Clinical Evaluation of New Diarex in Patients with Chronic Diarrhoea

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ABSTRACT
Forty patients with clinical manifestations of chronic diarrhoea attending the out patient department of State Ayurvedic College Hospital, Varanasi were selected for the study. New Diarex tablets were administered to all the patients in the dose of one tablet three times daily for 10 days and one tablet twice daily for the next five days. No other medication was administered during this period. Response was assessed using subjective evaluation criteria like frequency and consistency of stools, presence or absence of blood and mucous in the stools and tenesmus. Stool fat analysis was also done before and after treatment.

A significant improvement in frequency and consistency of stools, absence of mucous and blood in the stools was seen after treatment with New Diarex. Frequency and consistency of stools improved in 75% of the patients and tenesmus was relieved in 66% of the patients.

Fat content in stools also reduced significantly after treatment. Positive compliance to treatment was observed without any side effects.

Key words: Chronic diarrhoea; gut failure.

INTRODUCTION
Chronic diarrhoea is a commonly encountered gastroenterological disorder, which is characterised by minor degrees of abdominal pain and diarrhoea\(^1\). Diarrhoea may be intermittent or persistent but most patients have long-standing symptoms. The onset of symptoms is usually in early middle age with no blood in the stools, though mucous is frequently present. The aetiology and pathophysiology of chronic diarrhoea remains unknown but abnormalities in colonic motor function have been demonstrated and are thought to be due to an abnormal pattern of colonic slow wave rhythm\(^2\)\(^-\)\(^4\).

Chronic diarrhoea includes when the initial episode lasts for more than 2 weeks or symptoms recur after the initial attack. Many patients who present with chronic diarrhoea are not found to have an important organic disease, however, are of considerable importance due to its frequency and the magnitude of serious intestinal disorders that comprise the organic causes. The organic causes resulting in chronic diarrhoea comprise inflammatory bowel disease, parasitic infections, chronic laxative abuse, metabolic disorders, etc.

The treatment of chronic diarrhoea is a challenge to the treating physician, as most patients do not respond to conventional medications. Being a syndrome of gut failure, it deprives the body of essential nutrients and is responsible for morbidity in the human population\(^5\). A
better understanding of the absorption, secretion of fluid and solutes, and the motility of the intestine are essential for optimal management as the condition is thought to result when the absorptive capacities of the small or large bowel altered leading to faecal water and electrolyte loss.

Several drugs are currently available, but have little place in the management of chronic diarrhoea, as they do not affect the basic cause of diarrhoea and have potentially harmful side-effects. Apart from this, the problem of recurrence adds to difficulty in optimal management. Bearing this in mind, New Diarex, a herbomineral formulation of The Himalaya Drug Company, Bangalore, was evaluated in patients with chronic diarrhoea.

MATERIALS AND METHODS
Forty patients of either sex with chronic diarrhoea from the Kayachikitsa, out-patient department of State Ayurvedic College Hospital, S.S. University, Varanasi, were enrolled in the study. The symptomatology of the patients formed the diagnostic criteria. Patients were considered to be suffering from chronic diarrhoea, if the initial episode of diarrhoea persisted for more than 2 weeks duration or presented with an early recurrence after an acute episode. A detailed history was taken, and the findings of the physical examination and relevant laboratory investigations recorded on a proforma specially designed for the purpose before, during and after the study. Laboratory investigations included routine blood tests, stool analysis for sugar, fat, neutrophils and parasites. Other investigations such as stool culture were conducted as and when required.

Sixty percent of the patients belonged to the 3rd and 4th decades of life, while 20% were recorded in the 2nd and 5th decades of life. Sixty percent of the patients were men and 40% were women. Regarding the dietary habits, 70% patients were vegetarians, while 30% patients were accustomed to a mixed diet. Thirty five percent of the patients belonged to a low socio-economic status, 40% to the average and 25% to good socio-economic status.

After initial screening, the trial drug New Diarex was recommended at a dose of 1 tablet, thrice daily for ten days, followed by 1 tablet, twice daily for the next 5 days. No other anti-diarrhoeal drugs were administered during the study period. The subjective improvements of the patients were evaluated on a daily basis with stool analysis at regular intervals. A regular grading of loose motions, tenesmus, mucous, blood and fat in the stools was also done. Patient compliance and side effects, if any, were recorded at each follow-up.

