

Quality of prescriptions in hospitalized children suffering from acute and persistent diarrhoea

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ABSTRACT

Background: Diarrhoea is a major public health problem in children worldwide. It continues to be a major health challenge, especially in developing countries, despite the availability of regularly updated standard treatment guidelines. Non-compliance to such guidelines by the physicians has been a long standing story. The treatment is often marred with incapacitating prescription of drugs besides neglecting even the basic tenets of good prescribing. As a result, the quality of such prescriptions for diarrhoeal disorders in children remains poor. To gauge the magnitude of this problem in this setup towards possible corrective measures, the study was aimed to audit prescription practices in the management of acute and persistent diarrhoea in hospitalised children up to five years of age.

Methods: An observational study was conducted in 100 patients of either gender in the age group up to 5 years admitted with acute and persistent diarrhoea. A detailed medical history from the parents/guardians and the details of prescription from the time of admission till the discharge of the patient were obtained. Quality of prescriptions was analysed using prescription quality index (PQI) tool, a validated comprehensive tool described by Hassan et al in 2010. Based on this tool, prescription with the total PQI score of ≤ 31 were interpreted as poor quality, scores with 32 to 33 as medium quality and scores 34 to 43 as high quality with a possible maximum score of '43'.

Results: Based on the PQI tool for 100 children, 60 prescriptions were found to be of poor quality. Only 2 prescriptions were of medium quality, whereas 38 prescriptions were in high quality range. Average mean \pm SD score of prescriptions with poor quality was 25.2 \pm 1.48, ranging from 21 to 31. The mean \pm SD of prescriptions with medium quality was observed to be 32 \pm 0 and for prescriptions of high quality was 38.07 \pm 2.28. The total average mean score of all prescriptions was 30.23 \pm 6.50. Poor quality prescriptions were particularly observed for the patients with the diarrhoea with No dehydration.

Conclusions: Prescription appropriateness in spite of available guidelines continues to be a big challenge in the adequate management of patients with diarrhoeal disorders under the age group of five years in a tertiary care centre in India.

Keywords: Children, Diarrhoea, Prescription Quality Index tool, Quality of prescriptions

INTRODUCTION

Diarrhoea remains a common illness among infants and children throughout the world making it a leading cause of childhood morbidity and mortality. In developing

countries it is the second highest cause of death in children up to five years of age after pneumonia.¹ In 2016, it accounted for 9% of deaths due to diarrhoea in this age group in India.² The situation in the state of Uttarakhand is

abysmal with the 17% prevalence of diarrhoeal disorders as compared to overall Indian prevalence of 9.2%.³

World health organisation (WHO) defines acute diarrhoea as the passage of unusually loose or watery stools, usually at least three times in a 24 hour period and persistent diarrhoea that lasts for 14 days or longer. Although, the mild illness usually resolves without treatment, but varying degree of water and electrolytes loss occurs during the episodes which need prompt action to protect the health of the child.⁴

For treatment of diarrhoeal disorders, regularly updated standard guidelines are provided by WHO which clearly elaborates the management protocol for each type of the presentation along with all do's and don'ts. A significant progress was achieved with the introduction of reduced-osmolarity oral rehydration solution (ORS) and zinc supplementation as a part of the management of diarrhoeal disorders in children.⁴ However, these guidelines are often flawed and ignored in routine practice. Doctor's are usually apprehensive, more concerned for young baby that at times makes them unwilling to accept the standard guidelines. Moreover, the disappointing fact is that doctors fail to keep up the pace with changing guidelines on diarrhoea with the impression that the guidelines are too simple. Further parental desire of 'real' drug therapy to pressurise the physician to stop diarrhoea are some of the blatant reasons for poor quality of prescriptions in this setting.⁵ Even in India, even the routine use of ORS and zinc supplementation is still not practiced widely.³

In fact, inappropriate drug prescribing is a global problem despite the availability of standard guidelines. Currently, accurate prescribing decisions, rational use of drugs appropriate treatment and associated patient-instructions, are of major concerns in management of a patient. Realising the magnitude of the problem, the aim of the study was to conduct an audit of prescription practices in the management of acute and persistent diarrhoea in hospitalised children up to five years of age.

