Int J Pharm Bio Sci 2012 Oct; 3(4): (P) 97 - 103

Research Article **Pharmacology**

International Journal of Pharma and Bio Sciences **ISSN 0975-6299**

STUDY OF EFFICACY OF MEBARID - AN AYURVEDIC COMPOUND FORMULATION IN CHILDREN WITH ACUTE DIARRHEA

DR. S. BHUVANESHWARI *[1] AND DR. DANGE SURESH VISHNU [2]

*[1] * Department of Pharmacology, MIMER Medical College, Talegaon (D) - 410507, Maharashtra, India.*
[2] Department of Pharmacology, Dr. D. Y. Patil Medical College, Hospital & Research Centre, Pimpri, Pune-411018, Maharashtra, India.

ABSTRACT

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 prospective observational study was carried out at two private clinics run by pediatricians to find out the effect of Mebarid, an ayurvedic polyherbal formulation on the severity and duration of diarrhea and to assess its safety. 100 children aged 2 y to 10 y with acute diarrhea and fulfilling selection criteria were enrolled and divided into two treatment groups viz , Control and Mebarid. Data collection was done using case report forms and questionnaires. Outcome Measures used were 1.Duration of diarrhea 2. Stool frequency 3. Improvement in stool consistency. Mebarid improved stool consistency significantly earlier (d1 vs. d1.5) as compared to control group (P<0.001).It also reduced the frequency of stools significantly (P<0.001).However, there was no significant difference in duration of diarrhea.

Key words : Acute diarrhea, Mebarid, Nonspecific antidiarrheals, Children

DR. S. BHUVANESHWARI
Department of Pharmacology, MIMER Medical College, Talegaon (D) - 410507, Maharashtra, India

Corresponding author

INTRODUCTION

Diarrhea is a major health problem in developing countries. It kills more than 1 million children annually [1]. Diarrheal diseases cause a heavy economic burden on health services and the main consequences of diarrhea in children are dehydration and malnutrition. Acute diarrhea is defined as history of at least three loose or watery or unformed stools in a minimum period of 24 hours and usually lasting for the duration of less than 7 days [2]. In developing countries, it is mostly infectious in origin in children and is very often self limiting [3].

Antibiotics have a very limited role and do not alter the course of illness [4,5]. ORS forms mainstay in treatment of diarrhea[6]; but ORS does not reduce frequency & volume of stools or the duration of diarrhea.

Therefore, an effective anti-diarrheal treatment to prevent / reduce dehydration by reducing the frequency and duration of diarrhea would be beneficial. In clinical practice, nonspecific antidiarrheals (allopathic and ayurvedic) are most commonly used by clinicians along with routine treatment so as to hasten the recovery and to give psychological reassurance to patients / parents. Inspite of their extensive use in practice, there are variable reports regarding their efficacy [7,8,9].

A few nonspecific anti-diarrhoeals are available in allopathy like loperamide, diphenoxylate, racecadotril etc. However, their use is associated with adverse effects in children[5] .In traditional systems of medicine, many antidiarrheals are available [10,11,12, 13] .

Mebarid is one such preparation. It is a compound ayurvedic antidiarrheal formulation,(Table 1) commonly used in treatment of diarrhea.However,controlled clinical trials evaluating its efficacy in such cases are few [14,15] . Hence this study was designed to study the effect of Mebarid as add-on treatment in acute diarrhea in children.

Table 1
Composition of Mebarid
Each 10 ml of Mebarid contains

No.	Name of ingredient	Amount (mg)
1	*Bael*	100 mg
2	*Ajmoda*	100 mg
3	*Lodhara*	100 mg
4	*Dadim*	100 mg
5	*Badishep*	100 mg
6	*Daruhalad*	100 mg
7	*Jaiphal*	50 mg
8	*Sunth*	50 mg
9	*Atvish*	50 mg
10	*Kuda*	50 mg
11	*Sugar*	q.s

AIMS AND OBJECTIVES

1. To assess the effect of Mebarid on the frequency, severity and duration of acute diarrhea in children
2. To assess the safety and tolerability of Mebarid in children.

MATERIALS AND METHODS

Setting

This was a prospective, observational study done in clinical settings for a period of one year. Two private clinics,run by registered medical practitioners (pediatricians),were

selected after obtaining their informed written consent.The study protocol was approved by Institutional Ethics Committee of MIMER Medical College, Talegaon,Pune.

