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Prescribing Pattern and Appropriateness of Antimicrobials Use in Pediatrics for Gastroenteritis in a Tertiary Care Teaching Hospital

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Abstract: The Present study was carried out to analyse the prescribing pattern of drugs and appropriateness of antimicrobials use in gastroenteritis in hospitalized children. It was a prospective, observational, single centre study undertaken in gastroenteritis inpatients of paediatric department, aged one month to seventeen years, over a period of six months. Modified Kunin's criteria along with the guidelines set by the World Gastroenterology Organization were followed for assessing the appropriateness of the antimicrobials prescribed and prescribing patterns respectively. A total of 120 patients were enrolled, of whom 61% were in the age group below 5 years. Diarrhoea with mild dehydration was diagnosed in 53% patients followed by no dehydration (28%) and severe dehydration (19%). IV fluids (90.8%) and antimicrobials (86.6%) were the commonest drugs prescribed. 89% of antimicrobials were given in parenteral dosage form. 27.9% of antimicrobials were given for 3 days duration. Among the antimicrobials, ceftriaxone was frequently prescribed. Inappropriate antimicrobial therapy was given in 9.6% of the cases. Precise use of antimicrobials was preferred in 10.5% of cases. Microbiology report was missing in 79.9% of cases. No ADRs were observed during the study. Inappropriate use of antimicrobials was seen in the study. Emphasis on proper diagnosis, treatment, education and availability of effective guidelines may help in a judicious use of drugs in children.

Keywords: Adverse drug reactions, Gastroenteritis, Modified Kunin′s criteria, Paediatric inpatients, Prescribing pattern, World Gastroenteritis Organization guidelines

INTRODUCTION

Gastroenteritis is a catchall term for infection or irritation of the digestive tract predominantly the stomach and the intestine, it is frequently referred as the intestinal flu. The causative agent responsible for gastroenteritis may be viruses, bacteria or protozoan, however most of the cases observed is caused by rotavirus and mainly occur in children under the age of 5. The major symptoms of this disease are nausea, vomiting, diarrhoea and abdominal pain and it is sometime accompanied with fever and overall weakness [1].

Dehydration resulting from acute diarrhoea is the second leading cause of morbidity and mortality worldwide, infants and children younger than 5 years of age are at the higher risk. Among the 139 low to middle-income countries, there were approximately 1.7 billion episodes of childhood diarrhoea in 2010. The incidence of diarrhoea for all children younger than age 5 years was estimated to be 2.9 episodes per child per year. The incidence of diarrhoea was higher in children, with 4.5 episodes per child per year among children aged 6 to 11 months, compared with 2.3 episodes per child per year for children 24 to 59 months of age. Younger children also had a higher risk of death from acute dehydrating diarrhoea. For children younger than age 1 year and those aged 1 to 4 years, the median mortality rates were 8.5 and 3.8 per 1,000 children per year, respectively. Although incidence of childhood diarrhoea has been declining, diarrhoea remains a major health problem in children, especially in those younger than 1 year [2].However in Indian scenario, diarrhoea is the third most common cause of death in children under-five years of age, responsible for 13% deaths in this age-group, killing an estimated 300,000 children in India each year. Information on diarrheal diseases, its determinants in India and preventive and control strategies in light of recent developments need to be reviewed for better planning and organization of health services within the community [3].According to the World Health Organization (WHO) and UNICEF, there are about two billion cases of diarrheal disease worldwide every year, and 1.9 million children younger than 5 years of age perish from diarrhoea each year, mostly in developing countries. This amounts to 18% of all the deaths of children under the age of five and means that more than 5000 children are dying every day

as a result of diarrheal diseases. Of all child deaths from diarrhoea, 78% occur in the African and South-East Asian regions [4].

The purpose of conducting this study is to generate a rational and diligent attitude toward drug prescribing patterns and the awareness or insight about the rapid disseminating antimicrobials resistance. With this study, we are also aiming to simultaneously recommend the importance of counselling the patients and his/her guardian relating to breastfeeding, vaccination etc. which can be executed with ease, in collaboration with a pharmacist professional (i.e. Pharm. D).

MATERIALS AND METHODS

This study was prospective, observational, single centre study undertaken in paediatric inpatients department, aged one month to seventeen years, over a period of six months at a tertiary care teaching hospital. The study was approved by Institutional ethical committee.

A total of 120 paediatric patients with gastroenteritis were included in the study and data were procured from hospital records, medical records and the case sheet progress of the patients. The immunization status was determined in reference with the National immunization schedule (NIS).