METHODS

An observational descriptive study was conducted from January 2017 to December 2017 to analyse the prescribing patterns in the management of acute and persistent diarrhoea in hospitalized children. Patients were included in the study after obtaining written informed consent from parents/guardians and approval from the institutional ethics committee. A total of 100 patients of either gender in the age group up to 5 years admitted with acute and persistent diarrhoea were included in the study. Patients with concurrent severe illness, underlying septicemia, metabolic disorders or any other major organ failure were excluded. A detailed medical history was obtained from parents/guardians. All the relevant information including history, physical examination, investigations and treatment along with discharge summary were recorded from the time of admission till the discharge of the patient,

taken together as a single prescription for convenience of analysis. Follow up was done up to 28th day following admission. Compliance to treatment given at home was ascertained at repeated intervals. Prescriptions were analysed for adherence to the WHO standard guidelines put forward in 2005 for the management of diarrhoea in children up to 5 years of age.

The evaluation of quality of prescription was done using prescription quality index (PQI) tool, recently described by Hassan et al in 2010. The earlier WHO core prescribing indicators that measures only some dimensions that were mutually agreed upon to take care of majority of the countries, of appropriateness of drug prescribing behaviour, but not necessarily the important ones and to look for potential problems and possible corrections.^{6,7} This include only the average number of drugs prescribed, utilisation of drugs from essential drug list, prescribing with generic names, the percentage encounters with the antimicrobials and injectable in a prescription. Due to this inherent problem WHO core prescribing indicators are not a gold standard for rational prescribing. The PQI tool is an attempt to overcome the drawbacks of WHO core indicators, that was introduced as a more comprehensive tool encompassing drug related verification of correct indication, dosage, administration, their effectiveness with supportive evidence, duration of therapy, cost analysis, legibility of prescription and prescribers information along with adequate patient information, provision for possible drug-drug or drug-disease interaction, duplication of drugs, adverse drug reaction, and finally assessing whether the prescription fulfilled the patients requirement of drug therapy.

PQI tool mentions 22 criteria's for the above parameters in the form of questions. The scores in the PQI tool for each criteria varied as '0' to '4' for very important criteria (n= 2), '0' to '2' for criteria considered as important (n= 15), and '0' to '1' for less important criteria (n= 5). Prescriptions usually included more than one drug, hence each drug was rated individually. If a drug was not indicated, criteria 1 was scored as '0', subsequently criteria 2 (dosage), criteria 11 (duration) and criteria 12 (cost) were all scored as '0'. The individual PQI score was drawn for each drug in the prescription. The total PQI score for the prescription was calculated by adding minimum scores achieved for each criterion by the drugs. The possible maximum score of PQI was '43'. Prescription with the total PQI score of ≤ 31 was interpreted as poor quality, scores with 32 to 33 as medium quality and scores 34 to 43 as high quality as described by the PQI. The manual for the PQI includes an introduction to the PQI, a listing of the 22 criteria, steps on how to use the PQI, specific instructions with an operational definition of the terms, a scoring method for each criterion, and the assessment form to be used for the prescription rating.⁶

The data was collected and entered in MS Excel 2010. The one-sample Kolmogorov-Smirnov Test was employed to determine whether the data sets differed from a normal

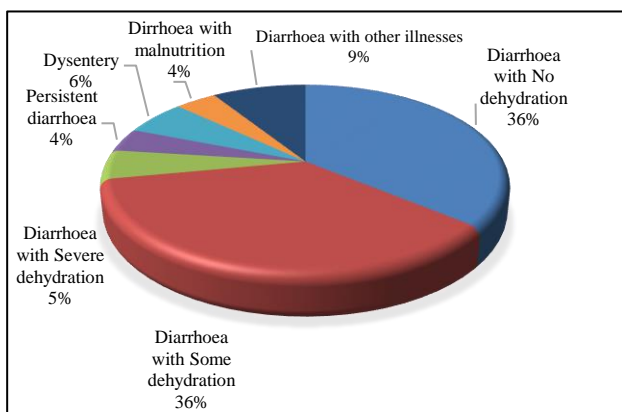
distribution. Descriptive statistics was calculated for quantitative data. Frequency and percentage were calculated for qualitative data and presented in the form of graphs and tables.