Study Population

Children suffering from acute diarrhea presenting with 3 or more unformed stools in 24 hours and fulfilling the selection criteria (Table 2) were enrolled in the study. Informed written consent was obtained from one of the parents.

They were divided into two treatment groups- Control and Mebarid at the discretion of pediatrician. Both groups were treated with routine antidiarrheal drugs,while Mebarid group received Mebarid in addition.Baseline demographic and clinical charecteristics were recorded which included-

Age, weight, height, immunization status, history of fever, vomiting, or other symptoms, prior use of any medication, Diarrhea- duration,frequency,character of stools (watery, mucoid, bloody etc), consistency of stool, degree of dehydration (mild, moderate or severe) etc.

A child could be enrolled only once, based on the inclusion criteria (Table 2)

Selection criteria

Table 2

Inclusion Criteria for enrollment was as follows

1. Age: 2 - 10 years
2. Acute Diarrhea of varied etiology
3. Diarrheal duration of less than 2 days.
4. Diarrhoea with co - morbidity which is not severe.

Child was excluded from the study if any of the exclusion criteria were met (Table 3).

Table 3

Children were excluded from the study based on following criteria

1.Children less than 2 yrs and above 10 yrs.
2.Chronic, iatrogenic or bloody diarrhea.
3.Children with severe diarrhoea and severe dehydration.
4.Children with severe malnutrition.
5.Children receiving pre/probiotics and/or zinc supplements or any other nonspecific anti-diarrheal drugs
6.Child with any other significant systemic illnesses

Data collection and data analysis

Prescription audit was conducted and prescription was analyzed in detail. Administration of concomitant medications such as antipyretics, antibiotics, antiemetics were recorded. Parents of children were informed in detail the study protocol in simple and lucid language. A questionnaire was provided to parents and they were instructed to fill and record the details of the diarrheal episodes till recovery.

All the information was recorded in a predestined CRF (Case Report Form) including the details of treatment drugs,which was filled on enrollment day in detail and on follow up days. Follow up was done on 3^{rd},$5^{th}$and 7^{th} day of treatment. In cases of failure to follow up, personal visit was done by investigator. A telephonic check was carried out daily. Any episode of complication, adverse effect or need for unscheduled use of IV fluids was recorded. Parents were sensitized to report the adverse effects like

abdominal distension, sleepiness, lethargy, vomiting or constipation etc, as early as possible.

Outcome variables

Efficacy criteria

1.The primary efficacy criterion was duration of diarrhea- time between initiation of treatment and production of the final diarrheal stool [16].

2. Secondary efficacy criteria consisted of frequency of stools after initiation of treatment until recovery and time needed for improvement in stool consistency[17,18].

Tolerability and safety were evaluated by recording the adverse effects experienced during treatment.

Recovery was defined as

1. Production of two consecutive normal stools
2. Production of one normal stool followed by 12 hours with no stool production.
3. No stool production for a period of 12 hours.

Stastical analysis: Statistical analysis was done using students unpaired t test. All the values are expressed as mean ± SEM. $P<0.05$ was considered as significant.

RESULTS

Total 100 children were enrolled ,50 in each group. Both the groups tolerated the treatment well and continued the medications as advised till the end of treatment. Compliance in our study was good.The base-line parameters are shown in Table 4. There was no significant difference between two groups.

Table 4
Base-line parameters of patients on enrolment :

Particulars	Control group	Mebarid group
1. No. of Patients	50	50
2. Age (y)	4.75 ± 0.29	4.22 ± 0.27
3. Sex (M:F)	28:22	30:20
4. Dehydration		
No Dehydration	12	16
Mild Dehydration	32	26
Moderate dehydration	06	08
5. Duration of diarrhea before enrolment (d)	1.83 ± 0.08	1.77 ± 0.10
6. Frequency of stools/day	5.40 ± 0.27	5.18 ± 0.26
7. Vomiting (No.of children)	06	09
8. Fever (No.of children)	04	08

Values are mean ± SEM.There was no significant difference between two groups.

