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A Prospective Study Conducted to Evaluate the Prescription Practices on Paediatric Patients Suffering From Acute Diarrhea

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ABSTRACT

Background: Diarrhea is a leading killer of children, accounting for 9% of all deaths among under-five children worldwide. WHO protocol deviation in management of diarrheas in children is likely due to various reasons. Aim: To study the prescription practices, regarding adherence to WHO protocol and deviations, in the management of acute diarrhea in children presenting at a tertiary care hospital and its impact on the outcome. **Methods:** This was a prospective observational hospital based study at a tertiary care carried out over a 12- month period including all cases of acute diarrhea (defined as 3 or more loose stools in last 24 hours) in children belonging to the age group of 6 months to 5 years. Patients were followed up on day 3,7,14 and 28 from the day of presentation. Software SPSS Version 17.0 was used for analysis. Correlation regression analysis was used to study predictiveness of different variables affecting outcome. **Results:** In this study, 447 children aged between 6 months and 5 years were enrolled, of which 45 cases were lost in follow-up and excluded. The median age was 14 months. Some deviation from WHO protocol was noted in 78.4% of the cases. Most common deviations from WHO protocol were addition of probiotics (78.1% of cases) and addition of race cadotril (15.9% of cases). Inadvertent use of antibiotics in diarrhea was noted in 12.2% of cases. Presence of fever was strong predictor for use of antibiotics. Cases of early recovery within 3 days of presentation were higher in WHO protocol deviation group. Use of probiotics had statistically significant association with early recovery. **Conclusion:** In diarrhea management, WHO protocol deviation is common. Probiotics are likely to help in early recovery.

Keywords: Gastroenteritis, Oral rehydration solution, Probiotics, Racecadotril, WHO.

INTRODUCTION

Diarrhea accounts for 9% of all deaths among children under 5 years of age worldwide.[1] In 2012, this resulted in deaths of more than 580,000 children around the world.[1] Every day 2,195 children die of diarrhea which is more than than AIDS, malaria, and measles combined.[2] Diarrhea is one of the top five causes of death among infants and under-five children in India.[3] Oral Rehydration Therapy (ORT) with Oral Rehydration Salt (ORS) is the most important and effective strategy to reduce mortality resulting from diarrhea in children. However, data from United Nations Children's Fund (UNICEF) Coverage Evaluation Survey (CES) and the third National Family Health Survey (NFHS-3) show that ORS usage rates were still un-acceptable; while unwarranted anti- diarrheal drugs and injections continue to be prescribed frequently.[3] In this study audit of prescription practices and outcome in terms of duration of illness and recovery or death was done in cases of diarrhea in children of age group of six months to five years presenting in a tertiary care center over a period of one year. This study was aimed to understand the patterns of deviations from WHO protocol for management of diarrhea in children of age group 6 months to 5 years.[4] The other objective of the study was to analyse the factors affecting the protocol deviation and its impact on outcome if any.

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MATERIALS AND METHODS

All children (6 months to 5 years) who presented with acute diarrhea (defined as presence of 3 or more episodes of loose stools in last 24 hours, as per WHO/F-IMNCI guidelines) at the tertiary care hospital attached to a medical college in Western India for a period of one year were included provided parents were willing to give consent for the study and after considering inclusion and exclusion criteria.

Inclusion criteria

1) Children of either gender in the age group 6 months to 5 years.
2) Children having acute diarrhea defined as three or more loose stools in last 24 hours (duration of loose stools less than 14 days).
3) Written informed consent provided by parents/guardian/ caretakers about participation in the study.

4) Parents/guardians/caretakers having mobile number/telephone number and willing to give information over phone calls as telephonic follow-up is a part of the study or parents willing to follow-up by four personal visits to the hospital for the purpose of the study.

Exclusion Criteria

1) Children who have been given probiotics/prebiotics or antibiotics or zinc or any other drugs for acute gastroenteritis/diarrhea from outside prior to presentation. (However, children being treated symptomatically with paracetamol for fever or antiemetics like domperidone or ondansetron for vomiting will not be excluded).