RESULTS

This study was done to analyse the prescribing patterns in the management of acute and persistent diarrhoea in hospitalized children up to 5 years of age. Out of the total 100 hospitalised patients 32 were females and 68 were males and followed for the period of their stay in the hospital. Median age of children was observed to be 14 months. Most of the children admitted were below the age of one year while almost 81% patients were below two years of age. Admissions were more from people who were from urban areas than rural areas. The parents were relatively more from poverty stricken status (Table 1).

Table 1: Demographic profile of the patients admitted with acute and persistent diarrhoea up to 5 years of age (n=100).

Demographic profile	Subgroup	Frequency (%)
Age-group	0-28 days	4 (4.0 %)
	1-6 months	22 (22.0%)
	7-12 months	21 (21.0%)
	13-24 months	34 (34.0%)
	>25 months	19 (19.0%)
Sex	Female	32 (32.0%)
	Male	68 (68.0%)
Residence	Rural	47 (47.0%)
	Urban	53 (53.0%)
Parent occupation	Self employed	38 (38.0%)
	Local vendor	57 (57.0%)
	Institutional job	5 (5.0%)



Data expressed in percentage

Figure 1: Distribution of diagnosis of the patients admitted with diarrhoea up to 5 years of age (n=100).

Children presented with varying degree of dehydration status (Figure 1). Equal numbers of patients were observed with no and some degree of dehydration, with only 5%

cases of severe degree of dehydration. Below 10% admissions were of the cases of persistent diarrhoea and dysentery. Underlying malnutrition with diarrhoea was observed in 4% cases. The average duration for which the child was admitted was 6.630±4.101 days with minimum one day of admission to up to a maximum of 21 days.

WHO guidelines recommend the use of ORS and zinc for all children. It was observed that ORS and zinc was used only in 62% and 81% of children respectively. Subgroup analysis of use of ORS and zinc was done. It was observed that all patients of persistent diarrhoea received ORS and zinc. Use of zinc was more frequent than the ORS. Surprisingly use of ORS and zinc was comparatively less in patients with no and some dehydration.

Antimicrobials were commonly prescribed in the study patients. From a total of 100 patients 97 patients received one or more antibiotics, out of which at least one antibiotic was prescribed to 61 patients, two antibiotics to 23 patients and three antibiotics to 12 patients. One patient was prescribed upto four antibiotics. Among the antibiotics prescribed, Cephalosporin's were the most commonly prescribed class followed by Aminoglycosides and Penicillins. Various other drugs were also prescribed during the hospital stay of children (Table 2). Antiemetic use was seen invariably in 50% of the prescriptions. Use of prebiotics and probiotics was frequently seen (43%). Multivitamin combinations were prescribed in almost 20% of the cases. Miscellaneous drugs included the drugs used for the management of associated complaints like perianal ulceration, anaemia, urinary tract infections etc.

Training of the mother has been the key focus in management of diarrhoea in children and well emphasized with documentation. Instructions for the use of ORS were documented in 62% prescriptions. Written documentation for encouragement of oral fluids and breast feeding during the episodes was observed only in 3% and 11% patients respectively.

Prescriptions were further evaluated according to the PQI tool as depicted in table 3. Out of a total of 100 prescriptions 60 prescriptions were found to be of poor quality. Only 2 prescriptions coming under medium quality, whereas 38 prescriptions were found to be of high quality. Average mean±SD of prescriptions with poor quality was 25.2±1.48, (range 21-31), for medium quality 32 (range 32-33) and for high quality was 38.07±2.28 (range 34-43). The total average mean score of all prescriptions was 30.23±6.50. Maximum poor quality prescriptions were observed for the patients with the diarrhoea with No dehydration (Table 3). Out of the total of 22 criteria's of PQI tool each criteria was separately analysed as expressed in Table 4 with the maximum score allotted to each question. It was observed that the mean score obtained for criteria one, three, four, ten, eleven, twelve, thirteen, fourteen and twenty-one were less than 50% of their maximum which reflects the reasons for the poor quality of the prescription.

Table 2: Distribution of other drugs used and pattern of prescribing in patients with acute and persistent diarrhoea up to 5 years of age (n=100).

