

Auditing of prescriptions in relation to diarrhea in children below 5 years of age: a multicenter study

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ABSTRACT

Background: This study was planned to determine the prescribing pattern of drugs in children below 5 years of age suffering from diarrhea by different categories of doctors in the city of Jaipur (Rajasthan).

Methods: This observational retrospective study was conducted in the Pediatric Outpatient Department of SMS Medical College and other hospitals in Jaipur (Rajasthan). In this study, 300 prescription (10% of total prescription) of the children aged below 5 years, suffering from acute diarrhea, were randomly selected.

Results: As alone, norfloxacin was noted in 49.2% prescriptions followed by ofloxacin in 24.6% out of 61 prescriptions. In combination, the most common antimicrobial (77.78%) prescribed was norfloxacin with either metronidazole or tinidazole.

Conclusions: Antimicrobials should be prescribed rationally for pediatric patients suffering from diarrhea to avoid potential adverse events and increased cost of the treatment. Regular prescription audits in hospitals should be undertaken to promote rational use of drugs.

Keywords: Drug utilization, Pediatric drug prescribing, Pediatric drug prescribing, diarrhea

INTRODUCTION

Diarrhea is a major cause of infant mortality in India. It affects both young and elderly. It is estimated that a child suffers about 2.6 episodes a year up to 5 years of age the most vulnerable period.¹

In the pediatric patient audit, the major problem of childhood illness were identified acute watery diarrhea, acute respiratory infection and viral fever² and in the developing

countries large part of population (9.3%) are infants and children.³

The guidelines published for the management of acute diarrhea in 2004, which were further revised in 2006 by the Indian Academic of Pediatric.⁴ Rehydration therapy is considered an adequate, safe and successful treatment of diarrhea due to any etiology and in all age groups. As per local standard treatment guidelines also antibiotics are not recommended for acute diarrhea in adults.⁵

The guidelines focused on the use of low osmolarity and zinc.^{6,7} Antibiotic use is recommended only for acute bloody diarrhea/dysentery.

However, it is not uncommon to find prescription of antibiotics, anti-motility drugs, antispasmodics, *Lactobacillus* and other drugs in a prescription of acute diarrhea. In most situations, many of these drugs are neither desirable nor necessary in diarrhea management. While the WHO recommended oral rehydration solution (ORS) as sufficient and adequate therapy in most cases of diarrhea, prescriptions containing anti-motility drugs, antimicrobials, antispasmodics, anti-amoebic, anti-emetics, *Lactobacillus* containing preparation, enzymes preparation are not uncommon. Some of these drugs are potentially dangerous for use in children, besides, being expensive, adds to the cost of treatment.^{8,9}

Unfortunately, diarrhea is a condition for which the misuse of antibiotics is common and is reported from different parts of the world.⁴

The physicians prescribing practices of antimicrobials seemed to be a more related to the agreement with social expectations rather than their knowledge and guidelines.

The overzealous use of the drug by medical practitioners to treat diarrhea has raised serious concern for the need to audit their prescriptions, to promote rational use of drugs (RUD).

The prescription audit is, an evolving field, a part of drug utilization study seeks to monitor, evaluate and if need suggests modification in medical practice and make it rational and cost-effective. The prescription audit of drugs is important for the economical, clinical and educational purpose.¹⁰ The prescription audit in pharmacology has been increasing importance because they have close relation with each other area like pharmacovigilance, pharmacoconomics, pharmacogenetics, and public health.

This study was planned to determine the prescribing pattern of drugs in children below 5 years of age suffering from diarrhea by different categories of doctors in the city of Jaipur (Rajasthan).

The study was designed to determine the prescribing behavior of pediatricians engaged in practice employed with the government hospital. The results of study could be useful in designing of interventions that need to be given to promote judicious and RUD.

METHODS

This observational retrospective study was conducted in the pediatric outpatient Department of SMS Medical College and other hospitals in Jaipur (Rajasthan). In this study, 300 prescription (10% of total prescriptions of the first approach of the patient to any health facility including government and private set up for the management for

diarrhea) of the children aged below 5 years, suffering from acute diarrhea, were randomly selected.