This study was done on outdoor patients as well as admitted patients at tertiary care hospital and was initiated after obtaining approval of the institutional ethics committee. Each enrolled case was evaluated in detail for clinical history, physical examination, prescription given by treating doctor at the hospital and associated co-morbidities were also noted. Data collected was entered in a pre- designed case record form. Follow-up was done over telephone/ during personal visits to hospital, by speaking to the parents on day 3,7,14 and 28 from the day of presentation and data was entered in the follow-up checklist in the case record form. Each prescription was scrutinized to determine whether WHO protocol for management of diarrhea in children was followed or not.[4] Case record form included parameters like use of probiotics, racecadotril, antispasmodics, inadvertent use of antibiotics, undue IV fluids and inadequate zinc or ORS prescription along with outcome parameters like duration of illness, complications, recovery or death and possible recurrence. Any change in prescription was also noted down in the case record form.

Statistical Analysis

At the end of data collection, complete data from all the case record forms were entered in a Master-chart in MS-EXCEL format for analysis. The statistical analysis was based on standard statistical tests using Microsoft Excel and SPSS software (version 17.0) and data was presented in form of tables and graphs.

RESULTS

In this study, 447 children aged between 6 months and 5 years were enrolled, of which 45 cases either did not take medicines as per advice or could not be traced on telephonic follow-up and were excluded from all statistical analysis. Mean age at presentation of children presenting with loose motions was 21.61 ± 16.67 months while median age of presentation was 14 months. The male-female ratio was 1.196:1. There was some deviation from WHO protocol in 78.4% of the cases. However in all cases, ORS and zinc were prescribed in adequate doses as per WHO protocol. Following were the major deviations from WHO protocol with respect to individual category of drugs:

a) Probiotics were added in 78.1% of cases.
b) Racecadotril was added in 15.9% of cases.
c) There was protocol deviation regarding antibiotic use in 12.2% of cases.
d) There was protocol deviation regarding use of intravenous fluids in 2.5% of cases. There was no prescription of anti-spasmodics or ayurvedic medicines.

Table 1: Table showing analysis between indoor (IPD) and outdoor (OPD) patient and use of antibiotics (as per WHO protocol or not) (N=402).

OPD/iPD		Antibiotic (used or not/Who protocol followed or not)			Total
		Used but deviated	Not used but followed	Used and followed	
IPD	No.	9	16	36	61
	%	14.8%	26.2%	59.0%	100.0%
OPD	No.	40	278	23	341
	%	11.7%	81.6%	6.7%	100.0%
Total	No.	49	294	59	402
	%	12.2%	73.1%	14.7%	100.0%

Chi-Square Tests	Value	df	p-value	association is-
Pearson Chi-Square	118.351	2	2.00 × 10-26	Significant

Table 2: Table showing analysis between duration of loose motion (days) and use of antibiotics (as per WHO protocol or not) (n=402).

Loose motion duration before presentation (days)		Antibiotic (used or not/Who protocol followed or not)			Total
		Used but deviated	Not used but followed #	Used and followed #	
1 to 3	No.	23	200	37	260
	%	8.8%	76.9%	14.3%	100.0%
4 to 6 ^	No.	10	89	14	113
	%	8.8%	78.8%	12.4%	100.0%
7 &> ^	No.	16	5	8	29
	%	55.2%	17.2%	27.6%	100.0%
Total	No.	49	294	59	402
	%	12.2%	73.1%	14.7%	100.0%

Chi-Square Tests	Value	df	p-value	association is-

Pearson Chi-Square $	64.493	4	3.29× 10-13	Significant
Pearson Chi-Square ^, #	7.593	1	0.006	Significant

$ 2 cells (22.2%) have expected count less than 5. ^, # Row & Column data pooled & Chi-Square Test reapplied with Continuity Correction.

