
ORIGINAL ARTICLE

Tinidazole versus Ornidazole in Amebic Dysentery in Children (a double blind trial).

by

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Abstract

Between January and June 1978, a double blind trial was conducted in 35 children, suffering from Amebic Dysentery in the OPD of the General Hospital Medan

The children were treated ambulatory, either with Tinidazole or Ornidazole, with a dose of 50 mg/kg body weight/day for 3 consecutive days, under close supervision. All the children, except one in the Tinidazole group (case no. 20), gave excellent responses.

Disappearance of ameba's, blood and mucus from the stools occurred in all of the patients after 2 days of treatment.

There was no significant difference in the results of treatment with Tinidazole and Ornidazole ($p > 0.05$).

Side effects were minimal. Marked vomiting occurred in one patient of the Ornidazole group.

Introduction

Amebic Dysentery, as in other parts of Indonesia, is still endemic in Medan. Yo Kian Tjay et al. (1971a, 1971b, 1972) reported that 3% of the outpatients at the Pediatric Department, General Hospital Medan, suffered from Amebic Dysentery. Extra-intestinal amebiasis was rare in Medan.

Today there are many effective drugs against Amebic Dysentery such as Metronidazole, Tinidazole and Ornidazole. Ahmed et al. (1976) gave Tinidazole in the treatment of 40 children with Amebic Dysentery, with a daily single dose of 50 mg/kg body weight for 3 consecutive days and found a parasitological cure of 100% and a clinical cure of 97.5%.

Lubis et al. (1977) have studied 33 children with intestinal amebiasis treated with single daily dose of 50 mg/kg body weight for 3 consecutive days, and reported a parasitological cure of 93.9% and a clinical cure of 90.9%.

In 31 cases with Amebic Dysentery, Tamsu et al. (1977), using a single daily dose of 50 mg/kg body weight of Ornidazole for 3—5 days, reported an excellent response in 77.5% and a good response in 96.8%.

The purpose of this paper is to compare the effectiveness of Tinidazole and Ornidazole in the treatment of Amebic Dysentery in children, at the Department of Child Health, Medical School, General Hospital Medan.

Material and methods

From January to June 1978, all children at the outpatient clinic of the Sub-Department of Gastroenterology, Department of Child Health, Medical School, General Hospital Medan, with the complaints of bloody stool were examined for Amebic Dysentery. Forty children with motile hematophagous of *Entameba histolytica* in the stools were included in this trial.

Stool examinations were performed at the first call and daily during the treatment period. On Sundays and holidays stool examinations were not performed.

Rectal examination was used to recover the stools. Microscopic fecal examinations of each specimen was done with the direct smear method with eosin 2%, at least 2 preparations from each specimen were examined.

The trial was a double blind method, 20 cases were treated with Tinidazole and 20 cases with Ornidazole, each with a single daily dose of 50 mg/kg body weight for 3 consecutive days.

These cases were randomly selected for either one of the groups. The children were treated ambulatorily and the tablets were administered in the hospital daily under supervision of the authors, without knowing which drug was being given.

On Sundays and holidays the tablets were administered at home under the supervision of their parents.

The therapeutic response was assessed clinically and parasitologically.

Clinical cure is the disappearance of blood and mucus in the stools at follow up examination.

Parasitological cure is achieved when there is disappearance of *Entameba histolytica* of all its form on microscopic fecal examination.

Reappearance of *Entameba histolytica* after the second month was considered as reinfection.

The complaints of the patient during treatment and the other symptoms were recorded.

Results

Only 17 cases out of 20 cases completed the 3 days treatment with Tinidazole. *Entameba histolytica* disappeared from the stools of 16 out of the 17 cases after completion of treatment (94.1%).

Symptoms also disappeared. One case (no. 20) relapsed in the second week after completion of treatment. This has been evaluated as a failure (Table 2).

Twenty children were treated with Ornidazole but only 18 cases could be used for evaluation. All of the patients recovered and the symptoms disappeared (Table 2).

The number of patients in both groups is comparable (Table 1). We found a case in each group under one year of age. The youngest case was 4 months in age and was treated with Tinidazole.

The difference in cure rate between Tinidazole and Ornidazole is statistically not significant ($p > 0.05$).

Follow up on the second day.

In the Tinidazole group the evaluation could be done only in 14 cases; while in 3 other cases it could not be done because it coincided with the holidays.

The parasitological cure was 85.7% and the clinical cure was 42.8% (Table 3 and Table 4).

In the Ornidazole group the evaluation could be done in 15 cases. It was not done in 3 other cases. The parasitological cure was 66.6% and the clinical cure was 40% (Table 3 and Table 4).

Follow up on the third day.

In the Tinidazole group, 16 cases came back to the hospital for control. We found the parasitological cure was 100% and the clinical cure was 93.7%.

In the Ornidazole group, 17 cases returned for control examination. The parasitological cure was 100% and the clinical cure was 94.1%.

Follow up on the first week of the treatment.

In the Tinidazole group 12 cases came back for control and we found the parasitological cure to be 100% and the clinical cure 83.3%.

In the Ornidazole group, 13 cases returned for control and the parasitological cure was 100% and the clinical cure was 100%.

Follow up in the second week after treatment.