Efficacy of Mebarid

Table 5

Group	Control (n=50)	Mebarid (n=50)
Time(h)needed for improvement in stool consistency	38.16 ± 1.96	23.88 ± 1.48 **
No. of stools till recovery	4.06 ± 0.20	3.12 ± 0.14 **
Duration of diarrhea (h)	55.56 ± 2.25	49.68 ± 1.96

Values are mean ± SEM
***** P<0.001 compared with Control.***

Assessment of efficacy

There was significantly earlier improvement in the consistency of stools in children treated with Mebarid as compared to control. The frequency of stools was also significantly reduced in Mebarid group.However,there was no significant difference in the duration of diarrhea in the two groups (table 5,Fig.1 , 2 & 3).

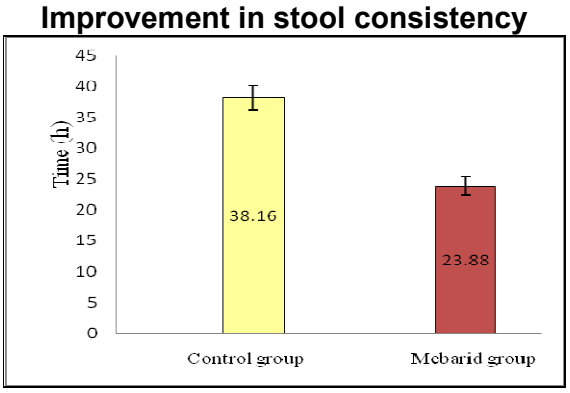

Figure 1
Time (h) required for improvement in stool consistency.
Data are mean ± SEM.

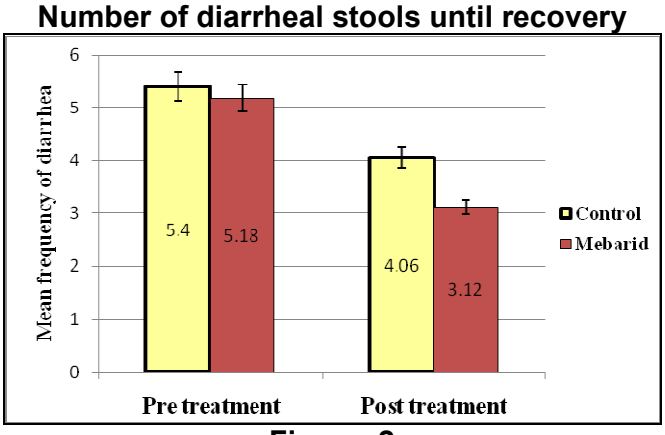

Figure 2
Number of stools passed during the 24 hours before and during treatment.
Data are mean ±SEM

Duration of diarrhea

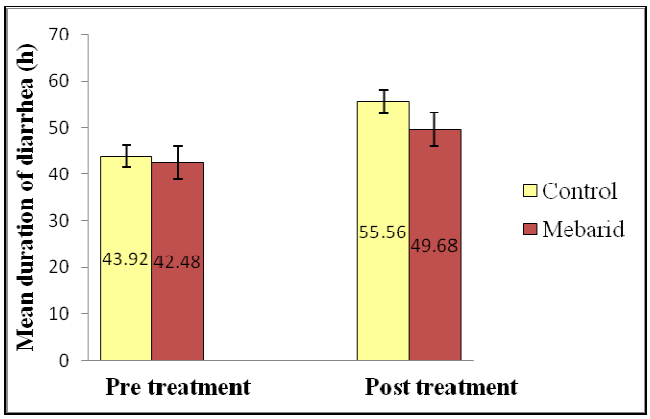

Figure 3
Mean duration of diarrhea (h) before and after treatment. Data are mean ± SEM.

Safety evaluation: Of 100 patients studied, 12 patients had fever on enrolment, which was cured by the second or third day of treatment with analgesics and appropriate antibiotics(Table 1). 15 patients had vomiting along with diarrhea which was controlled by day 3 with antiemetics. 3 patients from Mebarid group and 2 patients from control group complained of abdominal pain which was relieved by appropriate drugs. No serious adverse effects were recorded during the study.

DISCUSSION

Present study examined the effect of Mebarid treatment on clinical parameters in children suffering from acute diarrhea. The stool consistency and frequency,which are primary concerns of the parents, are significantly improved by Mebarid treatment. As is seen that the diarrheal frequency and duration was comparable in both groups initially, but after treatment, Mebarid treated group has shown faster improvement in frequency and consistency of stools. This may decrease the risk of dehydration and also give psychological satisfaction to the parents. There were no significant side effects or adverse reactions. Suffering of mothers and caretakers may be reduced to a great extent even by small improvement in symptoms by supplementation of Mebarid. Hence,Mebarid treatment could be a simple, acceptable and tolerable strategy in diarrhea treatment in children;although the duration of diarrhea is not altered by addition of Mebarid. The results obtained in the present open label study are preliminary in nature and require further confirmatory studies with larger sample size. Besides that,this study did not take into consideration effect on other associated symptoms in such patients and no laboratory tests were assessed.