Table 3: Table showing analysis between presence of fever and use of antibiotics (as per WHO protocol or not) (n=402).

Fever		Antibiotic (used or not/Who protocol followed or not)			Total
		Used but deviated	Not used but followed	Used and followed	
Yes	No.	41	80	49	170
	%	24.1%	47.1%	28.8%	100.0%
No	No.	8	214	10	232
	%	3.4%	92.2%	4.3%	100.0%
Total	No.	49	294	59	402
	%	12.2%	73.1%	14.7%	100.0%

Chi-Square Tests	Value	df	p-value	Association is-
Pearson Chi-Square	101.942	2	7.31× 10-23	Significant

Table 4: Table showing analysis between grade of dehydration and racecadotril addition (n=402).

Grading of dehydration		racecadotril added		Total
		Yes-deviation from protocol	no	
Severe Dehydration ^	No.	4	13	17
	%	23.5%	76.5%	100.0%
Some Dehydration ^	No.	8	18	26
	%	30.8%	69.2%	100.0%
No Dehydration	No.	52	307	359
	%	14.5%	85.5%	100.0%
Total	No.	64	338	402
	%	15.9%	84.1%	100.0%
Chi-Square Tests	**Value**	**df**	**p-value**	**association**
Pearson Chi-Square $	5.571	2	0.062	Not significant
Pearson Chi-Square ^	4.214	1	0.040	Significant

$ 2 cells (33.3%) have expected count less than 5. ^Row data pooled & Chi-Square Test reapplied with Continuity Correction.

Table 5: Table showing analysis between indoor (IPD) and outdoor (OPD) patient and probiotic addition. (n=402).

OPD/IPD		Probiotic added		Total
		Yes-deviation from protocol	No	
IPD	No.	54	7	61
	%	88.5%	11.5%	100.0%
OPD	No.	260	81	341
	%	76.2%	23.8%	100.0%
Total	No.	314	88	402
	%	78.1%	21.9%	100.0%
Chi-Square Tests	**Value**	**df**	**p-value**	**association**
Pearson Chi-Square	4.562	1	0.033	Significant
Continuity Correction	3.872	1	0.049	Significant

Table 6: Table showing analysis between indoor (IPD) and outdoor (OPD) patient and probiotic addition (n=402).

Loose motion duration before presentation (days)		Probiotic added		Total
		Yes-deviation from protocol	No	
1 to 3	No.	213	47	260
	%	81.9%	18.1%	100.0%
4 to 6	No.	75	38	113
	%	66.4%	33.6%	100.0%
7 &>	No.	26	3	29
	%	89.7%	10.3%	100.0%
Total	No.	314	88	402
	%	78.1%	21.9%	100.0%
Chi-Square Tests	**Value**	**df**	**p-value**	**Association**
Pearson Chi-Square	13.578	2	0.00113	Significant

Table 7: Table showing Binary Logistic Regression between WHO Protocol Deviation as dependent variable and a set of Independent (Predictor) Variables in cases (n=402).

Dependent Variable encoding				
Who Protocol Deviated		**Internal Value**		
Yes		1		
No		0		
Categorical variable coding		**Frequency**	**Parameter coding**	
			1	**2**
Grading of dehydration	No Dehydration	359	1	0

	Some Dehydration	26	0	1
	Severe Dehydration	17	0	0
Fever	No	232	1	
	Yes	170	0	
OPD/IPD	OPD	341	1	
	IPD	61	0	

Block 1: Method = enter Model Summary		
-2 Log likelihood	**Cox & Snell r Square**	**nagelkerke r Square**
348.075	0.164	0.253

Variables in the equation:

Variables	**b**	**S.e.**	**Wald**	**df**	**Sig.**	**exp (b)**
Age (months)	-0.017	0.008	5.159	1	0.02313	0.983
OPD/IPD (OPD)	1.205	0.783	2.370	1	0.124	3.338
Fever (No)	-2.605	0.451	33.369	1	7.62×10-09	0.074
Grading of dehydration			4.350	2	0.114	
Grading of dehydration (No Dehydration)	-2.096	1.341	2.443	1	0.118	0.123
Grading of dehydration (Some Dehydration)	-0.052	1.357	0.001	1	0.970	0.95
Constant	4.509	1.188	14.400	1	1.5×10-04	90.828

Table 8: Table showing Binary Logistic Regression between Loose motion duration after presentation (days) as dependent variable and a set of Independent (Predictor) Variables in cases (n=402).

