Pattern of Drug usage of non-Specific Anti-Diarrheal Agents in Acute Diarrhea in a Rural Set up in Pune District, Maharashtra

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ABSTRACT

Introduction: In clinical practice, nonspecific antidiarrheals (allopathic and ayurvedic) are most commonly used by clinicians along with routine treatment to hasten the recovery and to give psychological reassurance. This study was conducted to find out the pattern of drug usage in cases of acute diarrhea in clinical practice.

Material and methods: This was a prospective, observational study done in clinical settings for a period of 3 years at two pediatric clinics and at a tertiary care hospital. 600 prescriptions for acute diarrhea were analyzed. Use of two allopathic (loperamide and racecadotril) and two ayurvedic (Mebarid and Diarex) anti-diarrheal agents was assessed. No. and percentage of prescriptions having these nonspecific antidiarrheals were analyzed.

Results: A total of 600 patients were enrolled in the study. Racecadotril was the most commonly prescribed allopathic antidiarrheal (175) compared to loperamide (34). Mebarid was commonly prescribed ayurvedic antidiarrheal (123) compared to Diarex (78).

Conclusion: This study suggests that racecadotril was the preferred antidiarrheal in clinical practice in children with acute diarrhea.

Keywords: Acute diarrhea, Diarex, Drug Usage, Loperamide, Mebarid, Nonspecific antidiarrheals, Racecadotril

INTRODUCTION

Acute diarrhea, defined as diarrhea occurring within a minimum period of 24 hours and lasting usually for less than 7 days, accounts for significant morbidity and mortality in children.[1] Antimicrobial agents have limited role in its management as most episodes of diarrhea are self-limited. ORS forms the mainstay in treatment of diarrhea.[2-4] Its use prevents and corrects dehydration, reduces the morbidity and mortality; but it does not reduce frequency and volume of stools or the duration of diarrhea.[5] Hence, nonspecific antidiarrheals are commonly used in clinical practice.[6-8]

Both, allopathic and ayurvedic anti-diarrheal agents are freely available and are widely used. Present study was undertaken to know the trends of drug prescribing of nonspecific antidiarrheals in acute diarrhea in children. To find out the pattern of drug usage of nonspecific antidiarrheals in acute diarrhea in children.

MATERIAL AND METHODS

This was a prospective, observational study done in clinical settings from April 2011 to March 2014. The study protocol was approved by Institutional Ethics Committee. It was conducted at following centres after obtaining their permission

1. Pediatric clinic (secondary care hospital), Talegaon, Pune, Maharashtra.
2. Pediatric clinic (secondary care hospital), Chakan, Pune, Maharashtra.
3. Tertiary care hospital, Talegaon, Pune, Maharashtra.

Study population and study design: Children suffering from acute diarrhea and fulfilling the selection criteria (Table 1) were enrolled into the study. Their parents were informed about the study in simple and lucid language. Informed written consent was obtained from the parents and ascent was obtained from children between 7 to 10 years. Baseline demographic and clinical charecteristics were recorded.

Children were treated at the discretion of the pediatricians, who were explained about the study. All children received oral rehydration therapy (ORT).The antidiarrheals were prescribed till recovery. Control group consisted of patients who did not receive any nonspecific antidiarrheal. Exclusion criteria are shown in table 2.

Data collection and data analysis - Prescription audit was conducted and prescriptions were analyzed in detail. Use of

1. Age: 2 - 10 years.
2. Acute diarrhea of varied etiology.
3. Duration of diarrhea of < 2 days.
4. Diarrhea with mild co – morbidity.
5. No h/o of treatment with antimicrobials/antidiarrheals/antimotility drugs within the preceding 7 days.

Table-1: Inclusion criteria

1. Age < 2 and > 10 years.
2. Iatrogenic / bloody diarrhea / or severe diarrhea e.g. cholera.
3. Diarrhea with severe dehydration / significant systemic illnesses.
4.Children with severe malnutrition (BW<50% of expected for that age).
5. Children receiving pre / probiotics and / or zinc.