Drugs	Prescribed		Rationality behind prescribing
	Prescribed with generic name	Prescribed with brand name	
Antimicrobial drugs	0	97	40 patients had no absolute indication At least one antimicrobial was prescribed in Brand name in each prescription
Antipyretic drugs	1	46	23 patients were recorded to have temperature
Antiemetic drugs	0	50	Not recommended as per the WHO guidelines
Antacids drugs	0	58	Not recommended as per the WHO guidelines
Pre/probiotics	0	43	Not recommended as per the WHO guidelines
Multivitamins	0	20	2 patients of malnutrition were prescribed multivitamins rationally.
Anti-diarrhoeal	1	5	Not recommended as per the WHO guidelines
Miscellaneous	0	58	For use of perianal ulceration, anaemia, urinary tract infections

Table 3: Quality of prescriptions in patients with acute and persistent diarrhoea up to 5 years of age according to PQI scores (n=100).

	Poor quality < 31		Medium quality 32-33		High quality 34-43		Total
	Count	%	Count	%	Count	%	
Diarrhoea with no dehydration	30	83.30%	0	0.00%	6	16.70%	36
Diarrhoea with some dehydration	20	55.60%	2	5.60%	14	38.90%	36
Diarrhoea with Severe dehydration	1	20.00%	0	0.00%	4	80.00%	5
Persistent diarrhoea	1	25.00%	0	0.00%	3	75.00%	4
Dysentery	4	66.70%	0	0.00%	2	33.30%	6
Diarrhoea with malnutrition	0	0.00%	0	0.00%	4	100 %	4
Diarrhoea with other illnesses	4	44.44%	0	0.00%	5	55.56%	9
Total	60	60.00%	2	2.00%	38	38.00%	100

Table 4: Average score obtained for 22 criteria of Prescription Quality Index Tool (n=100).

Variable	Maximum score	Mean	±SD
Is there an indication for the drug?	4	0.96	1.25
Is the dosage correct?	4	1.53	1.90
Is the medication effective for the condition?	2	0.65	0.79
Is the usage of drug supported by the evidence?	2	0.56	0.72
Are the directions for administration correct?	2	1.97	0.171
Are the directions for administration practical?	2	1.96	0.24
Are there clinically significant drug-drug interactions?	2	2.00	0.00
Are there clinically significant drug-disease/condition interaction?	2	1.98	0.20
Does the patient experience any adverse drug reaction(s)?	2	1.94	0.31
Is there unnecessary duplication with other drug (s)?	1	0.90	0.30
Is the duration of therapy acceptable?	2	0.71	0.94
Is this drug the cheapest compared to other alternatives for the same indication?	1	0.28	0.45
Is the medication being prescribed by generic name?	1	0.07	0.25
Is the medication available in the formulary or essential drug list?	1	0.55	0.50
Does the patient comply with the drug treatment?	2	2.0	0.0
Is the medication's name on the prescription clearly written?	2	1.89	0.34
Is the prescriber's name on the prescription legible?	2	1.88	0.35
Is the prescriber's information on the Prescription adequate?	2	2.0	0.0
Is the patient's information on the prescription adequate?	2	1.97	0.17
Is the diagnosis on the prescription clearly written?	2	1.92	0.33
Does the prescription fulfil the patient's Requirement for drug therapy?	1	0.51	0.50
Has the patient's condition (s) improved with treatment?	2	2.0	0.0

PQI tool assessed whether there was a sufficient reason for the use of drug. Each drug prescribed was evaluated for the indication of the drug and it was observed that 60 % prescriptions had at least one drug which was not indicated as per the recommended WHO guidelines. Only 7% prescriptions were found to adhere to the WHO criteria in all perspectives.

DISCUSSION

Children determine an important and a major part of demography in developing countries. They suffer from high morbidity and mortality rate as a result of diarrhoea. Unfortunately, this morbidity and mortality statistics have remained high over a period of time in spite of the medical advancement in availability of medicine. The primary management of diarrhoea aim to focus on restoring the hydration status of the child by paying attention to early rehydration and judicious re-feeding.