Dependent Variable encoding	
Loose motion duration after presentation (days)	**internal Value**
4 & >	1
1 to 3	0

Block 1: Method =enter Model Summary		
-2 Log likelihood	**Cox & Snell r Square**	**nagelkerke r Square**
525.91	0.057	0.076

Variables in the equation:

Variables	**b**	**S.e.**	**Wald**	**df**	**Sig.**	**exp (b)**
Age (months)	-0.001	0.006	0.040	1	0.841	0.999
Probiotics addition (deviation)	-0.760	0.269	7.974	1	0.005	0.468
Racecadotril addition (deviation)	0.029	0.308	0.009	1	0.924	1.03
Antibiotic deviation	0.458	0.322	2.028	1	0.154	1.582
Intravenous fluid deviation	-1.267	0.831	2.327	1	0.127	0.282
SAM present	1.012	0.514	3.871	1	0.049	2.751
Constant	0.105	0.271	0.150	1	0.698	1.111

Table 9: Table showing comparision of findings of different published studies conducted on management of diarrhea in children (in different parts of India) with the present study.

Serial no.	**Name of the study**	**Journal/ Year of publication/author**	**Study design**	**Place of study (age group of children selected in study)**	**Salient points.**	**Comparison with present study**
1.	Lactobacillus GG for treatment of acute childhood diarrhea: an open labelled, randomized controlled trial.[12]	Indian J Med Res 2014 S Aggarwal et al.,	Open labelled Randomized controlled trial.	Teaching hospital in Northern India/ outpatients (6 months to 5 years).	Lactobacillus GG resulted in shorter duration of diarrhea and faster recovery of consistency of loose stools.	Present study also showed early recovery (duration of loose motion after presentation up to 3 days was higher in the group where probiotics were added compared to the group where probiotics were not added).
2.	Prescribing pattern and appropriateness of drug treatment of diarrhea in hospitalised children at a tertiary care hospital in India.[7]	Int J Med Public Health, 2013 J R Panchal et al.,	Prospective observational study.	Tertiary care teaching hospital in western India, only hospitalized children (1 month to 12 years).	99.02 % of children received ORS while 95.15% received zinc; 100% received antibiotics though indicated in only 38.83 % of cases.	ORS and zinc were prescribed in 100 % of cases. Antibiotics were used in only 26.9% of cases with inappropriate use in 12.2% of cases.