All the admitted patients at intensive care unit and an emergency and patient with HIV infection with diarrhea and those patients with evidence suggestive of dysentery, systemic illness, and those who had stayed in the hospital for more than 24 hrs were excluded in this study.

Details regarding the history, nature of diarrhea and its management were collected from the prescription of these children. The prescriptions were audit from the months of April to December of previous year.

To avoid the selection bias, the collection of prescription was done without the knowledge of the prescribing doctor.

The results were subjected to statistical analysis the qualitative data were expressed in percentage and quantitative data were expressed in mean and standard deviation. The difference in proportion was analyzed by Chi-square test, and differences in means were analyzed by Student's t-test. The level of significance was considered as $p < 0.05$.

RESULTS

This study involved auditing of prescriptions of 300 children suffering from diarrhea. The mean age of the study group was 28.6 months with the M:F ratio was 2:7.

Most (45%) of the cases were in age groups 1-12 months of age group and rest were almost equal (28%) in 13-24 and 25-60 months of age groups.

The majority (72.5%) of children suffering from diarrhea were below 2 years of age.

Parents of the children below 2 years of age preferred treatment of a pediatrician. In older age groups, there was no noteworthy preference of parents.

Males' predominance was observed among all age groups (Table 1). Most of the prescriptions were contained more than one medication. Out of 300, only 9% prescriptions mentioned a single medication, 129 (43%) mentioned two drugs, 128 (41%) prescriptions contained three drugs, whereas four or more drugs were mentioned in 21 (7%). Average no of drugs prescribed a patient was 2.49, and proportion was increased with the age.

A significant difference was observed between the age group and a number of drugs prescribed by the doctors. A Higher proportion of single or two medications were prescribed in the early age groups was 55.6% and 53.49%, respectively while prescriptions contained 3 or 4 drugs were observed in 25-60 months of age group was 43.9% and 42.8%, respectively. (Table 2)

Table 1: Association of age with distributions of number of drugs prescribed.

Age (month)	Number of drugs in a prescription, n (%)				Total number of patient drugs (n)
	1	2	3	4+	
Up to 12	15 (55.6)	69 (53.49)	43 (34.96)	3 (14.29)	129
13-14	3 (11.1)	36 (27.91)	27 (21.95)	9 (42.86)	75
25-60	9 (33.3)	24 (18.60)	54 (43.90)	9 (42.86)	96
Total	27 (100.0)	129 (100.00)	123 (100.00)	21 (100.00)	300

Chi-square=29.232 with 6 degrees of freedom; p<0.001 S

Table 2: Association of prescribing habit of ORS and antimicrobials with the age groups.

Age (months)	Total (n)	ORS, n (%)		Antimicrobials		
		Yes	No	Alone, n (%)	Combination, n (%)	Not given
0-12	129	93 (72.09)	36 (27.91)	38 (29.46)	21 (16.28)	70
13-24	75	63 (84.00)	12 (16.00)	9 (12.00)	3 (4.00)	63
25-60	96	90 (93.75)	6 (6.25)	14 (14.58)	3 (3.13)	79
Total	300	246 (82.00)	54 (18.00)	61 (20.33)	27 (9.00)	212
Chi-square test		17.761 with 2 df; p<0.001 S		31.398 with 4 df; p<0.001 S		

ORS: Oral rehydration solution

Table 3: Age group wise distribution of different categories of drugs prescribed by government doctors.

Age (in months)	n	n (%)							
		ORS	<i>Lactobacillus</i>	Antimicrobial alone/combination	Antiemetic	Antispasmodic	Anti-motility	Analgesic antipyretic	Diet advise
0-12	129	93 (72.1)	90 (69.7)	59 (45.7)	21 (16.3)	21 (16.3)	3 (2.33)	6 (4.65)	99 (76.7)
13-24	75	63 (84)	51 (68)	12 (16)	15 (20)	9 (12)	15 (20)	6 (8)	57 (76)
25-60	96	90 (93.8)	84 (87.5)	17 (17.7)	24 (25)	21 (21.8)	30 (31.25)	3 (3.13)	81 (84.4)
Total	300	246 (82)	225 (75)	88 (29.3)	60 (20)	51 (17)	48 (16)	15 (5)	227 (75.7)
p value LS		<0.001 S	0.003 S	<0.001 S	0.27 NS	0.224 NS	<0.001 S	0.339 NS	0.29 NS