The prescriptions were chosen randomly and/or the details were followed till the discharge of the patients. The data for present study was collected by chart review method. During the study inpatients case records was reviewed, which includes patients case history, diagnosis, physician medication order sheets, nurse medication administration records, progress chart, laboratory investigations and report of other diagnostic tests. This information was documented in the patient profile form. The prescriptions were checked for number of drugs given in the total patients, number of antimicrobials given in patients, route of administration of antimicrobials, dosage form of antimicrobials and adverse drug reactions. The dehydration status has also been categorized based on the complaints of the patient and with reference to the WGO guidelines 2012. The Modified Kunin's criteria have been used for evaluating the appropriateness of antimicrobials, for which the cases were categorized as follows:

- Agree with the use of antimicrobial therapy; the protocol (choice, route, duration, and dosage) is appropriate.
- Agree with the use of antimicrobial therapy; the protocol (choice, route, duration and dosage) is probably appropriate. Usually a microbiology report is missing to classify the protocol in another category.
- Agree with the use of antimicrobial therapy; but a different antimicrobial (less expensive, less toxic, narrower spectrum, other combination) is preferred.
- Agree with the use of antimicrobial therapy but a modified dose, interval, duration or route of administration is preferred.
- Disagree with the use of antimicrobial therapy, administration is unjustified.

The data was recorded and analysed using Microsoft Excel spreadsheet 2007.

RESULTS

A total of 120 patients were included in the study with a gender distribution of male 59% and female 41% (Table1). The age distribution of patients is less than 1 year (26%), 1 year to less than 3 years (22%), 3 years to 5 years (13%) and above 5 years (39%) (Table.2).

Table-1: Gender distribution of the patients

Gender	Number of patients	Percentage (%)
Male	71	59
Female	49	41

Table-2: Age distribution of the patients

Age	Number of patients	Percentage (%)
>1month to < 1yr	31	26
>1yr to <3yrs	26	22
>3yrs to <5yrs	16	13
>5yrs	47	39

The immunization status of AGE inpatients shows, 91% completely immunized followed by 7% partially immunised and 2% non-immunised status (Table.3). The dehydration status was found to be in 53% patients (mild dehydration) and 19% (severe dehydration). However, there were no signs of dehydration in 28% patients. (Table.4).

Table-3: Immunization status of the patients

Immunization status	Number of patients	Percentage (%)
Complete	109	91
Partial	9	7
Non-immunized	2	2

Table-4: Hydration status of the patients

Status of dehydration	Number of patients	Percentage (%)
No dehydration	34	28
Mild dehydration	64	53
Severe dehydration	22	19

A total of 709 drugs were prescribed to 120 patients as shown in Fig1, out of which antimicrobials (20%), IV Fluids (17%) and antiemetics (11%) were most widely prescribed.