Table-2: Exclusion criteria

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Parameters	Control (n=190)	Racecadotril (n=175)	Mebarid (n=123)	Diarex (n=78)	Loperamide (n=34)
Age(y)	4.79±0.16	4.16±0.14	4.43±0.20	7.05±0.19 *	7.65±0.26 *
Sex (M:F)	103:87	84:91	54:69	40:38	19:15
Weight (Kg)	16.07±4.24	15.03±3.62	15.45±4.47	20.54±3.32*	21.59±3.06*
No dehydration Some dehydration	102 (54) 88 (46)	78 (45) 97 (55)	69 (56) 54 (44)	31 (40) 47 (60)	20 (59) 14 (41)
Duration of diarrhea before enrolment (h)	45.16±1.13	41.55±1.27	42.24±1.34	40.61±1.70	39.84±2.35
Frequency of stools/day	4.98 ±0.12	5.18 ±0.14	5.27 ±0.17	5.49±0.21	5.68±0.30
Vomiting (No.of children)	24 (13)	18 (10)	26 (21)	9 (12)	5 (9)
Fever (No.of children)	35 (18)	21 (12)	11 (9)	14 (18)	3 (9)
Comedication: Antiemetics Antpyretics (No.of children)	 12 (50) 21 (60)	 8 (44) 15 (71)	 19 (73) 10 (91)	 6 (67) 10 (71)	 5 (100) 2 (67)
Antibiotics for co-morbidity (No.of children)	40 (21)	37 (21)	30 (24)	25 (32)	4 (12)
Figures are Mean +/- SEM, No significant difference between the various groups.					

Table-3: The base-line parameters of patients in the study

Group	Number	Percentage
Control	190	32
Racecadotril	175	29
Mebarid	123	20
Diarex	78	13
Loperamide	34	6
Total	600	100

Table-4: Distribution of 600 children studied

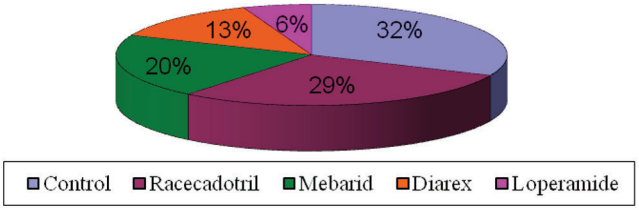

Figure-1: Pie Diagram showing pattern of use of nonspecific antidiarrheals

two allopathic (loperamide and racecadotril) and two ayurvedic (Mebarid and Diarex) anti-diarrheal agents was assessed. Administration of concomitant medications such as antipyretics, antiemetics etc.were recorded. All the information was recorded in a predesigned CRF (Case Report Form). Follow up was done on 3rd, 5thand 7th day of treatment. In cases of failure to follow up, personal visit was done by investigator. A telephonic check was carried out daily.

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS version 17 and primer of biostatistics. Statistical analysis was done by appropriate methods using Chi-square test, Student's unpaired "t" test, ANOVA followed by Tukey's multiple comparison tests as required. Data obtained are expressed as mean ± SEM. $P<0.05$ was considered as significant.

RESULTS

600 patients were enrolled and out of which 584 successfully completed the study as per the protocol. Sixteen patients did not turn for the follow up. However, telephonic feedback was obtained successfully from them. Overall compliance in our study was good (90%). The base-line parameters are shown in Table 3. There was no significant difference between the five groups.

Racecadotril was the most commonly used allopathic antidiarrheal (29%). Mebarid was commonly used ayurvedic antidiarrheal (20%) (Fig-1 and table 4)

DISCUSSION

Racecadotril was the most commonly used allopathic antidiarrheal (29%) compared to loperamide (6%). This finding is consistent with study by Uhlen et al (2004), who surveyed the pattern of drug usage by private pediatricians in France.[9] Loperamide was used preferably in older children and proved to be a useful adjuvant drug to ORS.

Racecadotril was preferred over loperamide in clinical practice because it does not affect gut motility, hence may not affect clearance of pathogens. The pure antisecretory action of racecadotril, its high therapeutic index even in young children, lack of significant CNS related adverse effects make it a preferred anti-diarrheal agent in practice.

There is less incidence of adverse events like constipation and abdominal distension with racecadotril. Some comparative studies carried out in adults and children support these advantages.[6]

Mebarid was more commonly used ayurvedic antidiarrheal (20%) as compared to Diarex (13%). Mebarid, a polyherbal preparation contains Bael, Ajmoda, Lodhara, Dadim, Badishep, Daruhalad, Jaiphal, Sunth, Ativis and Kuda. Diarex is a herbomineral ayurvedic preparation containing Kuda, Guduchi, Bael Dadim, Shankh bhasma and Musta. There is no satisfactory explanation for preferential use of Mebarid over that of Diarex. However, use of Diarex in children > 5 years of age might be due to its availability in tablet form.

CONCLUSIONS

This study suggests that racecadotril was the preferred antidiarrheal in clinical practice in children with acute diarrhea, may be because of its anti-secretory action,leading to symptomatic relief and its lack of effect on gut motility, assuring the clinicians of no effect on the clearance of pathogens.

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