ORS: Oral rehydration solution

Out of all, most common medication prescribed was ORS (82%), followed by *Lactobacillus* (75%), antimicrobial alone/combination (29.4%), antispasmodic (17%), anti-motility (16%), and analgesic antipyretic (5%). Most important observation (dietary advice) that was present in 75.67%. (Table 3)

Prescriptions with ORS was 82% while only <1% prescription was observed ORS with zinc and it was significantly associated with the age group. At least >72% of prescriptions were observed with ORS in all age groups. Maximum proportion with ORS was 93.75% in 25-60 months which was significantly higher in proportion than 0-12 months of children which were 72.1%.

Antimicrobial alone or in combination were prescribed in a total of 88 (29.4%) patients, and it was significantly associated with age group. Prescriptions with antimicrobials alone or combination were observed more (29.46% and 16.28%, respectively) in 0-12 months of age groups as compared to other age groups.

As far as antimicrobials were concerned, out of total 300, prescription with antimicrobial alone and in combination were 29.33% (20.33% alone and 9% combination). Norfloxacin was the most common antimicrobial agent used alone or in combination with either metronidazole or tinidazole.

As alone, norfloxacin was noted in 49.2% prescriptions followed by ofloxacin in 24.6% out of 61 prescriptions. In combination, the most common antimicrobial (77.78%) prescribed was norfloxacin with either metronidazole or tinidazole.

DISCUSSION

Auditing of prescriptions of diarrhea was undertaken to evaluate rationality of drug use. RUD means prescribing right medication to a patient appropriate to their clinical need. They should also fulfill SANE criteria: safety, affordability, need, and efficacy. Rational prescribing, therefore, involves a right decision of the prescribers.

Prescriptions of doctors were evaluated for rationality in the present study. Pediatricians in working hospital attached to a medical college are generally more aware and are constantly exposed to the recent advances in the management and treatment of diseases in children.⁷

The mean age of the study population of the prescription audit was 28.6 months. This study was involved auditing of prescriptions of acute diarrhea in children below 5 years of age because of the greater incidence of diarrheal episode in this age group.

Majority (72.5%) of children suffering from diarrhea were below 2 years of age., suggesting thereby that this period is the most vulnerable period in children this finding is in agreement with for diarrheal disease. A study was conducted in Jaipur on diarrhea where it was observed that 44% of the patients were below 1 year of age Kumar et al.¹¹ who observed that the incidence of acute diarrheal disease was maximum between 1 and 2 years of age. However, the present study is not in agreement with Kumar et al.¹¹ finding of low-incidence of diarrhea in children under 1 year of age and above 4-6 years of age.

Barrell and Rowland¹² observed a higher incidence of diarrheal disease after weaning was started. Rowland and McCollum¹⁰ reported a particularly higher incidence between 7 and 8 months. In the present study, children were divided into 0-12, 13-24 and 25-60 months of age. It was observed that the incidence of diarrheal disease in children between 0-12 and 13-24 months was not much different. There is, however, broad agreement with observations, of other workers that the incidence of diarrheal disease was maximum in children below 2 years of age.

Most of (73%) patients were male children. The male and female distribution viz. it showed in different studies that most of hospital visiting patients were male.

This may be possible due to a sex bias on the part of the parents to get the male child treated properly even if it involves covering a greater distance to reach a government hospital. The female child is often neglected and treated with household remedies.

This data indicates that there is a definite lack of communication of the WHO guidelines among the practitioners. This lack of knowledge is also reflected the fact that most of the children under study received 2 or 3 drugs. The average number of drugs prescribed a child was 2.49.

It needs not to be stated that greater the number of drugs administered to the patient, greater will be the incidence of side effects, adverse effects and greater will be the likelihood of drug-drug interaction. Unnecessary medication also imposes an economic burden on the parents and the community to treat an ailing infant of diarrhea.⁷

The other drugs prescribed by various categories of doctors were antimicrobials (alone or in combination), *Lactobacillus*, anti-motility, antispasmodics, antiemetics, non-steroidal anti-inflammatory drugs, etc.

