 42.32% patients were pre-terms and 57.67% were full terms, while Neubert et al. (2009)[7] have reported admission of 69% preterm infants. Results in our study are not similar to the findings of previous studies.[8-10] Another study done by Shrestha et al.[11] showed that number of pre-term neonates admitted were 33%.

The reasons for the lower admission rate of pre-term in this study may be better postnatal care in pre-terms and different rate of admission to our hospital as compared to others.

This study showed that majority of the patient (58.73%) had low birth weight. Mean birth weight of patient was 2068.2±559 g. This is in accordance to the studies done by Uppal et al.[9] who reported mean birth weight of 2250±96.8 g while Warrier et al.[8] reported mean birth weight of 2498±1000 g.

In the present study, early onset sepsis was encountered in 64.02% of patients and late onset sepsis was observed in 35.97% patients which may be because of the fact that during early neonatal age neonates are more vulnerable to infection. Furthermore, prematurity is a major cause of low birth weight in preterm babies and these two factors, i.e. prematurity and low birth weight may be responsible for higher chances of infection.

In this study, the most frequent encountered comorbid condition was prematurity (42.30 %) followed by respiratory distress syndrome (13.76%) and birth asphyxia (9.52%). These conditions may significantly affect outcome of the neonate.

In this study, medicines were prescribed by generic name in 50.9% of cases. Almost half of the drugs were prescribed by brand name which unnecessarily adds to the cost of therapy. Increasing generic prescribing would rationalize the use and reduce the cost of drugs.[12]

Percentage of drugs prescribed from National List of Essential Medicine (India) was 36.87%. However, more drugs should be prescribed from the essential medicine list.

Essential medicine list usually includes drugs which are routinely prescribed in the community, while in neonatal sepsis many broad spectrum, as well as new and potent antimicrobials are used which may not belong to the list. This may be because many of the antimicrobials in the national list of essential medicines are not effective against main causative organisms of neonatal sepsis or maybe these organisms are resistant to these drugs. So pediatricians usually prefer to prescribe newer and broad spectrum antimicrobials in neonatal sepsis. This may be the reason for observation that lower percentage of antimicrobials from National List of Essential Medicine were prescribed in our study.

In this study, all neonates received drugs via parenteral (intravenous) route. This result complies with prospective study done by Chatterjee et al.[13] who reported 92.1% of drugs were given by parenteral route. Use of oral route in neonates is usually not preferred as in neonatal sepsis faster onset of action is usually needed and in neonates oral administration is difficult.

Out of total patients of neonatal sepsis, we observed that majority of the patients were given either 2 (48.67%) or 3 (40.07%) antimicrobials.

We observed that during the study period most frequent prescribed antimicrobials were amikacin in 27.65% of patients, cefotaxime in 24.44% of patients and piperacillin + tazobactam combination in 15.63% of patients.

It is generally established that combination therapy of penicillin/cephalosporin and aminoglycoside is effective. Due to emerging resistance to ampicillin, cephalosporin and aminoglycoside combination is recommended as first-line therapy.[14] This is evident from our study too, where cefotaxime and amikacin were used as first-line therapy.

From the previous studies done by Italian collaborative study group (1988)[8] and Lesko et al.,[15] it was concluded that penicillins and aminoglycosides were the most commonly used antibiotics. Ampicillin and gentamicin were commonly prescribed antibiotics in a study done by Clark et al.[10]

As per this study, it can be seen that majority of the neonates were exposed to amikacin in 73.01% of patients, followed by cefotaxime 64.55% patients, and piperacilllin + tazobactam combination in 41.26% of patients. Number of neonates exposed to ampicillin and cefotaxime were highest in study done by Warrier et al.[8] The results in our study reflect the fact that in our hospital, the first line empirical therapy for neonatal sepsis includes cefotaxime and amikacin. When a patients of neonatal sepsis is admitted to NICU in our hospital depending on the clinical status of the patient these two drugs are started in majority of cases. These results in higher percentage of neonatal exposure to these two drugs.

In this study, none of the antimicrobial was able to reach the DU 90% criteria for drug utilization. In our hospital despite cefotaxime and amikacin being the first line therapy, many times other broad spectrum and newer antimicrobials are prescribes according to status of the patients at the time of the admission and later because the presentation of neonatal sepsis is variable in terms of microbial pattern and clinical condition, which needs various antimicrobials to be prescribed. These may be the reason for the inability of any AMA to reach DU 90% parameter.

In the present study, out of the total patients recruited, 58.20% were declared cured and discharged while 22.75% patients died. The mortality rate was higher as compared to study done by Mhada et al.,[16] in which mortality rate was 15%.

In this study average duration of hospital stay per patient was 12.07±7.26 days. In previous studies, mean duration of stay in NICU was 17±16.4 days and 21.1±24.8 days respectively.[6,9] Results in our study may reflect appropriate antimicrobial prescriptions in our NICU or earlier discharge of patients as compared to other studies as undue prolongation of hospitalization may itself increases chances of nosocomial infection in neonates.

CONCLUSION

1. Drug utilization studies are powerful exploratory tools to ascertain the role of drugs in society and create sound socio-medical and health economic basis for health care decision-making
2. Scant information is available regarding the extent and pattern of Antimicrobial drug use in NICU. As pediatric patients are not simply small adults, there is a great need to study the drug utilization pattern
3. The present study was carried out in Sir Sayajirao hospital for 6 months and 189 patients of the neonatal sepsis were included with the objective of analyzing prescription pattern of AMAs and culture and sensitivity patterns in patients of neonatal sepsis
4. Early onset sepsis was more commonly observed, almost 2/3 of the total patients
5. Majority of the patients received either two or three antimicrobials during the course of therapy
6. Average number of antimicrobials prescribed per patients was 2.78
7. Just half of the antimicrobials were prescribed by generic names
8. Antimicrobials prescribed from National List of Essential Medicine were 36.87 % of the total antimicrobials prescribed
9. Most commonly prescribed antimicrobials were amikacin and cefotaxime
10. During course of the therapy antimicrobials were changed in almost half of the total patients
11. In outcome, 58.20 % patients were discharged but mortality rate was bit higher
12. Limitations of current study were shorter duration of study and study was conducted in single center only.

Despite the above limitations, our study fulfilled the desired objectives as:

a. We were able to find out overall pattern of drug use profile in a tertiary care NICU
b. This study is intended to be a step in the broader evaluation of antimicrobials prescribed in NICUs at different hospitals.

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Ethical approval: Prior permissions were taken from the Head and Professor of the Department of Paediatrics, SSG Hospital, Vadodara and Head of the study unit. Necessary ethical permission was taken from Institutional Ethics Committee

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