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Drug utilization study in the management of acute diarrhoea in the Paediatrics department at a tertiary health care institution

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ABSTRACT

To evaluate the drug utilization pattern and to assess the use of zinc in the management of acute diarrhoea in the Paediatrics department at a tertiary health care institution.This was a Prospective hospital based study which was carried out in the Paediatrics Department at Gauhati Medical College and Hospital, Guwahati after obtaining permission from the Institutional Human Ethics Committee. About 80 prescriptions were analyzed during the study period of 6 months. All the patients of either sex (male/ Female) between 0-5years age who were coming to the Paediatrics department (outdoor and indoor) suffering from any type of diarrhoea and was prescribed different drugs were included in the study. Patients coming to the Paediatrics department not suffering from diarrhoea were excluded from our study.Out of 96 inpatients, 84 patients were admitted, cured and discharged, while 12 patients were seen as outdoor patient and were not admitted. No complication, deaths or ADR were reported during the hospital stay. Out of these, majority 51 (53.1%) were females. The mean age of the patients was 1.92 years. Most patients (59.4%) were between 1-3years of age. Majority 62.5% were suffered from acute watery diarrhea. Out of 96 patients, 33 (34.4%), 54 (56.2 %) and 9 (9.4%) were diagnosed with no, some and severe dehydration, respectively. No reports on routine examination and culture of stool were obtained. A total 312 drugs were prescribed in these inpatients. Out of the various drugs prescribed, 93 patients (96.9%) were prescribed rehydration fluids like ORS, 81 patients (84.4%) were given intravenous fluids. Other frequently prescribed drugs were Zinc to 96 patients (100 %) followed by antimicrobials in 39 patients (40.6%) and probiotics in only 3 patient (3.1%).Only Two different antimicrobials were prescribed; among these ceftriaxone (30) was the most prescribed followed by metronidazole (9).Out of the 312 formulations prescribed, 102 (32.7%) were oral formulations and 210 (67.3%) were intravenous injections. The mean number of drugs prescribed per patient was 3.25 (range 1 to 4). Regarding utilization of zinc preparations; they were prescribed in 100 % inpatients as monotherapy (mostly zinc gluconate) regardless of any age or any type of diarrhoea. The findings of this study suggested that there is a relatively rational approach to oral and parenteral rehydration therapy, antimicrobials and FDC.

Keywords: Acute diarrhoea, paediatrics, zinc

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INTRODUCTION

Children represent about 40% of India's population. Most suffer from frequent, usually self limiting illnesses. Drug use in children has not been as extensively researched as in adults. It has been observed that 18.2% of children take drugs that are not required.[9] Respiratory tract and gastrointestinal tract are the common sites for infections in children.

Diarrhoea is defined by the World Health Organization as having three or more loose or liquid stools per day, or as having more stools than is normal for that person.[1]Acute diarrhoea is defined as an abnormally frequent discharge of semisolid or fluid faecal matter from the bowel, lasting less than 14 days, by World Gastroenterology Organization.[2]

The most common cause is an infection of the intestines due to a virus, bacteria, or parasite; a condition known as gastroenteritis which are acquired from contaminated food or water or directly from another infected person.[3]

It may be divided into three types: acute watery diarrhoea (duration <1 week), diarrhoea with blood and mucus (dysentery), and if it lasts for more than two weeks, persistent diarrhoea.[4]

It causes dehydration due to fluid loss of body fluid and electrolyte. This can progress to decreased urination, loss of skin colour, a fast heart rate, and a decrease in responsiveness as it becomes more severe.[5]

In most cases of diarrhoea, replacing lost fluid and salts is the only treatment needed. This is usually by mouth, oral rehydration therapy or in severe cases, intravenously. While antibiotics are beneficial in certain types of acute diarrhoea, they are usually not used except in specific situations because of antibiotic resistance and antibiotic associated diarrhoea.[7] Zinc supplement benefits children with diarrhoea in developing countries.[6] Probiotics reduces the duration of symptoms and can prevent antibiotic associated diarrhoea in adults but possibly not children.[8]

So the present study has been taken to analyse the rational use of different group of drugs in different types of diarrhoea in children and to assess the extent of use of zinc in correct formulation in acute diarrhoea.

Aims and objectives:

- To evaluate the drug utilization pattern in the management of acute diarrhoea in the Paediatrics department at a tertiary health care institution.
- To assess the use of zinc in the management of acute diarrhoea in the Paediatrics department at a tertiary health care institution.