3.	Antibiotic-prescribing practices of primary care prescribers for acute diarrhea in New Delhi, India.[6]	Value Health, 2012 Kotwani A et al.,	Prospective observational study.	Public sector facilities and private clinics in Delhi (children and adults).	Private practitioners prescribed antibiotics in 51.5% of children with diarrhea, whereas public sector pediatricians prescribed antibiotics in 23% of children. At public facilities, the most commonly prescribed antibiotic was norfloxacin.	In this public sector teaching hospital facility, antibiotics were used in 26.9% of cases with cefixime being the most common oral antibiotic used.
4.	Adherence to treatment guidelines for acute diarrhea in children up to 12 years in Ujjain, India--a cross-sectional prescription analysis.[5]	BMC Infect Dis 2011, D Pathak et al.,	Cross-sectional study.	Major hospitals and pharmacies (children upto 12 years were included).	Antibiotics were prescribed in 71 % of cases. Only ORS and zinc were prescribed in 1% of cases.	Antibiotic usage lower (26.9%), only ORS and zinc in 20.9% of cases.
5.	Prescribing practices of doctors in management of acute diarrhea.[13]	Indian Pediatr 2011 S Chakraborti.	Prospective observational study.	Government teaching hospital, out patients (6 months to 5 years).	Pre/probiotics were prescribed in 66.6% of cases , ORS was not prescribed by the paediatricians in 5.7% of cases.	Probiotics were prescribed in 78.1% of cases whereas ORS was prescribed in all cases.
6.	Management of Diarrhea in Under-fives at Home and Health Facilities in Kashmir.[14]	Int J Health Sci (Qassim). 2009 Fayaz Ahmed et al.,	Cross sectional study.	Villages in Kashmir (under 5 children).	Antibiotics were prescribed in 77% of cases whereas only 8.7% of children just received ORS.	ORS was used in 100 % of cases whereas antibiotics were prescribed in only 26.9 % of cases.
7.	Prescribing pattern of zinc and antimicrobials in acute diarrhea.[15]	Indian Pediatr, 2008 S Balasubramanian et al.,	Retrospective analysis of case records.	Private tertiary care hospital in Chennai, only hospitalized children (1 month to 5 years).	Zinc was prescribed in 65% of cases,41.8 % received antibiotics with ceftriaxone being most common injectable antibiotic.	Zinc used in all patients, antibiotic usage lower with ceftriaxone being the most common injectable antibiotic.

Most commonly used injectable antibiotic among the total antibiotics used was ceftriaxone (10.6%), whereas most commonly used oral antibiotic among all the antibiotics used was cefixime (31.7%).

Parameters like admitted patient [Table 1], longer duration of loose motions prior to presentation [Table 2] and associated fever [Table 3] had statistically significant association with prescription of antibiotics with p-value less than 0.05 where-as grade of dehydration had no significant association.

Presence of dehydration (some or severe) at presentation, had statistically significant association with prescription of racecadotril [Table 4] where-as grade of dehydration and duration of loose motion prior to presentation had no significant association.

Factors like admitted patient [Table 5] and longer duration of loose motion prior to presentation [Table 6] had statistically significant association with prescription of probiotics with p-value less than 0.05 where-as grade of dehydration had no significant association. In majority of the cases, duration of diarrhea was one to three days (57%) and only a few cases had persistence of diarrhea for seven or more days (2.7%). Mean duration of loose motion in days after presentation was 3.53 ± 1.72 (mean ± standard deviation) days.

In [Table 7], it is seen that age of the child and presence of associated fever was significant predictor of WHO protocol deviation. Lesser the age group among the study subjects more were chances of deviation from WHO protocol. Also, presence of associated fever was associated with more deviation from WHO protocol.

In [Table 8], it is seen that use of probiotics and presence of associated Severe Acute Malnutrition (SAM) had significant association with duration of loose motions after presentation. Lesser probiotic use was associated with more chances of having longer duration of diarrhea (4 or more days). Also, presence of SAM was associated with more chances of having longer duration of diarrhea.

DISCUSSION

Only in 21.6% of patients, WHO protocol for management of diarrhea in children was strictly followed, whereas in remaining there was some deviation from WHO management protocol. In this study, use of adjunct medications (like probiotics, racecadotril, antibiotics) apart from ORS and zinc were found in 79.1% similar in other hospital based cross-sectional quantitative studies.[5] The phrases

"WHO protocol deviation and adherence" were not used in most of the studies till date.

WHO protocol for management of diarrhea is primarily based on provision of extra fluids (in form of ORS, home based fluids) orally or intravenously according to grade of dehydration (plan A,B or C) along with use of oral zinc for 14 days.[4] The routine use of antimicrobials in management of diarrhea in children is not recommended by WHO except for the following situations:[4]

- Cases of bloody diarrhea (dysentery).
- Suspected cases of cholera with severe dehydration.
- Laboratory proven, symptomatic infection with Giardia.
- Admitted cases of diarrhea with severe acute malnutrition.
- Diarrhea associated with another acute infection, (e.g., pneumonia, urinary tract infection) that infection also requires specific antimicrobial therapy.

