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A Clinical Trial of CIBA 32644-Ba in *Schistosomiasis mansoni*

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This paper reports on 48 patients with *Schistosoma mansoni* infection who were treated with CIBA 32644-Ba, while in-patients at the Hospital Clinic of Tropical Diseases, Rio de Janeiro.

1. Details of the Study

a) The *material* consisted of 24 males and 24 females, of whom 34 were Whites, 13 Mestizos and a Negro. Their ages ranged from 3 to 46 years. All were in the active stage of the disease before treatment, as revealed by the finding of eggs in the faeces (37 cases) or on rectal biopsy (39 cases), the majority of patients having positive findings in both respects. No patients were in bad general health or had overt evidence of liver disease or palpable spleens. One of them, however, had clinical manifestations of bronchial asthma and another portal hypertension.

b) The *investigations* carried out before treatment, in addition to those already mentioned, included urinalysis and, in 27 patients, a series of liver function tests (thymol turbidity, thymol flocculation, zinc sulphate turbidity and cephalin cholesterol determinations), red cell count, haemoglobin and haematocrit, total and differential white cell count and an electrocardiogram. Studies of the spermatozoa were also made in 12 patients (these are reported in the chapter on side effects) and liver biopsies were obtained from two. The same investigations were repeated at the end of the course of treatment.

The initial investigations showed the liver function tests to be within normal limits with the exception of the occasional isolated

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positive flocculation test, which was felt to be of no significance. Eight of the 27 patients had haemoglobin levels below 12 g. Total white cell counts were slightly elevated in two patients only, but eosinophil counts were generally above normal, with values of up to 26%. Electrocardiograms were normal except for evidence of ventricular hypertrophy in two patients and non-specific wave changes in two.

c) *Treatment* was given according to 2 schedules. Twenty-eight patients received 20-25 mg/kg/day for 10 days and the remaining 20 patients 30-40 mg/kg/day for 7 days. In both cases the drug was given in two divided doses. One of the cases on the higher dose failed to attend for follow-up.

2. Results

Stool examinations have been carried out repeatedly in a total of 38 patients, and rectal biopsies in 16 of these, the period of follow-up ranging from 30 to 120 days or more (10 patients). Without exception these studies have been negative, no mature or immature ova being found.

Side effects have been common but generally minor, consisting mainly of headache, gastro-intestinal upsets which could be controlled with anticholinergic or antispasmodic drugs, and some aching in the limbs. In addition, three patients developed mental symptoms: excitation in one instance and hallucinations in the other two. This was transient in one case, but more serious in the other. However, we managed to control it with sleep therapy. It should be stressed that in no instance were we unable to complete the course of treatment (except for one case with asthmatic complaints who developed marked dyspnoea after 3 days of therapy) because of these side effects. It is interesting to note also that they almost all occurred with higher frequency in the patients treated for 10 days; a shorter regime may therefore be beneficial in this respect.

Of the various laboratory studies, the urinalyses remained normal and so did the liver function tests, including the two repeat liver biopsies. Haemoglobin levels tended to rise; 12 patients showed an increase of 1 g or more, and the average level in the 27 patients studied rose from 12.7 g to 14.0 g. Total white cell counts remained essentially normal and there were fluctuations in the eosinophil counts, changes without a consistent pattern being registered in both directions.

The electrocardiographic pattern showed changes in 18 of the 27 patients investigated, but these were generally of a non-specific

nature, being interpreted as disturbances of ventricular recuperation in 7 cases. The others showed flattening or inversion of T waves. We do not consider these findings of any clinical significance.

3. Comment

When I was first contacted by Dr. PETERS and asked to conduct trials with CIBA 32644-Ba, I was very sceptical about the possibility of its replacing the established schistosomicides. But I have never seen results as good as those just presented.

Of course, we want to observe the patients for not less than 6 months, and carry out at least ten stool examinations and two rectal biopsies in each case. We expect to have these results within three months and we shall then be in a better position to assess the over-all effectiveness of the drug. Meanwhile, I can only say that it appears most promising.

Summary

Forty-eight patients with *S. mansoni* infections were treated with CIBA 32644-Ba, 28 of them receiving 20-25 mg/kg daily for 10 days and 20 patients 30-40 mg/kg for 7 days.

Stool examinations were performed repeatedly for 30-120 days, and in 10 cases for even longer. Rectal biopsies were carried out in 16 cases. Parasitological examinations yielded negative results in all cases after treatment.

Side effects, which were generally minor and easily controlled, consisted of headaches, gastro-intestinal disorders, and pruritus. A state of agitation was observed in 1 case, and hallucinations in 2 others. Blood findings, and renal and hepatic function tests revealed no toxic effect of the drug. Non-specific ECG changes were found in 18 patients.

Résumé

Une série de 48 malades infestés par *S. mansoni* ont été traités par le CIBA 32644-Ba à raison de 20 à 25 mg/kg/jour pendant 10 jours, pour 28 d'entre eux, et 30 à 40 mg/kg/jour pendant 7 jours, pour les 20 autres.

Chez 38 malades, les examens répétés des selles ont été pratiqués pendant 30 à 120 jours, ou davantage pour 10 d'entre eux. 16 malades furent également contrôlés par des biopsies rectales. Sans exception, chez tous les malades, les examens parasitologiques furent négatifs après le traitement.

Les effets secondaires, signalés comme généralement mineurs et facilement contrôlables, ont consisté en céphalées, troubles gastro-intestinaux et prurit. En plus 3 malades ont présenté l'un un état d'excitation, 2 autres des hallucinations. Les tests sanguins, rénaux et hépatiques (ponctions hépatiques répétées) n'ont montré aucune action toxique du traitement. Des modifications ECG non spécifiques furent observées chez 18 malades.