

Clinical Study on the Trial Drug New Diarex in Cases of Irritable Bowel Syndrome

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ABSTRACT

A clinical study was conducted in 45 patients to test the efficacy of New Diarex in reducing the symptoms of irritable bowel syndrome. There were 26 females and 19 males aged between 20-69 years, who had increased frequency of motion, abdominal pain, mucous in stools, gas formation, anorexia, irritability, painful defaecation and others. Psychological symptoms included depression, lack of concentration, insomnia and body pain. These patients were dispensed New Diarex tablets at a dose of 2 tablets, thrice daily, for 10 days followed by 2 tablets, twice daily for a further 50 days. They were followed up every week for 2 months. At the end of 2 months most of the patients had relief from the symptoms. The average relief was moderate with percentage ranging from 52.94%-87.50%. These results indicate that New Diarex gives good relief from the symptoms of irritable bowel syndrome. No side effects or undesirable events were seen in any of the participants.

INTRODUCTION

Irritable Bowel Syndrome (IBS) is one of the most common complaints that account for 23% of the patients visit to the physician. Although not a life-threatening illness, irritable bowel syndrome causes great distress to those afflicted and the physician feels frustrated and helpless in attempting to treat it¹.

Irritable Bowel Syndrome is a functional gastrointestinal tract disorder associated with abdominal pain, disturbed defaecation with bloatedness or distension of the abdomen^{2,3}. Irritable bowel syndrome can be characterised as a chronic disorder of intestinal motility in the absence of structural changes in the gut⁴. The diagnosis of irritable bowel syndrome is usually made after excluding other diseases of the gastrointestinal tract⁵. It is generally believed that the motility disorders of the colon plays an important role in irritable bowel syndrome. Many times it has been seen that the abnormal motility may affect the whole alimentary tract, which involves the small intestine and may even involve the oesophagus⁶.

Patients with irritable bowel syndrome may also have a broad range of non-gastrointestinal symptoms such as fatigue, urologic dysfunction and gynaecological complaints. There is

often an irritable bladder in irritable bowel syndrome⁷. Moreover, ill-health is a common complaint encountered by the physicians in patients with irritable bowel syndrome. Psychological factors also play an important role in irritable bowel syndrome. A close association between psychological disorders and irritable bowel syndrome has been noted for several years⁸. Irritable bowel syndrome patients have been found to have depressive psychosis, depressive neurosis, anxiety neurosis and hysterical neurosis⁹.

Proper history and physical examination findings often lead to proper diagnosis, thus avoiding unnecessary laboratory investigation¹⁰. Clinical medicine in Ayurveda has unique approach, which seldom has exact co-relation with that of conventional medicine. There is no direct reference to irritable bowel syndrome in Ayurveda. However, many diseases have been mentioned that have similar symptoms to irritable bowel syndrome. These diseases have symptoms, which co-relate with irritable bowel syndrome such as excess abdominal pain or discomfort, increased peristaltic movement, constipation and pain in the sacral region.

The present study was undertaken to assess the therapeutic effect of New Diarex consisting of Bilwa (*Aegle marmelos*), Dadima (*Punica granatum*), Mustaka (*Cyperus rotundus*) and Kutaja (*Holarrhena antidysenterica*) in patients suffering from irritable bowel syndrome.

MATERIAL AND METHODS

In this study, 45 male and female patients with irritable bowel syndrome were selected for the study. Due to the small sample size male and female cases were clubbed in the present series of investigation. But interestingly, the incidence of irritable bowel syndrome has been observed more in the women.

The patients with symptoms relating to irritable bowel syndrome were selected after routine clinical evaluation. Routine laboratory investigations including haematological, stool and urine was done. These investigations even though did not to help to diagnose irritable bowel syndrome, it helped to exclude other disorders, which have similar symptoms. The patients who complained of incomplete evacuation, passing of loose motions alternatively with constipation, presence of mucous in stools, relief in abdominal pain after defaecation, onset of pain associated with more frequency of defaecation, feeling of inability to concentrate, headache and backache were diagnosed as irritable bowel syndrome cases. Patients having high ESR levels, ova/cyst or occult blood in the stool, abnormal liver function tests or any abnormal lesion found on barium meal swallow radiographic examination were excluded from the study. They were advised 2 tablets of New Diarex, thrice daily for 10 days followed by 2 tablets twice daily for the next 50 days. Two months of treatment schedule was advocated in all the patients. The main aim of this clinical study was to evaluate the therapeutic effect of the drug in all the cases of irritable bowel syndrome. The final assessment was done on the basis of clinical symptomatology.

RESULTS

All the patients completed 2 months study period and the results were quite encouraging. Before treatment 8 patients passed 2-3 stools per day, 28 passed 3-6 times per day, 7 patients passed 7-10 stools per day and 2 patients passed more than 10 times stools per day. After treatment it was seen that there was relief in 82.23%, mild relief in 15.55% and only 2.22% passed stools more than 7-10 times per day. The abdominal pain, which was present in all the patients before treatment had absence of pain in 84.45%, there was mild pain in 13.33% and moderate pain in 2.22%. Forty three patients passed mucous in stools and after the study period it was observed that 66.67% had complete absence of mucous, 20% had mild mucous and it was moderately present in 13.33%. The other symptoms relief noted at the end of the study period included painful defaecation (63.33%), change in bowel habit (60.97%), post-prandial call (76.92%), gas formation (59.52%), abdominal discomfort (65.38%), anorexia (78.78%), weight loss (87.5%), nausea and vomiting (84.61%), irritability (52.94%), depression (56.41%), loss of concentration (58.06%), insomnia (65%) and head and back ache (59.45%).

