

Clinical evaluation of New Diarex in acute and chronic diarrhoea

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SUMMARY

A polyherbal formulation New Diarex was tested in 50 patients with acute and chronic diarrhoea. A dose of 2 tablets three times daily for 3 days followed by 1 tablet thrice daily for 2 days was administered in acute diarrhoea. Chronic diarrhoea patients were given 2 tablets thrice daily for 10 days. There was a significant reduction in frequency of stools in acute as well as chronic diarrhoea. The associated symptoms were also controlled.

INTRODUCTION

Diarrhoeal diseases are notorious for the huge morbidity and mortality they inflict on human population¹⁻³. Diarrhoea is formally defined as an increase in the frequency, fluidity or volume (weight) of bowel movements relative to the usual habits of the individual. Changes in the characteristics of the stools may also be associated with abdominal pain, rectal discomfort or tenesmus or passage of blood, mucous or pus⁴. It is considered acute when it lasts less than 7 - 14 days and chronic when it lasts more than 2-3 weeks. Diarrhoeal diseases due to their high mortality rates have always drawn the attention to adopt more measures for their control. In Ayurveda herbal drugs are used to treat diarrhoeal diseases⁵⁻⁶. New Diarex, an herbal formulation has been found to have antidiarrhoeal properties in experimental and pilot clinical studies⁷⁻⁹. The herbal formulation consists of Musta, Bilwa, Dadima and Kutaja.

MATERIAL AND METHODS

In the present study 50 indoor and outdoor patients of uncomplicated acute and chronic diarrhoea were selected randomly from the Department of Kayachikitsa, S.S. Hospital, B.H.U., Varanasi. The necessary investigations and relevant clinical symptomatology were evaluated before and after treatment to draw conclusions regarding the effect of New Diarex. Besides routine clinical examination of general symptomatology, certain laboratory investigations like stool, urine and blood were also done to confirm the diagnosis and to evaluate the response.

Treatment schedule

Dose: New Diarex was given at a dose of two tablets thrice daily.

Duration: In acute diarrhoea the drug was given at a dose of two tablets thrice daily for 3 days followed by one tablet thrice daily for 2 days.

Criteria of Assessment: The final assessment of response was done on the basis of its effectiveness in relieving clinical symptoms and eradication of pathogens in stool culture.

RESULTS

The present clinical trial was conducted to study the antidiarrhoeal activity of New Diarex which contain four common herbs, Musta, Bilwa, Dadima and Kutaja, used commonly in Ayurveda. Ayurvedic drugs not only act as antidiarrhoeal agents in acute diarrhoea but also correct the entire system to bring about symptomatic relief in associated symptoms, therefore the above combination was also tried in patients of chronic diarrhoea. A total of 50 patients registered for the trial, out of which 12 patients (24%) presented with diarrhoeal symptoms for more than a month. These patients were diagnosed with chronic diarrhoea and were given the trial drug at a dose of 2 tablets thrice a day for 10 days. The rest of the patients (76%) were suffering from acute diarrhoea, who received the trial drug, 2 tablets thrice a day, for 3 days, followed by one tablet thrice a day for 2 days. Seventy percent of the patients were between 21-40 years (Table 1). There was a 60:40 ratio of male to female patients (Table 2).

A definite decrease in the frequency of motions was recorded in almost all the patients. Improvement was also recorded in consistency of stools which was initially watery/loose in most of the patients and became semisolid to normal in all the patients. The other associated features like pain during defecation, gas formation, mucous in the stools, postprandial abdominal discomfort also significantly reduced. Frequency of 3-6 motions/day decreased in 14 patients after treatment compared to 21 patients before treatment. Out of 17 patients who showed frequency of 7-10/day before treatment, 16 showed improvement. All the 12 patients with frequency of more than 10/day improved completely (Table 4).

DISCUSSION

Thus, the preliminary study conducted in 50 patients of diarrhoeal diseases, irrespective of their aetiology, using the four commonly used Ayurvedic antidiarrhoeal agents, showed a marked reduction in the frequency and consistency of the stools in the short trial period. It is

Table 1: Age incidence in 50 cases of diarrhoea

Age groups (years)	No. of patients	Percentage
10-20	6	12
21-30	28	46
31-40	12	24
>40	4	8
Total	50	100

Table 2: Sex incidence in 50 cases of diarrhoea

Sex	No. of patients	Percentage
Female	20	40
Male	30	60
Total	50	100

Table 3: Showing incidence of duration of illness in 50 cases of diarrhoeal diseases

Grade	No. of patients	Percentage
I (0-10/d)	29	58
II (11-30/d)	9	18
III (1-6/m)	4	8
IV (>6/m)	8	16
Total	50	100

Table 4: Showing response of the treatment on frequency of loose motions

Grade	Before treatment		After treatment	
	No. of patients	%	No. of patients	%
0 (2-3/d)	0	0	35	70
I (3-6/d)	21	42	14	28
II (7-10/d)	17	34	1	2
III (>10/d)	12	24	0	0
Total	50	100	50	100

important to note that patients suffering from several months with chronic diarrhoea also responded positively to the trial treatment. Decrease in the suffering of patients was noted as evidenced from symptomatic improvement, shown in the tables. The trial drug has been found to be useful in bringing about a relief of moderate to significant degree of symptomatic relief. More intensive investigations and a larger number of patients are needed to make positive claims, but based on the results of the present preliminary study, it can be definitely concluded that New Diarex is a moderate to highly effective remedy in the management of non specific diarrhoea and it is recommended to be used in all patients with the ailment with definite results.

Symptom		Before treatment		After treatment	
		No. of patients	%	No. of patients	%
Painful defecation		42	84	9	18
Consistency	Watery/loose	47	94	0	0
	Semi-solid	3	6	12	24
	Normal	0	0	38	76
Change in bowel habit		35	70	13	26
Postprandial call		29	58	16	32
Gas formation		32	64	20	40
Stool with mucous/blood		15	30	7	14
Abdominal discomfort		12	24	6	12
Anorexia		4	8	2	4
Nausea		37	54	8	16
Vomiting		40	80	38	76
Weight loss		2	4	2	4

Acknowledgement

We are highly thankful to Dr. S.K. Mitra, *M.D.*, Executive Director, Research and Technical Services, The Himalaya Drug Company, Bangalore, for financial and technical support to the present project.

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