Report

Effectiveness of praziquantel in treatment of intestinal amoebiasis and giardiasis

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Introduction

Praziquantel, in addition to its well known effectiveness in the treatment of schistosomiasis, has been frequently investigated in many protozoal and helminthic infections, such as neuro- and ocular cysticercosis, hydatid disease, fascioliasis, clonorchiasis and opisthorchiasis, in addition to *Hymenolepis nana* and other taenia infections [*1–5*].

However, to our knowledge, the use of praziquantel in the treatment of intestinal amoebiasis and giardiasis has not been examined clinically apart from in a survey performed by Flisser et al. [*6*]. In that survey, stool examination was performed after administration of praziquantel to normal subjects in two rural communities.

In 1993, we began a randomized clinical trial to compare the efficacy of praziquantel with that of metronidazole in intestinal infection with *Entamoeba histolytica* and *Giardia lamblia*.

Subjects and methods

From 1993 to 1995, a total of 111 adult outpatients, shown clinically and by stool examination to have *E. histolytica* ($n = 90$), vegetative trophozoite or cyst form, or *G. lamblia* ($n = 21$) infections, were treated with praziquantel (Distocide, Shin Poong Pharm Company Ltd, Korea) 40 mg/kg body weight, in a single dose divided into two portions taken 4–6 hours apart or with metronidazole, 800 mg three times a day for 5 days for *E. histolytica* trophozoites and 400 mg three times a day for 7 days for *G. lamblia* cysts and trophozoites.

All essential diagnostic tests were carried out and the necessary criteria, including the occurrence of vegetative trophozoites, cysts and haemotophages of *E. histolytica*, were met. Randomization was done according to a predesigned dispensing list (10 patients each) constructed from a table of random numbers with an equal number of eligible patients for each treatment. A follow-up form was used, containing details of the patients' clinical manifestations (abdominal pain, discomfort, tenderness and/or distension, loose stools or diarrhoea, mucus, blood) as well as their laboratory findings during each visit. On the basis of these details, clinical evaluation was made using terms such as improvement or good response.

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Results

Praziquantel was found to be very effective, with the clinical response preceding the laboratory one. It was also useful in eliminating cysts of *E. histolytica* where metronidazole is known to be ineffective.

Vegetative trophozoite form of *E. histolytica* (acute amoebic dysentery)

Of the 37 patients diagnosed as acute amoebic dysentery and randomly allocated for treatment with praziquantel, 26 of them were followed up on subsequent visits. Of these, 23 (88%) showed a good response, both clinically and by stool examination. The remaining three patients had their treatment changed to metronidazole because of lack of response (Table 1).

It was observed that the disappearance of clinical signs and symptoms after treatment with praziquantel was remarkably fast (within the first day in most cases), while the laboratory response (negative stool examination) was delayed and was observed about one week after treatment. The response of patients with vegetative amoebic dysentery to praziquantel was comparable to that obtained in matched patients randomly selected for treatment with metronidazole (Table 1).

Table 1 **Acute amoebic dysentery (vegetative trophozoite form of *E. histolytica*): a comparison between praziquantel and metronidazole treatment**

Treatment	Number of patients		Good response	
	Total	Follow-up	No.	%
Praziquantel	37	26	23	88
Metronidazole	32	24	20	83

Cyst form of *E. histolytica*

There were 21 patients with the cyst form of *E. histolytica* and they were treated with praziquantel only. Cysts disappeared in 18 patients (86%) about a week after a single dose of praziquantel.

Intestinal giardiasis

Patients with intestinal giardiasis, diagnosed by stool examination as having the vegetative or cyst form of *G. lamblia* (n = 21), were randomly treated with praziquantel (n = 11) or metronidazole (n = 10) using the doses previously described. A good clinical and laboratory response was obtained in 70% and 78% in the praziquantel and metronidazole groups respectively.

Adverse effects of praziquantel

The main adverse effects reported by patients treated with praziquantel were nausea and vomiting (5.3%), especially if the whole dose was given undivided, as noticed in a preliminary study, and dizziness (5.3%). Other adverse effects encountered occasionally included mild fever, joint pain, sore throat, dysuria, retention of urine and severe apprehension.

Conclusion

Praziquantel, in a single dose of 40 mg/kg body weight, was effective in more than 80% of patients with amoebic dysentery and in 70% of those with intestinal giardiasis. These results were comparable to the effect of metronidazole, the difference being the use of a single dose of praziquantel, the rapid disappearance of clinical signs and symptoms and the ability of praziquantel to eradicate the cysts of *E. histolytica*.

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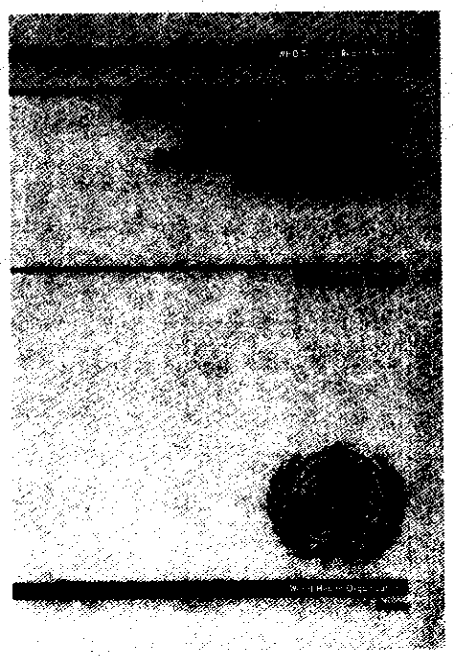

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities, the report discusses activities related to the further development of The international pharmacopoeia, *as well as simple test methodology, the stability of dosage forms, good manufacturing practices, legal and administrative aspects of the functioning of national drug regulatory authorities, and quality assurance in the supply system.*

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