In the Tinidazole group, 10 cases came for control, we found the parasitological cure was 90% and the clinical cure was 90%.

In the Ornidazole group, 7 cases came control and we found the parasitological and the clinical cure were 100%.

Follow up in the third week after treatment.

In the Tinidazole group, 5 cases came for control and the parasitological and the clinical cure were 100%.

In the Ornidazole group, 6 cases came for control and the parasitological and the clinical cure were 100%.

Follow up in the fourth week after treatment.

In the Tinidazole group, 5 cases came for control and the parasitological and the clinical cure were 100%.

In the Ornidazole group, only one case came for control there was neither ameba nor clinical symptoms in this patient.

Case no. 21 was 4 months in age and she was the youngest patient.

The patient relapsed from Amebic Dysentery 15 weeks after treatment.

This has been considered as reinfection. The baby was treated again with Tinidazole for 3 days.

Besides suffering from Amebic Dysentery, 35 cases in this study also suffered from Helminthiasis. *Ascaris lumbricoides* eggs were found in 22 out

of 35 cases, 10 cases of the Tinidazole group and 12 of the Ornidazole group.

Trichuris trichiura eggs were found in 26 cases of the Tinidazole group and 12 cases of the Ornidazole group. Five cases suffered from Ancylostomiasis, 2 of the Tinidazole group and 3 of the Ornidazole group (Table 5).

After disappearance of ameba's, blood and mucus from the stools, these children were treated with a single dose of 10 mg/kg body weight of Pyrantel pamoate, and in children with Trichuriasis continued with Mebendazole with a dosage of 1 tablet, 2 times daily for 3 consecutive days.

Mild side effects were noticed in case no. 6, that is vomiting 2 hours after ingestion. This patient was included in the Ornidazole group.

Discussion

In this double blind trial we found that the results of treatment of Amebic Dysentery with Tinidazole and Ornidazole for 3 consecutive days were very good.

There was no ameba in the stools on the following days and the symptoms of bloody and mucoid stools disappeared rapidly.

Relapse occurred in one case (no. 20) only within 2 weeks after treatment. This case was evaluated as a treatment failure, although the probability of reinfection could not be excluded. The case was treated with Tinidazole.

Side effects with both drugs were minimal. Only one patient vomited, 2 hours after ingestion of Ornidazole. On the third day, the parasitological and clinical cure of 100% in both groups were achieved.

The clinical symptoms disappeared in 93.7% of the patient receiving Tinidazole and in 94.1% receiving Ornidazole.

Conclusion

In 35 babies and children suffering from Amebic Dysentery and treated with either Tinidazole or Ornidazole with a single daily dose of 50 mg/kg

body weight for 3 consecutive days, the results were very good. The cure rate was 94.1 — 100%.

The difference in cure rate with Tinidazole and Ornidazole was statistically not significant ($p > 0.05$).

Even treatment for 2 consecutive days resulted in a parasitological cure of 100% in both groups.

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TABLE 1 : *Age and sex of material*

Age	Tinidazole		Ornidazole	
	Male	Female	Male	Female
0 —	—	1	—	1
1 —	—	2	3	1
3 —	6	2	4	4
> 6	4	2	3	2
Total	10	7	10	8

TABLE 2 : *Results of treatment*

	Number of cases	Clinical and parasitological cure	%
Tinidazole	17	16	94.1
Ornidazole	18	18	100

TABLE 3 : *Parasitological cure*

Follow up	Tinidazole (%)	Ornidazole (%)
Second day **	85.7	66.6
Third day	100	100
1 week after treatment	100	100
2 weeks after treatment	90	100
3 weeks after treatment	100	100
4 weeks after treatment	100	100

** On second day, all the patients got the therapy once only.

TABLE 4 : *Clinical cure*

Follow up	Tinidazole (%)		Ornidazole (%)	
	Blood	Mucus	Blood	Mucus
Second day	78.6	42.8	66.6	40
Third day	100	93.7	94.1	94.1
1 week after treatment	91.6	83.3	100	100
2 weeks after treatment	90	90	100	100
3 weeks after treatment	100	100	100	100
4 weeks after treatment	100	100	100	100

TABLE 5 : *Helminthic infection in the 35 cases*

Worm	Tinidazole	Ornidazole (%)	Total (%)
1. <i>Ascaris lumbricoides</i>	10 (58.8)	12 (66.6)	22 (62.8)
2. <i>Trichuris trichiura</i>	14 (82.3)	12 (66.6)	26 (74.2)
3. <i>Ancylostoma</i>	2 (11.7)	3 (16.6)	5 (14.2)
Number of cases	17	18	35

TABLE 6 : *Trade name, generic name, and chemical name of the amebic drugs*

No.	Name			
	Trade	Company	Generic	Chemical
1.	Flagyl	Specia	Metronidazole	1 beta hydroxyethyl — 2 — methyl — 5 — nitroimidazole
2.	Fasigyn	Pfizer	Tinidazole	Ethyl (2 — (2 — methyl — 5 nitro — 1 — iminazole) ethyl) sulphone.
3.	Tiberal	Hoffmann-La-Roche	Ornidazole	Alpha — (chloromethyl) — 2 — methyl — 5 — nitroimidazole (ornidazole).