MATERIALS AND METHOD

This was a Prospective hospital based study which was carried out in the Paediatrics Department at Gauhati Medical College and Hospital, Guwahati after obtaining permission

from the Institutional Human Ethics Committee. About 80 prescriptions were analyzed during the study period of 6 months. All the patients of either sex (male/ Female) between 0-5years age who were coming to the Paediatrics department (outdoor and indoor) suffering from any type of diarrhoea and was prescribed different drugs were included in the study. Patients coming to the Paediatrics department not suffering from diarrhoea were excluded from our study.

Data analysis

The overall information generated was analyzed and presented using appropriate statistical method under the following headings:

PROFORMA I

Prescription Pattern

Sl. No.	Age of the patient	Sex of the patient	Type of diarrhoea	Formulation of drugs prescribed	Category of drugs prescribed	Frequency of drugs

Along with the above parameters we also analysed the **most common group of antibiotic.**

Assessment of Use of Zinc

Sl.no.	Age of the patient	Indication	Zinc prescribed or not	Pattern of prescription (monotherapy /combination)

Proforma II

I. NAME: HOSP.NO:

II. AGE: OPD NO:

III. SEX: INDOOR PATIENT REG.NO:

MRD NO:

IV. HISTORY :

1. H/O diarrhoea- yes/no
2. Duration- <14 days/ >14 days
3. Character of stool- watery(bacillary) / semisolid(amoebic)
4. Presence of blood and mucus- yes/no
5. Other symptoms- yes/no

(fever, pain abdomen)

V. EXAMINATION: **1. STATUS OF DEHYDRATION:**

- SEVERE DEHYDRATION
  - lethargic and unconsciousness
  - Sunken eyes
  - Skin pinch goes back very slowly
- SOME DEHYDRATION
  - Restless/irritable
  - Sunken eyes
  - Drinks eagerly
  - Skin pinch goes back very slowly
- NO SIGNS OF DEHYDRATION

2. EXAMINATION OF

*ABDOMEN *CVS * CNS *RESPIRATORY

VI. DIAGNOSIS: (Investigation in selected cases)

- Stool R/E and C/S
- TLC, DLC, Hb%
- S. Na^+, K^+
- S. Creatinine

VII. DRUGS:

- ORS/ IV fluid
- Zinc
- Antibiotics in specific cases
- Probiotics
- Diet

RESULTS AND OBSERVATION

A total of 96 patients of diarrhoea were enrolled over the period of 6 months. Out of 96 inpatients, 84 patients were admitted, cured and discharged, while 12 patients were seen as outdoor patient and were not admitted. No complication, deaths or ADR were reported during the hospital stay.

Out of these, 51 (53.1%) were females and 45 (46.9 %) were males (female to male ratio was 1.13: 1) .The mean age of the patients was 1.92 years with a range of 1m to 5years. Most patients (59.4%) were between 1year to 3years of age. Out of 96 patients, 62.5% suffered from acute watery diarrhea, 28.1 % suffer from bacillary dysentery (acute bloody diarrhea) and only 9.4% suffered from amoebic dysentery. 6 patients with bacillary dysentery came

with complication like convulsion and maculopapular rash. Out of 96 patients, 33 (34.4%), 54 (56.2 %) and 9 (9.4%) were diagnosed with no, some and severe dehydration, respectively. No reports on routine examination and culture of stool were obtained. The average duration of diarrhoea varies from 1 day to less than 14 days. **(Table 1)**

A total 312 drugs were prescribed in these inpatients. Out of the various drugs prescribed, 93 patients (96.9%) were prescribed rehydration fluids like ORS, 81 patients (84.4%) were given intravenous fluids. Other frequently prescribed drugs were Zinc to 96 patients (100 %) followed by antimicrobials in 39 patients (40.6%) and probiotics in only 3 patient (3.1%).Only Two different antimicrobials were prescribed; among these ceftriaxone (30) was the most prescribed followed by metronidazole (9). [Figure 1]

Out of the 312 formulations prescribed, 102 (32.7%) were oral formulations and 210 (67.3%) were intravenous injections. [Figure 2]

The rationality of the prescriptions was also evaluated in reference to the WHO core indicators. The mean number of drugs prescribed per patient was 3.25 (range 1 to 4). 43.8 % patients were prescribed 4 drugs. [Figure 3]

A total of 93(29.8%) out of 312 drugs were prescribed as fixed dose combinations (FDCs) which include ORS and is a rational FDC. The doses and frequency of all the intravenous rehydration fluids and oral rehydration fluids were appropriate and as per the IAP guidelines. Antimicrobials were prescribed to only 39 patients (40.6%) and they received only 1 antimicrobial during their hospital stay.

Regarding utilization of zinc preparations, they were prescribed in 100 % inpatients as monotherapy (mostly zinc gluconate) regardless of any age or any type of diarrhoea. All 96 prescriptions of zinc salts were considered as rational as per IAP and WHO guidelines.