The following criteria were adopted for grading the number of stools per day and consistency of stools during treatment:

I. **Grading the number of stools per day:**
   i. Grade 0 - 1-2 stools/ 24 hours
   ii. Grade I - 3-4 stools/ 24 hours
   iii. Grade II - 5-7 stools/ 24 hours
   iv. Grade III - More than 7 stools/ 24 hours.
II. Stool consistency grading:
   i. Grade 0 - Well formed consistency
   ii. Grade I - Semisolid consistency
   iii. Grade II - Semifluid consistency
   iv. Grade III - Watery consistency.

The final assessment was done based on amelioration in clinical symptomatology and the stool analysis report after 15 days of treatment. The response to treatment was recorded as cured, improved or unchanged on the basis of the criteria mentioned below:
   i. **Cured**: when the number of motions in 24 hours reduced to 1 or 2 and consistency improved to normal, with symptomatic relief for more than 75%.
   
   ii. **Improved**: when the number of motions and consistency returned to normal with symptomatic relief for more than 50%.
   
   iii. **Unchanged**: when the number of motions, consistency of stools and the symptomatology remained unchanged.

**RESULTS**

Symptomatic evaluation showed a significant improvement in the consistency of the stools in 75% of the patients. There was a decrease in frequency of stools in 70%, presence of mucous in stools among 75%, tenesmus in 66.6% and restoration of normal body weight in 100% of the patients.

Table 1 shows the effect of New Diarex on the varied symptomatology of the patients.

The gradation of the number of stools per day is shown in Table 2.

The improvement in the consistency of stools is shown in Table 3.
Stool fat analysis was done in 12 patients, both before and after 15 days of treatment. An average of 5.88 fat globules per high power field was observed at the initiation of treatment, which subsequently reduced to 3.2 fat globules per high power field by the end of treatment.

The overall response to New Diarex treatment is as shown in the Figure 1.

There was good patient compliance with no observation of side effects during the course of treatment with New Diarex.

**DISCUSSION**

Intestinal infections usually cause acute transient diarrhoea. If the host has immune deficiency, if there is repeated exposure to an infectious agent or if a severe infection damages a substantial proportion of the absorptive surface of the gut, chronic diarrhoea may follow an acute episode. Certain organisms such as *Escherichia coli*, *Yersinia enterocolitica*, *Giardia lamblia*, *E. histolytica*, etc., can cause chronic diarrhoea. Irritable colon, diverticular disease of the colon, chronic laxative abuse, idiopathic ulcerative colitis and Crohn's disease are significant disease problems that can cause chronic diarrhoea.

Many inherited defects of function of specific enzymes or transport pathways in the intestine have been described in recent years. The most important of these are the congenital disaccharidases deficiencies, either lactase or combined sucrase-isomaltase deficiency. Cystic fibrosis is also a common cause of chronic diarrhoea associated with steatorrhoea. Of the varied aetiology, a continuing mucosal dysfunction is generally the primary inciting factor.

Clinical assessment, rectal examination, stool examination, routine blood tests and other specific investigations provide clues to the diagnosis and management of chronic diarrhoea. The treatment involves comprehensive care with insights into the problem, the treatment and prognosis. The main treatment in conventional medicine comprises the use of antidiarrhoal
drugs, antimicrobial agents and occasionally, corticosteroids. However, these drugs do not affect the basic cause of the diarrhoea and also possess potentially harmful side effects.

New Diarex, a herbomineral formulation of The Himalaya Drug Company, Bangalore comprises *Holarrhena antidysenterica*, *Tinospora cordifolia*, *Aegle marmelos*, *Punica granatum*, *Cyperus rotundus* and Shankha bhasma. *Holarrhena antidysenterica* possesses significant antimicrobial activity, which is beneficial in dysentery. *Tinospora cordifolia* is an effective immunomodulatory agent with hepatoprotective, antistress and antiulcer activity. *Aegle marmelos* has antibacterial and anti-inflammatory properties beneficial in diarrhoea and dysentery. The anthelmintic, antidiarrhoeal and antiamoebic actions of *Punica granatum* are of immense value in the treatment of diarrhoea. The anthelmintic, anti-inflammatory, astringent and antispasmodic properties present in *Cyperus rotundus* are valuable in the treatment of diarrhoea, dysentery and dyspepsia.

**CONCLUSION**

From the above clinical study, it can be concluded that New Diarex is an effective and safe remedy in the treatment of chronic diarrhoea of varied aetiology.

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**REFERENCES**