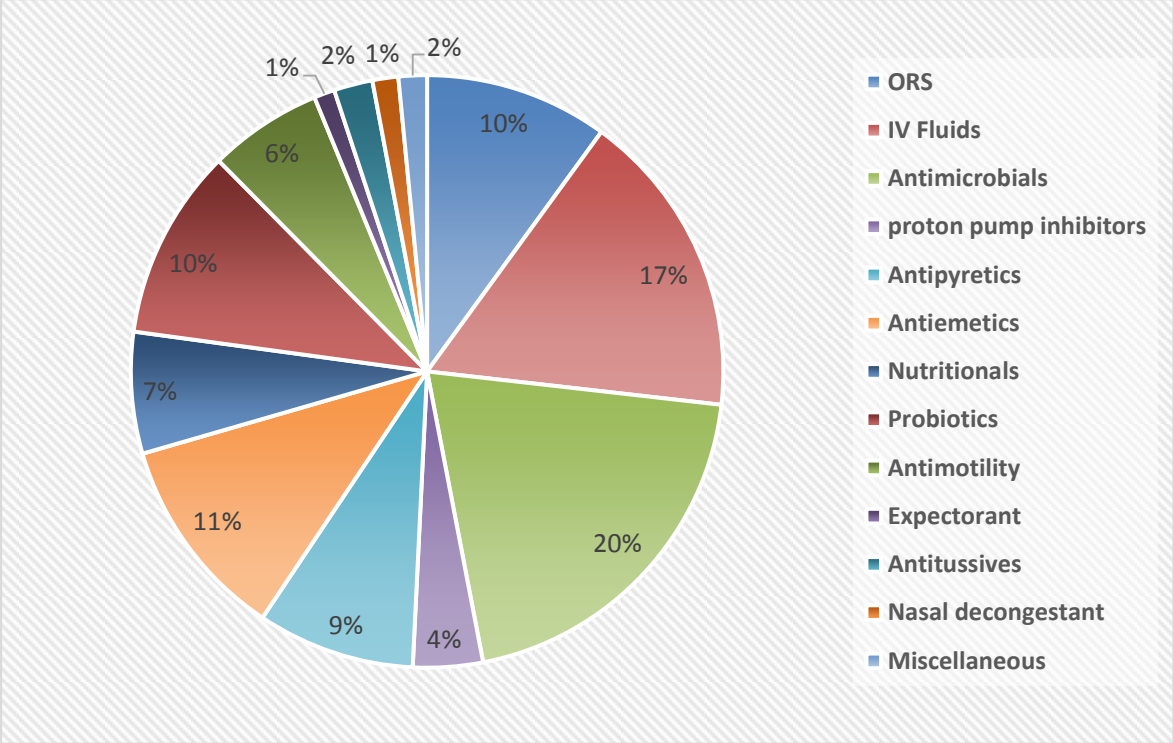

Fig-1: Drugs prescribed in paediatric inpatients of Acute Gastroenteritis (n=709)

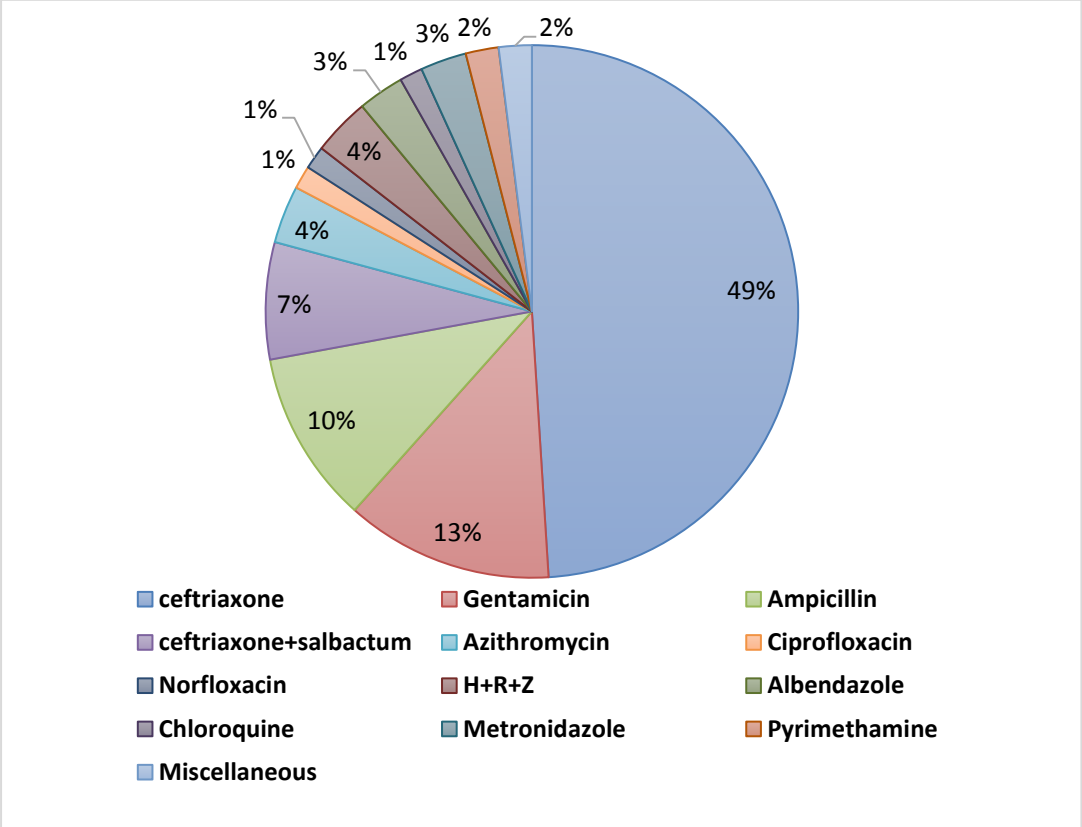

Fig-2: Number of antimicrobials prescribed (n=143)

The antimicrobials were prescribed in 104 patients and were mainly administered in parenteral form (81%) followed by tablets (10%) and syrups (9%). The routes of administering these antimicrobials were mainly parenteral with 81% and oral 19% as shown in Table.5. In most of the cases, the antimicrobials were given for the duration of 3 days & 4 days (27.9% & 26.5%) as shown in Fig.3.