These results indicate that while the WHO guidelines advocate the use of ORS in the management of diarrhea, all categories of doctors whose prescriptions were audited prescribed various other categories of drugs to their patients perusal of the list of drugs other than ORS commonly prescribed that *Lactobacillus* containing preparations and antimicrobials prescriptions far exceed those for other group of drugs.

As far as antimicrobials were concerned, out of total 300, prescription with antimicrobial alone and in combination were 29.33% (20.33% alone and 9% combination). Norfloxacin was the most common antimicrobial agent used alone or in combination with either metronidazole or tinidazole.

As per the WHO treatment guidelines, antimicrobials may be prescribed in patients suffering from infective diarrhea caused by *Shigella*, *Salmonella*, *Yersinia*, cholera, campylobacter *Clostridium difficile*, amoebiasis, giardiasis, etc. and in travelers diarrhea. Even in some cases of infective diarrhea, use of antimicrobials may not be either necessary or effective because of the self-limiting nature of the disease.

Not unexpectedly frequent use of antimicrobial was observed.⁹ The reason for this may be in anticipation of a quicker response, which is obviously not justified and shows a lack of awareness on the use of antimicrobials in cases of diarrhea. The role of *Lactobacillus* containing preparations even as adjuvant therapy in the treatment of acute diarrhea specially in children is uncertain; while some workers have reported beneficial effects, others mention no benefit or even worsening of the condition.¹³ WHO does not advocate routine use of *Lactobacillus* containing preparation in management of diarrhea, frequent use of this preparation as has been observed in the present study, therefore, constitute an inappropriate use. Though, its use is not associated with significant toxicity, it definitely adds to the cost of prescriptions.

In a study, Kabra et al.¹⁴ noted that majority of the children suffering from diarrhea received multiple drug therapy.¹⁴

In this study, lack of awareness of standard treatment guidelines is difficult to comprehend. It only reflects an indifferent attitude on the part of government doctors to adopt WHO guidelines on the treatment of diarrhea disease.

In this study, antimicrobial alone or in combination were prescribed in a total of 88 (29.4%) WHO guidelines⁹ and Indian guidelines⁴ for the treatment of acute diarrhea clearly mention that antimicrobials should not be used routinely.

This is because most episodes of acute diarrhea are caused by virus, not bacteria. Furthermore, it is not possible to distinguish clinically the episodes of diarrhea caused by enterotoxigenic *Escherichia coli* from those caused by agents unresponsive to antimicrobials, such as rotavirus or cryptosporidium.¹⁵ In addition, the use of antimicrobials adds to the cost of treatment, risks adverse reactions, and enhances the development of resistant bacteria.¹⁷ The exact amount of cost saved is difficult to analyze from the study, but it is clear that whatever amount was spent on antibiotics by each patient could have been saved if prescribers fully adhered to the guidelines recommended for the treatment of acute diarrhea.

There are many studies¹⁷⁻¹⁹ conducted in other countries mainly for children that have shown frequent prescription of antibiotics for the treatment of acute diarrhea.

Our study revealed that overall prescriptions with ORS were 82% while only <1% prescription was observed ORS with zinc. A recent cross-sectional study conducted in India²⁰ showed that 6 prescriptions out of 843 adhered to the recommended treatment of ORS along with zinc for the treatment of acute diarrhea in children and antibiotics were prescribed to 71%.

Our study observed that as alone, norfloxacin was noted in 49.2% prescriptions followed by ofloxacin in 24.6% out of 61 prescriptions. In combination, the most common antimicrobial (77.78%) prescribed was norfloxacin with either metronidazole or tinidazole.

Surveillance of antibiotic use in these areas has shown a very high use of fluoroquinolones.^{13,15}

The study suggests that the use of antimicrobials without a rational basis constitute an inappropriate use which should be discouraged. Implications of the study are discussed in relation with standard treatment guideline, suggestion of intervention; other approaches to rationalized drug use are discussed.

Recommendations

This study clearly underscores an urgent need to impart training through CME, workshop, seminar, etc. to generate awareness among all treating doctors to use drugs appropriately, judiciously and rationally.

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