

## A Controlled Trial of Diarex and Tinidazole in Chronic Intestinal Amebiasis

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### INTRODUCTION

Amebiasis is a condition caused by the parasite *Entamoeba histolytica*. The trophozoite is the parasitic form and dwells in the lumen and/or wall of the colon, divides by binary fission, grows best under anaerobic conditions and requires the presence of either bacteria or tissue substrates to satisfy its nutritional requirements. It is estimated that 10% of the world population is infested with this intestinal protozoan, while in the tropics (including India) the prevalence is as high as 50%<sup>1,2</sup>.

Amebiasis may persist in an asymptomatic carrier state in most individuals. But ranging from chronic, mild diarrhoea to fulminating dysentery, it may occur usually presenting with vague symptoms, e.g. abdominal pain/discomfort, feeling of incomplete evacuation, anorexia, dyspepsia, tenesmus etc. The modern drugs used produce troublesome side-effects/toxicity without satisfactory results and relapses are frequent.

The present study was undertaken to assess the effect of Diarex, an antiamebic/antidiarrhoeal preparation of The Himalaya Drug Co., in chronic intestinal amebiasis along with a widely used antiamebic drug tinidazole.

### MATERIAL AND METHODS:

In this controlled trial between October and December 1983 only 100 male cases of chronic intestinal amebiasis with off and on complaints of more than 6 months' duration were selected. They were in the age group of 25-35 years and from the well-to-do and educated class. Selection was based on the following criteria.

1. Detailed history did not reveal any other systemic disease.
2. Stool had no other parasite except *E. histolytica*, cyst or trophozoite.
3. Patients agreed to take the treatment for the specific period and send the stool for examination on the 6<sup>th</sup>, 15<sup>th</sup> and 30<sup>th</sup> days after treatment.

The diseases which may mimic amebiasis, viz., shigellosis, salmonellosis, ulcerative colitis etc., were ruled out by simple microscopic examination on the basis of polymorphonuclear leucocytes which are present in large number in these diseases and by other simple tests<sup>3</sup>.

These 100 cases were divided into two groups of 50 each and their complaints/symptoms were noted in detail as shown in Table 1.

<b>Table 1: Complaints prior to and after treatment</b>								
Complaints	No. of cases prior to treatment		No. of cases after treatment on the					
	Study group	Control group	6 <sup>th</sup> day		15 <sup>th</sup> day		30 <sup>th</sup> day	
			Study group	Control group	Study group	Control group	Study group	Control group
Foul smelling loose motion	12	9	-	-	1	3	5	9
Mucus with stool	37	35	1	2	6	5	3	7
Flatulence	41	39	1	2	-	9	2	13
Feeling of incomplete evacuation	47	49	2	5	2	13	3	27
Tenesmus	23	31	-	1	-	2	1	5
Pain in the right iliac fossa	17	14	1	1	-	3	3	9
Cramps	19	24	-	1	1	5	4	17
Tender hepatomegaly	5	2	1	1	-	-	-	-
Constipation and/or diarrhoea	12	16	-	1	2	7	3	15

The stool examination details are shown in Table 2.

<b>Table 2: Stool examination details</b>								
Microscopic findings	No. of cases prior to treatment		No. of cases after treatment on the					
	Study group	Control group	6 <sup>th</sup> day		15 <sup>th</sup> day		30 <sup>th</sup> day	
			Study group	Control group	Study group	Control group	Study group	Control group
Cyst, trophozoite present (either or both)	50	50	2 (4%)	5 (10%)	3 (6%)	12 (24%)	9 (18%)	27 (54%)
No Cyst/trophozoite	-	-	48 (96%)	45 (90%)	47 (94%)	38 (76%)	41 (82%)	23 (46%)

The two groups were put on the following drug schedule.

(a) Control Group: Tinidazole tablets, 1200 mg, in divided doses for 5 days.

(b) Study Group: Tinidazole tablets, 1200 mg, in divided doses for 5 days and Diarex tablets 2 tablets, t.i.d. for 5 days.

Both the groups were advised strictly not to take any other antidiarrhoeal, antimicrobial or antacid preparation throughout the trial period.

After completion of the treatment a follow-up was done to note the symptoms/complaints and the stool sent for examination on the 6<sup>th</sup>, 15<sup>th</sup> and 30<sup>th</sup> days.

#### **OBSERVATIONS:**

The most common presenting complaints prior to start of treatment in both the groups were a feeling of incomplete evacuation, flatulence, mucus with stool etc.

On the 6<sup>th</sup> day (in 9 cases on the 7<sup>th</sup> and in 4 cases on the 8<sup>th</sup> day) after completion of treatment, the study as well as control group cases responded almost equally to antiamebic regimens and the difference between the presenting complaints was also statistically insignificant.

The observations were further substantiated by the stool examination which was negative for *E. histolytica* in 96% of the study group cases as compared to 90 per cent in the control group, creating an impression that neither regimen has any superiority over the other or that each one exerts similar anti-amoebic effects (See Table 2).

However, as is evident from Table 1 on the 15<sup>th</sup> day (in 7 cases on the 16<sup>th</sup> and in 5 on the 17<sup>th</sup> day) of follow-up, the average number of complaints in the study group was less in comparison to the controls and this difference in overall complaints in both the groups was statistically significant.

At the same time the repeat stool examination for *E. histolytica* revealed that the stool positivity was significantly higher in the controls (24%) than in the study group (6%) (Table 2).

The surprising and interesting results were obtained in the follow-up on the 30<sup>th</sup> day (in 8 cases on the 31<sup>st</sup> and in 7 cases on the 32<sup>nd</sup> day) when the superiority of the study group regimen (Diarex and tinidazole) was well established over the control group (tinidazole alone), by the observation that the average number of complaints still remained less in the study group, while they were twice as much in the controls.

The stool positivity for *E. histolytica* was also more than double in the controls as compared to the study group and the difference was again statistically significant.

## CONCLUSION

The present controlled trial has revealed that in the study group cases who were put on Diarex + tinidazole therapy, 82% had no form of *E. histolytica* in the stool even on the 30<sup>th</sup> day after completion of treatment, whereas 54% of the control group cases who received tinidazole alone were found to have trophozoites and/or cysts of *E. histolytica* in their stool. At the same time the average number of complaints still remained less in the study group as compared to the controls.

The role of Diarex as an antidiarrhoeal and antiamebic has also been observed by other workers<sup>3,4</sup>.

The present trial has clearly established the superiority of Diarex + tinidazole therapy over tinidazole alone in the management of chronic intestinal amebiasis.

The authors are of the opinion that further extensive, detailed biomedical studies must be carried out to know the exact mechanism of action of Diarex as an adjuvant in the management of amebiasis along with other antiamebic drugs.

## REFERENCES

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