Table 1: Demographic and Clinical characteristics of pediatric patients with diarrhoea (*n* = 96)

Patient characteristics	No. of patients (%)
Gender	45 (46.9 %)
Male	51 (53.1%)
Female	
Age	30(31.3%)
>1 month to ≤ 1 year	57(59.4%)
>1 year to ≤ 3 years	9(9.3%)
>3 years to ≤ 5 years	
Indication	60(62.5%)
Acute watery diarrhoea	27(28.1%)
Acute bacillary dysentery	9(9.8%)
Amoebic dysentery	
Status of dehydration	
No dehydration	33(34.4%)
Some dehydration	54(56.2%)

Severe dehydration	9(9.4%)

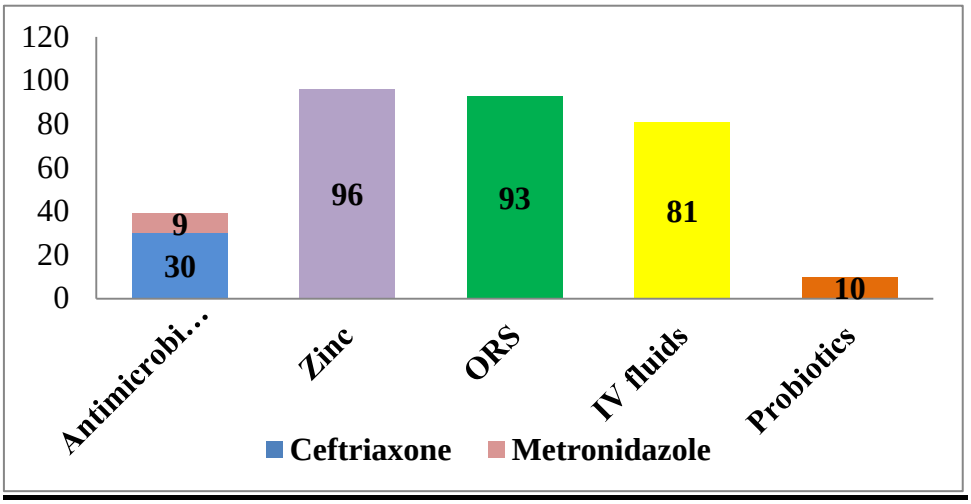

Figure 1- Distribution of Drugs In Patients (n=96)

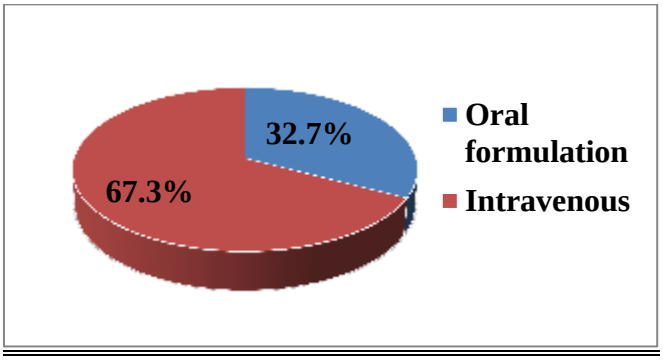

Figure 2- Routes of Administration

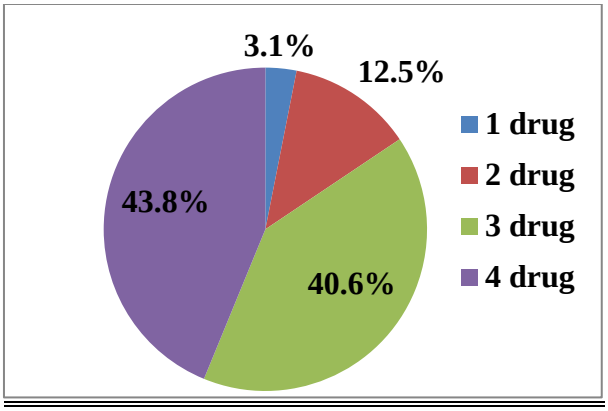

Figure 3:No. of drugs per prescription (%)

DISCUSSION

Each year, an estimated 2.5 billion cases of diarrhoea occur in children under five years of age and 12 million of them die in developing countries.[10] The WHO and Indian Academy of Pediatrics have recommended guidelines for its treatment emphasizing early rehydration therapy and restrictions on use of drugs like antimicrobials and anti-diarrhoeals. In spite of guidelines, misuse of drugs like antimicrobials, anti-diarrhoeal etc. has been observed in various studies hence, the present study was undertaken to analyze drug use pattern in

diarrhoea patient in our set up among pediatric age group and to suggest some measures to prevent misuse.