Table-5: Antimicrobials dosage forms prescribed in paediatrics inpatients

Dosage forms	**Number**	**Percentage**
Parenterals	115	81
Oral		
Tablets	15	10
Syrups	13	9

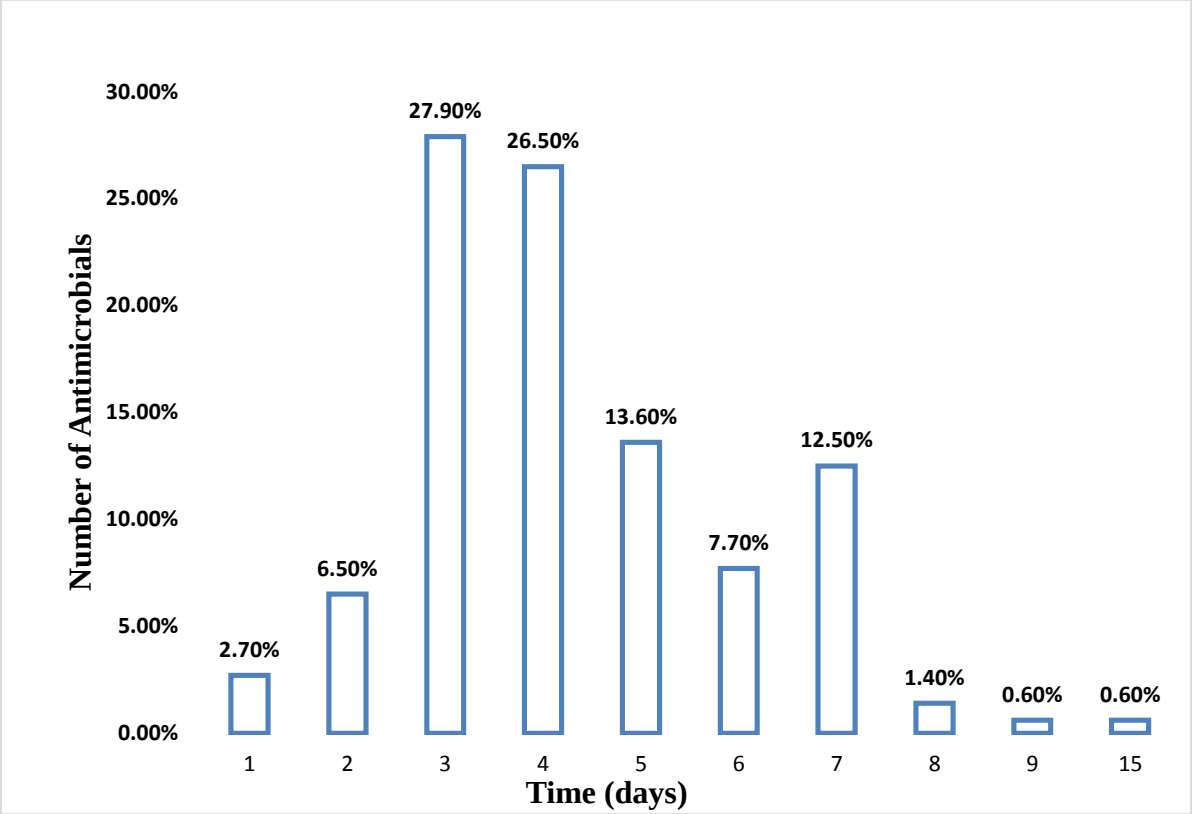

Fig-3: Duration of Antimicrobials Treatment

The appropriateness of antimicrobial use was being evaluated as per Modified Kunin's criteria and it was found out that most of the cases (79.9%) fall in category II, which signifies that the treatment protocol is appropriate, however there is lack of microbiological testing. (Table 6)

Table-6: Assessment of appropriateness of antimicrobials in paediatric in patients with acute gastroenteritis

Category	Kunin's criteria	Number of patients (%)	Justification
I	Agree with use of antimicrobial therapy, protocol is appropriate.	-	Most cases are initiated with empirical therapy.
II	Agree with use of antimicrobial therapy, protocol is probably appropriate but microbiology report is missing to classify protocol in another category.	83(79.9%)	Microbiology testing was not performed. However protocol was appropriate.
III	Agree with use of antimicrobial therapy, but precise use of antimicrobial is preferred.	11(10.5%)	Too many antimicrobials were prescribed concomitantly, combination of IV antimicrobials was not synergistic or antimicrobials cover was inadequate in some cases.
IV	Agree with use of antimicrobial therapy but modified dose, interval, duration or route of administration is preferred.	-	No patients are observed with a compromised metabolising or eliminating organ functions.
V	Disagree with use of antimicrobial therapy, administration is unjustified.	10(9.6%)	Antimicrobials used without certain evidence.