Use of probiotics, racecadotril or anti-spasmodics is not recommended by WHO.

In the study, there was no deviation from WHO protocol in use of ORS and zinc in management of diarrhea. There was only minor deviation in use of intravenous fluids (2.5%) whereas deviation in antibiotic use was higher (12.2%). Most common deviation was use of probiotics (78.1%) followed by use of racecadotril (15.9%).

In study by Kotwani et al., while paediatricians working in government sector prescribed antibiotics to only 23% of children, private practitioners prescribed antibiotics to 51.5% of children with diarrhea.[6] Compared to other similar studies,[7,8] inappropriate prescription of antibiotics was much lower in this study, as being a tertiary care centre there was increased awareness among prescribers about WHO protocol for antibiotics in management of diarrhea. However, inappropriate use of antibiotics continues to be much higher in community and among primary care prescribers.

Most common protocol deviation among all the cases was addition of probiotics. The possible reasons may be they are easily available, cheap, available free of cost from hospital supply (in many government centres) and overwhelming evidence about their efficacy in reducing duration of diarrhea and stool frequency. Meta-analysis on use of probiotics in diarrhea by Allen et al., revealed that probiotics were effective in reduction of frequency of stools and were safe.[9] The study also concluded that probiotics helped in shortening of duration of loose stools when used alongside rehydration therapy, Next most important deviation was use of racecadotril. Recent studies including meta-analysis along with the facts that racecadotril is cheap,[10] easily available and has negligible side effects, often leads to their use as an adjunct to routine rehydration and zinc therapy particularly in more severely affected cases having some or severe dehydration. However, in spite of these studies, racecadotril was not included in WHO essential list of drugs as concerns were raised regarding its use outside hospital settings and in less severely affected infants.[11]

By binary logistic regression between WHO protocol deviation as dependant variable and a set of independent (predictor) variables, it was found that 'age group' and associated fever were significant predictors of WHO protocol deviation. Lower age and presence of fever were associated with more deviation from WHO protocol. Whereas, parameters like grading of dehydration and OPD/ admitted patient were not significant. This is likely to be due to the fact that presence of fever often leads to unnecessary prescription of antibiotics and thus deviation from WHO protocol.[4]

In [Table 9], findings of different published studies conducted on management of diarrhea in children (in different parts of India), is compared with those of the present study.

Limitation

Firstly, follow-up in this study was largely based on telephonic conversation with parents on day 3, 7, 14 and 28 from day of presentation. Secondly, all the cases who had taken treatment or medications for current episode of diarrhea from outside, prior to their presentation in the hospital, were excluded and this led to exclusion of a significant number of cases.

CONCLUSION

In the study, majority (57%) had duration of loose motion between 1 to 3 days after presentation with mean duration of loose motion in days after presentation being 3.53 ± 1.72 (mean ± standard deviation) days. Most of the patients had recovered from loose motions and mortality rate was only 1.2 % with most common cause of sepsis. There was no case of persistence of loose motions beyond 28 days of presentation. On analysis of co-morbidities, it was found that most common co-morbidity was severe acute malnutrition (7.2% of cases).

Presence of associated SAM had statistically significant association with longer duration of diarrhea (for more than 3 days). Also, in cases where probiotics were not used, there were more chances of diarrhea persisting for more than 3 days ($p<0.05$). There were no cases of recurrence in first 28 days and only a minority of cases developed complications. Poly-pharmacy was prevalent in 80.8 % of the cases.

Recommendations

Firstly, identification of specific pathogen involved in diarrhea like Rotavirus etc. will be more effective in analysing the outcome of diarrhea and duration of illness. Secondly, Questionnaire based study for doctors regarding prescription practices should be

included to determine doctors' perspective and perception regarding use of different medications.

A multicentre study with large sample size will be required to confirm the need or significance of protocol deviation in a substantial contributory manner to find out need for any modification the WHO protocol.

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