CONCLUSION

Addition of Mebarid significantly hastens the recovery of children suffering from acute diarrhea by reducing frequency & improving consistency of stools. However, it does not significantly reduce the duration of diarrhea.

ACKNOWLEDGEMENTS

Authors are thankful to all participants of study for their participation and pediatricians and nursing personnel for their valuable support.

REFERENCES

1. Strand TA, Sharma PR, Gjessing HK, Ulak M, Chandyo RK ,Adhikari RK, et al. Risk factors for extended duration of acute diarrhea in young children. PLoS ONE 7(5): e36436. doi:10.1371/journal.pone.0036436, (2012).
2. Ravi Shankar,Singh SP,Tripathi CB.Persistent diarrhea:approaches for the management among under- five children.Indian J.Prev.Soc.Med , 35(3,4):112-120, (2004).
3. Ingle SB, Hinge CR. Gastroenteritis-overview. International Journal of Pharma and Bio Sciences, 3(2): www.ijpbs.net. (2012)
4. Ghai OP.Ghai essential pediatrics,6th Edn,New Delhi:CBS publisher: 276, (2005).
5. Tripathi K. D., Essential of medical pharmacology, 6th Edn,p (2008).
6. Students Handbook for Integrated Mangement of Neonatal&Childhood illness. New Delhi. WHO (Dept of Child &Adolescent Health &development) Ministry of health &Family Welfare, Govt of India; p 15,(2003).
7. Turck D, Berard H, Fretault N, et al. Comparison of racecadotril and loperamide in children with acute diarrhea. Aliment Pharmacol Ther, 13 (suppl.6):27-32, (1999).
8. Li Su-Ting , Grossman DC, Cummings P. Loperamide therapy for acute diarrhea in Children: Systematic review and meta-analysis . Plos med: 4(3):e98. Doi:10.1371/journal. Prned.0040098, (2007).
9. Santos M, Maranon R, Miguez C, et al.Use of racecadotril as outpatient treatment for acute gastroenteritis: a prospective, randomized, parallel study. J pediatr,155(1):62-67, (2009).
10. Rajamanickam V, Rajasekaran A, Anandarajagopal et al.Antidiarrheal activity of *Dodonaea Viscosa* root extracts. International Journal of Pharma and BioSciences, 1(4): www.ijpbs.net. (2010)
11. Srivastava RK, Singh RC, Bharadwaj SK, et al. A comparative study of antidiarrhoeal drugs most commonly used - allopathic, ayurvedic and homeopathic. Probe, 27(3):181-184, (1988)
12. Irfan S, Prabhakar B. Efficacy of new diarex in diarrhoea. Indian Pract, 54(7): 497-499 , (2001).
13. Shamkuwar PB, Sadhana R. Shahib, Deepak PP. Efficacy of Aegle marmelos L. Corr. (Rutaceae) in Ayurvedic antidiarrhoeal formulation. Euro. J. Exp. Bio, 2 (1):194-198,(2012).
14. Bafna P, Bodhankar S.Gastrointestinal effects of Mebarid, an ayurvedic formulation,in experimental animals. J of ethnophamacol,86(2-3):173–176,(2003).
15. Shamkuwar PB,Sadhana R,Shahi.Evaluation of antidiarrhoeal activity of Mebarid: an ayurvedic formulation. Int J Pharm Pharm Sci,4(2): 714-716, (2012).
16. Wang HH,Shieh MJ,Liao KF. A blind , randomized comparision of racecadotril and loperamide for stopping acute diarrhea in adults.World J Gastroenterol, 11(10):1540-1543,(2005).
17. Agarwal K N, Bhasin S K. Faridi MA, Mathur M, Gupta S. Lactobacillus Cassei in the Control of Diarrhea – a pilot study. Indian Pediatr, 38: 905-910,(2001).
18. Sajid A, Sajid S , Ahmad M. Therapeutic role of zinc;evaluation in patients with diarrheal illness.Professional Med J,17(3):472-478,(2010).