In the present study, the male to female ratio was 68:32. A similar pattern was observed in studies conducted in other parts of the country blaming partly for the unfortunate practices for preferring male child over female.⁸ Appropriate management of the child depends on the recognition of the signs of dehydration and managing the patient based on the degree of dehydration. Maximum admissions observed were with no dehydration and with some degree of dehydration (36%). This is in contrast to the guidelines that suggest if the child has no signs of dehydration, he/she can be managed at home and parents can be counselled to bring the child to the physician only if signs of dehydration develop. It reflects rather more apprehensive care both from parents as well as from the treating physician. The reason for some admissions could be that out of 36 patients who showed no signs of dehydration, 13 had associated illness in the form of anaemia, febrile seizures, and extra intestinal infection for the remaining 22% of the admissions with no dehydration no compelling reason was found. Another reason for admission could be that the maximum patients (81%) were below the age group of 24 months. Since these are at greater risk of accounting to morbidity and mortality the management was preferred in the hospital setup.

Patients with some dehydration are at relatively greater risk of landing into severe dehydration. In the present study, 36 patients were admitted with some dehydration. Associated illnesses were observed in 16 patients. The magnitude of admission due to severe diarrhoea was only in 5 patients. These findings are contrary to an audit conducted in the year 2016 on prescriptions of 103 patients in the age group of up to 12 years admitted with diarrhoea where maximum admissions were of the patients with some (50.5%) dehydration and severe dehydration (36%).⁹ Below 10% admissions were of the cases of persistent diarrhoea and dysentery in the present study which are similar to a study conducted in Italy in 2014.¹⁰ Diarrhoea is of great concern when it is associated with severe malnutrition, as the focus is not only at careful

management of the nutrition status in addition to the prevention of dehydration, but also at the prevention of systemic infection and fatality associated with it. Underlying malnutrition with diarrhoea was observed in very few cases, as not being a government hospital. This finding was in contrast to a study from other parts of government hospitals in India where the associated malnutrition was observed in relatively more patients.⁸

WHO guidelines recommend the use of ORS and zinc for all children who present with or without some degree of dehydration. Even if the child needs intravenous therapy, he or she should be shifted to oral therapy as soon as the signs of dehydration improve. ORS and zinc were prescribed in 62% and 81% of children respectively in the present study. The use of ORS was comparatively more than studies reported from elsewhere in the country but a long journey is yet to be covered in achieving 100% results.¹¹ It has been recorded to be as low as 2% in the neighbourhood countries, although up to a maximum of 100% reported earlier in India.^{9,12} In the last national health survey conducted in the state of Uttarakhand, zinc supplementation was observed in 30.4 % of the children. It is quite assuring that zinc prescribing was frequent in this hospital setup.

Clinical guidelines are developed to give recommendations about appropriate health care aim to improve the quality of care. WHO guidelines do not support the use of antiemetic, antacids, anti-diarrhoeal and Pre- and probiotics. Unfortunately, deviation from the protocol was observed in substantial number of patients in this study. Use of probiotics was frequently seen (43%), although anti-diarrhoeal use was seen in only 6% patients. Although the values are comparatively less when compared to other study where probiotics was prescribed to 68% patients and racecadotril to 19%.¹³ One more study records the use of Pre/probiotics to be 66.6%.¹⁴ Deviation was noticed for the use of Multivitamin that were unnecessarily prescribed in 18 patients which is slightly more than earlier data reported in India.⁸

The inpatients in this study were followed up till discharge from the time of admission. As per PQI tool, 10% of prescription had at least one drug that duplicated in one or other formulation. The duplication was mostly observed for zinc preparations. Similar poor quality of prescription (36%) by PQI tool was reported in patients suffering from hypertension and bronchial asthma also in India.¹⁵ The findings in this study confirms rational approach to the use of ORS and zinc in majority of patients while a huge deviation from the WHO standard guidelines with poor quality of prescription was observed in context of parenteral therapy, antiemetic, probiotics, antidiarrheal and antimicrobials use.

Overall the quality of prescription in the study as observed elsewhere also was poor with utter disregard to adherence to the standard guidelines. A variety of unnecessary drugs were in use that may not have any rationality in treating

acute and persistent diarrhoea in children up to five years of age. Such studies will definitely expose the pitfalls of present management and it may lay down the path for corrective measures for successful management of such a common disorder of children that is still linked with substantial morbidity and mortality. Still a lot needs to be done to set the standards of treatment in line with WHO standard guidelines for rational prescription in diarrhoeal disorders in children under the age group of five years.

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