DISCUSSION

Gastroenteritis is "passage of loose, liquid or watery stools more than three times a day with/without bloody stools, vomiting or dehydration". Each year 12 million children in developing countries die before they reach their 5th birthday, many during the first year of life. Among these, 16% of deaths are due to acute diarrheal disease. Among five years children nearly one's death is due to diarrhoea. This toll is greater than that caused by AIDS, malaria and measles combined. In India, diarrheal disease accounts for 8.2% of total burden of disease, contributing 22 million Disability Adjusted Life Years (DALYs), the highest among communicable diseases. On an average, a child suffers from around 12 episodes of diarrhoea, 4 such episodes occurring in infancy [5]. The WGO guidelines, IAP Recommendation and Guidelines like NIS and Kunin's criteria were the recommended guidelines followed in our study for evaluating the treatment approaches such that, the required aims of our study conducted are established [4-6].

The demographic reports of our study showed that majority of the patients with gastroenteritis were males and below 5 years of age, which was also observed in a study conducted by Jigar R Panchal et.al (Table 1 & 2). The main cause of this illness is due to early weaning from breast feeding leading to an indirect contamination to the paediatric patients, possibly from an improper and unhygienic feeding process and alleviation of immunity development associated with breast milk. The increase of incidence of this illness in male cannot be explained. Most inpatients (91%) were fully immunized as per the National immunization schedule [6]. This reflects a general awareness among the caregivers about immunization and a good functional immunization program for children by health care providers (Table 3)The hydration status of the patient were found out to be mostly mildly dehydrated followed by no dehydration and severely dehydrated, with a percentage of 53%, 28% and 19% respectively (Table.4). The hydration status of the patient set a notions regarding the treatment approaches, involving rehydration therapy.

A total of 709 drugs were prescribed in 120 inpatients. Out of which, rehydration fluids and Antimicrobials were the most commonly prescribed drugs groups with a percentage of 10+17= 27% of ORS and IV fluids combined and 20% of antimicrobials followed by antiemetic, probiotics, antipyretics, nutritionals, antimotility, antitussives, miscellaneous, nasal decongestant and expectorants with a percentage of 11%, 10%, 9%, 7%, 6%, 2%, 2%, 1%, and 1% respectively (Fig.1). Thirteen different types of antimicrobials were being prescribed in all the included cases in our studies, among these prescribed antimicrobials ceftriaxone were mostly prescribed by the physician with the percentage of 49% followed by gentamicin, ampicillin etc, with the percentage of 13%, 10% respectively (Fig.2). These antimicrobials were maximally administered parenterally (81%) followed by orally in the tablets and syrups form (10% and 9% respectively) (Table.5). The mean duration of antimicrobials treatment is 3 days (27.9%) while the maximum duration of antimicrobials treatment is 15 days (2.7%) and the minimum duration of antimicrobials treatment is 1 day (0.6%) (Fig.3).

Use of ORS and IV fluids were observed in most of the cases in our studies being prescribed as per WGO guidelines, subjective evidence and objective evidence; however some of the cases in our study were ascertained to use Isolyte P as a replacement fluid in severe dehydration rather than RL. Isolyte P is recommended in literature as a maintenance fluid in pediatric patients; however the WGO guidelines do not recommend this fluid for maintenance fluid therapy.

Appropriateness of antimicrobial use was being evaluated as per Modified Kunin's criteria and it was found out that most of the cases falls in category II. The drawback of our study is lack of microbiological test data which led to an empirical treatment, which are likely to cause medication errors.

CONCLUSION

The findings of our study suggest a relative rational approach to oral and parenteral rehydration therapy, but an inappropriate and overuse of antimicrobials lacking microbiological testing. Some of the recommendations that may be established, based on this study includes reduce polypharmacy, reduce empirical prescribing, procurement of microbiological reports before initiating an antimicrobial therapy, encouraging the prescribers to glue on the standard guidelines to reduce the morbidity rate of gastroenteritis in children.

It should also be noted that the inputs contributed by the clinical pharmacist in areas of patient care, drugs of choice, possible drug interactions, possible ADRs etc. should be acknowledged, as this collaboration can reproduce a better outcome in weighing the benefit and risk ratio. During the construction of guidelines, ideas and knowledge of a clinical pharmacist should be appreciated and accepted while formulating the guidelines.

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