It was observed that majority of the patients were females and between one year and 3 years of age, which was different from seen in a study conducted in Chennai[11] the Leeds study[12] and the USA study[13].The possibility of infection by faeco-oral route is more likely during this period because of improper and unhygienic feeding practices. Further, while maternal antibodies are declining over this period, the child is yet to develop its own defenses against infections.[14] While the predominance of diarrhoea in female children cannot be explained, it is assumed that the female children were more ignored when dealing with nutrition and also regarding hygiene practice and hence likely to be brought to the hospital for treatment than the males. This is an unfortunate but common practice in India.

The inpatients in this study were followed up till discharge from hospital. The average number of drugs/injections per encounter is an important index in prescribing practices.[16]The values in our study are higher than the recommended limit of two drugs per encounter and the international average of 2.2 drugs per prescription.[17] Polypharmacy was evident in the study as in 84% of inpatients; 3-4 drugs were concomitantly prescribed. A cluster survey conducted in under-five children of acute diarrhoea at Bangladesh found that the average number of drugs prescribed per patient was 1.5; a figure much lower than that found in our study[18] while a Nepal study[15]found that the average number of drugs per pediatric inpatient was 4.5. Hence, it is evident that the practice of polypharmacy is prevalent in our setup; thereby suggesting irrational prescribing practice in this regard. Polypharmacy practice is well known to be associated with drug related adverse drug reactions, medication errors, clinically significant drug interactions and an increased rate of admissions to hospital. The reasons for this practice could range from lack of accuracy/confidence in diagnosis or lack of awareness of the various treatment guidelines and needs further evaluation.

A total 312 drugs were prescribed in 96 patients. Zinc, rehydration fluids and antimicrobials were the most commonly prescribed drug groups. No anti-diarrhoeals agents were prescribed to these patients. The average number of antimicrobials prescribed per inpatient in our study was 1. When compared with other studies conducted in central Thailand[19] and Chennai[11], it was observed that antimicrobials were prescribed significantly less in our study. Zinc salts were prescribed more often in our study as compared to that reported in the Chennai study. Ceftriaxone was the most commonly used antimicrobial followed by metronidazole. The use of antimicrobials was significantly lower in our study than in other studies mentioned above. Zinc mostly as zinc gluconate was prescribed in 100% inpatients which was better than the Chennai study (65%). A questionnaire based national survey found that 16.9% of prescribers

prescribe zinc supplements for treatment of diarrhoea.[20] Zinc supplements are recommended in patients of diarrhoea because it reduces the severity and frequency of diarrhoea.

Certain good prescribing practices have been observed in our study. For example, around 29.8% drugs which were used as FDCs like ORS in patients are included in EML (National and WHO) and there is no irrational FDC prescribed in our study. A study conducted in pediatric inpatients at a tertiary care hospital in Nepal found that FDCs constituted 6.9% of all drug used.[15] Prescription of single drug formulations instead of FDCs may make better prescribing sense in terms of cost and safety. Generic prescribing and use of essential medicines are important parameters to evaluate the rational use of medicines (RUM). It was observed in this study that all the drugs in indoor patients were prescribed by their generic names. Our study fares similar or better than other studies, in this regard. This is attributed to the fact that most drugs supplied by hospital pharmacy are generic products, which are likely to be chosen by prescribers. This practice suggests there is no gap in communication between the hospital pharmacists and the prescribers regarding the list of available drugs. Essential drugs offer a cost-effective solution to many health problems in a developing country. Knowledge, availability and access to drugs in the EML promote rational therapeutics. There is no injudicious use of antimicrobials in our study and it's not prescribed to every case also. Inappropriate use of antimicrobials in children with diarrhea has been reported by other researcher. Appropriate use of ORS as well as intravenous rehydration fluids as per WHO and IAP guidelines was observed in most cases. No ADR, complication or death was reported during the study period. Under-reporting of minor or non serious ADRs like nausea or vomiting which were either not detected or reported could contribute to low reporting.

Hence simple measures like curtailing polypharmacy, generic prescribing, appropriate selection of drugs and their formulations and definitive instead of empirical therapy can minimize the cost burden in these patients.

CONCLUSION

The findings of this study suggested that a relatively rational approach to oral and parenteral rehydration therapy, antimicrobials and FDC. One problem is values in our study are higher than the recommended limit of two drugs per encounter which indicate polypharmacy and another problem is lack of any stool examination and culture which can help in better way to choose appropriate antimicrobials. However; further studies in this area are warranted before suggesting ways to reduce the economic impact of the disease. This is important for a centre like ours with a huge patient population, most of whom belong to the lower and lower middle socioeconomic groups. Some of the recommendations that may be made based on this study include reducing polypharmacy and empirical prescribing, use of routine examination and

culture of stool, precise reporting of ADR, maintaining generic prescribing and appropriate choice of drugs and their formulations

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