
Forty infants with a uropathy diagnosed during the first two months of life were studied. Presenting signs were urinary tract infection in one-half of the cases, disorders of micturition, pelvic or abdominal wall malformations, abdo-
minal-pelvic mass, and macroscopic hematuria. Obstructive uropathy was ob-
erved in 17 children and vesicoureteric reflux in 29. We noted a high incidence of extra-
renal malformations (14 of the 40 cases) in this series of uropathies diagnosed during the neonatal period. Despite early diagnosis, the course was not favourable in 11 cases with congenital anomalies of the renal parenchyma.

PPD TESTING AS A DIAGNOSTIC AID IN NON-TUBERCULOUS MYCO-

Four children suffering from unilateral cervical lymphadenitis with histopa-
thological changes typical of mycobacteriosis were seen during a short time. None of the children had been BCG vaccinated. Mycobacteria belonging to the Mycobacterium aviumintracellulare complex were isolated from excised lymph nodes in two of the patients. Intracutaneous tests with PPD from M. tuberculosis were negative in all the children, whereas two children responded to each of 3 PPDs prepared from atypical mycobacteria. Two patients were unreactive in all the skin tests. Lymphocyte transformation tests in vitro with a battery of various PPDs indicated sensitization to atypical mycobacteria in two children, one of which was negative in the skin tests.

All the patients had normal plasma Ig concentrations but two patients had low proportions of T lymphocytes in the peripheral blood. One of these also had reduced total numbers of T cells. Nevertheless, lymphocyte responses in vitro to phytohaemagglutinin were normal in all the children. The results show that cutaneous and in vitro tests with a battery of different PPDs have a place as diagnostic adjuncts in atypical mycobacteriosis. We suggest that immunological competence is analysed in such patients.

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. Yoi Chian Tjia 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 Mepronidazole, Tinidazole and Ornidazole. Ahmed et al. (1976) gave Tinidazole to 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 90.3%.

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 hematophasous 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.

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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 his-
tolytica of all its form on microscopic
fecal examination.

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

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

Results

Only 17 cases out of 20 cases comple-
ted 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
Ondizole 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 group-
s 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 Ondizole is statistically
not significant (p>0.05).

Follow up on the second day

In the Tinidazole group the evalu-
ation could be done only in 14 cases;
while in 3 other cases it could not be
done because it coincided with the ho-
lidays.

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

In the Ondizole group the evalu-
ation could be done in 15 cases. It was
not done in 3 other cases. The parasitologi-
cure was 66.6% and the clinical cure
was 40% (Table 3 and Table 4).

Follow up on the second 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 Ondizole group, 17 cases re-
turned 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 parasit-
ological cure to be 100% and the clini-
cal cure 83.3%.

In the Ondizole group, 13 cases re-
turned 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 forth 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 amebas 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 re-infection. 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 Ornidaole 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 case (no. 20) only within 2 weeks after treatment. This case was evaluated as a treatment failure, although the probability of re-infection could not be excluded. The case was treated with Tinidazole.


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Side effects with both drugs were mi-

timal. Only one patient vomited, 2 ho-

urs after ingestion of Ornizadole. 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 Tinida-
zole and in 94.1% receiving Ornizadole.

Conclusion

In 35 babies and children suffering from
Amebic Dysentery and treated with
either Tinidazole or Ornizadole 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 Tin-
idazole and Ornizadole was statistically
not significant (p > 0.05).

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

Acknowledgement

We wish to express our appreciation to
PT. Pfizer Indonesia and PT. Hof-
mann-La Roche, for their help to make
this study possible.

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Table 1: Age and sex of material

<table>
<thead>
<tr>
<th>Age</th>
<th>Tinidazole (Male)</th>
<th>Tinidazole (Female)</th>
<th>Ornidazole (Male)</th>
<th>Ornidazole (Female)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>&gt;6</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>7</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 2: Results of treatment

<table>
<thead>
<tr>
<th>Number of cases</th>
<th>Clinical and parasitological cure</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinidazole</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>Ornidazole</td>
<td>18</td>
<td>18</td>
</tr>
</tbody>
</table>

Table 3: Parasitological cure

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Tinidazole (%)</th>
<th>Ornidazole (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second day**</td>
<td>85.7</td>
<td>66.6</td>
</tr>
<tr>
<td>Third day</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1 week after treatment</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>2 weeks after treatment</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>3 weeks after treatment</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>4 weeks after treatment</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

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


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TABLE 4: Clinical cure

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Tinidazole (%)</th>
<th>Ornidazole (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood</td>
<td>Mucus</td>
</tr>
<tr>
<td>Second day</td>
<td>78.6</td>
<td>42.8</td>
</tr>
<tr>
<td>Third day</td>
<td>100</td>
<td>93.7</td>
</tr>
<tr>
<td>1 week after treatment</td>
<td>91.6</td>
<td>85.3</td>
</tr>
<tr>
<td>2 weeks after treatment</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>3 weeks after treatment</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>4 weeks after treatment</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

TABLE 5: Helminthic infection in the 35 cases

<table>
<thead>
<tr>
<th>Wurm</th>
<th>Tinidazole (%)</th>
<th>Ornidazole (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ascatis lumbricoides</td>
<td>10 (58.8)</td>
<td>12 (66.6)</td>
<td>22 (62.8)</td>
</tr>
<tr>
<td>2. Trichurus trichiura</td>
<td>14 (82.3)</td>
<td>12 (66.6)</td>
<td>26 (74.2)</td>
</tr>
<tr>
<td>3. Necyeloma</td>
<td>2 (11.7)</td>
<td>3 (16.6)</td>
<td>5 (14.2)</td>
</tr>
<tr>
<td>Number of cases</td>
<td>17</td>
<td>18</td>
<td>35</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>No.</th>
<th>Trade</th>
<th>Company</th>
<th>Generic</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Flagyl</td>
<td>Specia</td>
<td>Metronidazole</td>
<td>1 beta hydroxyethyl — 2 — methyl — 5 — nitroimidazole</td>
</tr>
<tr>
<td>2.</td>
<td>Fasigyn</td>
<td>Pfizer</td>
<td>Tinidazole</td>
<td>Ethyl (2 — (2 — methyl —5 nitro — 1 — iminazole) ethyl) sulphone.</td>
</tr>
<tr>
<td>3.</td>
<td>Tiberal</td>
<td>Hoffmann-La-Roche</td>
<td>Ornidazole</td>
<td>Alpha — (chloromethyl) —2 — methyl — 5 — nitroimidazole (ornidazole).</td>
</tr>
</tbody>
</table>