DISCUSSION

This present clinical trial was carried out to study the effect of a polyherbal preparation New Diarex on clinical symptomatology of irritable bowel syndrome. There was a definite decrease in the frequency of loose motions as recorded in almost all the patients. Improvement was seen in abdominal pain and the consistency of stool, which was initially loose in the patients had become semisolid to normal

Table 1: Age incidence in IBS (n=45)

Age groups (in years)	No. of cases	Percentage
20-29	24	53.34
30-39	10	22.22
40-49	8	17.77
50-69	3	6.67

Table 2: Sex incidence in cases of IBS (n=45)

Sex	No. of cases	Percentage
Female	26	58
Male	19	42

Table 3: Showing response to the treatment on frequency of motion (n=45)

Grade	Before treatment		After treatment	
	No. of cases	Percentage	No. of cases	Percentage
0 (2-3/day)	8	17.78	37	82.23
I (3-6/day)	28	62.22	7	15.55
II (7-10/day)	7	15.56	1	2.22
III (10 or more)	2	4.44	0	0.00

Table 4: Showing response to the treatment on abdominal pain (n=45)

Pain	Before treatment		After treatment	
	No. of cases	Percentage	No. of cases	Percentage
Nil	6	13.33	38	84.45
Mild	32	71.11	6	13.33
Moderate	7	15.56	1	2.22
Severe	0	0.00	0	0.00

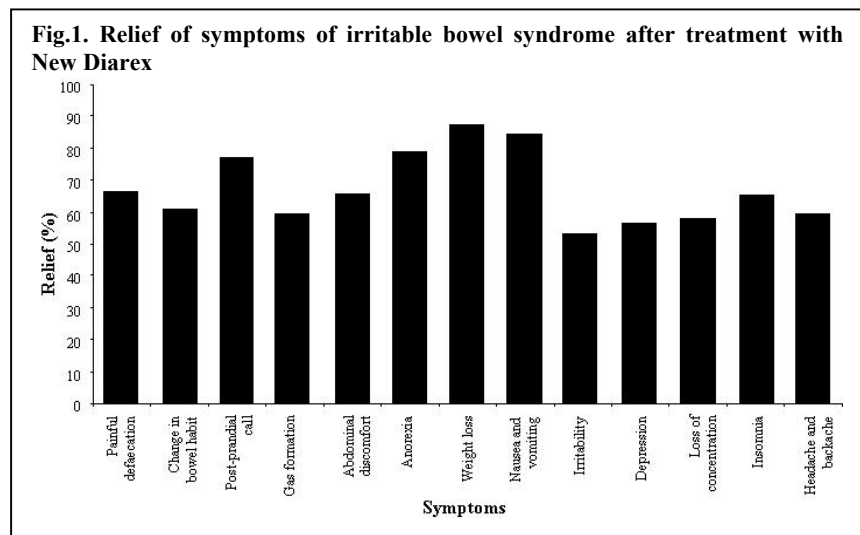
Table 5: Showing response to the treatment on passing of mucous in stool (n=45)

Severity	Before treatment		After treatment	
	No. of cases	Percentage	No. of cases	Percentage
None	2	4.45	30	66.67
Mild	28	62.22	9	20.00
Moderate	14	31.11	6	13.33
Severe	1	2.22	0	0.00

Table 6: Symptoms present before and after treatment with New Diarex (n=45)				
Symptoms	Before treatment		After treatment	
	No. of cases	Percentage	No. of cases	Percentage
Painful defaecation	30	66.67	11	24.44
Change in bowel habit	41	91.11	16	35.55
Post-prandial call	26	57.78	9	20.00
Gas formation	42	93.33	17	37.77
Abdominal discomfort	26	57.75	9	20.00
Anorexia	33	73.33	7	11.55
Weight loss	8	17.77	1	2.22
Nausea and vomiting	13	28.89	2	4.44
Irritability	34	75.56	16	35.55
Depression	39	86.67	17	37.77
Loss of Concentration	31	68.88	13	28.88
Insomnia	20	44.45	7	15.55
Headache & backache	37	82.22	15	33.33

in most of the patients. The other associated features such as pain during defaecation, passage of mucous in stool, increased frequency of bowel evacuation, abdominal discomfort, feeling of incomplete evacuation, etc. showed response in the first phase of the study but later in the study there was considerable amount of variability in the later phase of the trial. In the final phase, a few cases reported to have reduced the symptoms to levels of attaining 50% relief.

This drug has been found to be mild to moderately useful in combating the clinical symptomatology of irritable bowel syndrome. New Diarex has the ingredients to counter the somatic symptoms but as far as physical symptoms are concerned, they have been unaffected and there is



definitely a psychological aspect in these patients. Whenever there is a psychological disturbance the symptoms of gastrointestinal tract ailments seem to flare up¹¹.

CONCLUSION

The results obtained in the present study are preliminary in nature and require extensive scientific studies and larger sample size to determine the problems associated with the management of irritable bowel syndrome in depth. As far this trial study is concerned, it can

be concluded that New Diarex is mild to moderately effective in countering the clinical symptoms associated with irritable bowel syndrome.

ACKNOWLEDGEMENT

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

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