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Praziquantel for cestode infections in man

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Introduction

Praziquantel, a new schistosomicide[1], showed to be very effective in experimental cestode investigations in animals (Thomas and Goennert, 1977). The recommended dosage in humans with *Taenia* sp. infections was demarcated at about 5–10 mg/kg as a single dose and at 10–25 mg/kg in humans with *Hymenolepis nana* infections. In *Diphyllobothrium latum* experimental data indicated a single dose of 25 mg/kg in humans (Bylund et al., 1977). Clinical trials were planned and initiated accordingly. All investigators agreed upon protocol and trial sheet design.

Patients and methods

Geographical distribution

Patients had to be found in non-european countries for *Taenia* and *Hymenolepis* infections as cestodiasis is a rare infection in Europe. Some cases, however, could be found among immigrants from North Africa in France. For the fish-tapeworm, *Diphyllobothrium latum*, patients were available in Finland, the classical country for this infection. The majority of cases was derived from Latin America, mainly Brazil, Argentine, Chile, Peru, Ecuador and Venezuela. Egyptian carriers of *H. nana* were included as well as patients from South Korea. A total of 1046 patients was treated.

Age and sex criteria

Patients' age was restricted to 6–70 years, but some patients were younger (the youngest 2 years old), and some very old cestode patients were also included, apparently without any negative consequences.

There was no distribution between male and female cases before the trials began. At the end the number of male and female patients was about equal. Most of hymenolepiasis patients were children and adolescents.

Exclusions

Patients with severe liver and intercurrent diseases were excluded from the trials. Pregnant women did not take part as well as lactating women.

[1] Praziquantel is a joint development of E. Merck and Bayer AG, West-Germany

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Specimen collection

Stool specimens were collected one to thirty days prior to treatment. In *Taenia* cases collection was repeated 30, 60 and 90 days after treatment.

In *Hymenolepis* cases collection was repeated at days 5–7, 10–14, and 19–23, after treatment. Three samples were taken at each three-day period, one per day. In about one third of the cases even three aliquots of each sample were taken.

In *Diphyllobothrium latum* cases stool samples were collected on day 21 after treatment, in *Diphyllobothrium pacificum* cases samples were taken 30, 60 and 90 days after treatment, in one case as late as 270 days.

Stool examination

Stools were examined by well documented techniques according to routine methods carried out in the respective hospitals.

Definition of cure

A patient was considered cured if his stool was found free from cestode eggs and/or proglottids in all specimens tested. For example, only a few *H. nana* eggs in one of the aliquots of the nine stool examinations should list the case as "non cured".

Clinical chemistry

Clinical chemistry tests were performed covering liver and kidney function, urine analysis, fasting glucose, WBC, erythrocytes, haemoglobin and reticulocytes. Samples were taken 24 h before and after treatment. Some of these tests were repeated 30, 60 and 90 days after intake of the drug.

General physical examination

All patients were examined by a medical doctor before and 24 h after treatment. This physical check-up should enable the investigator to register symptoms caused by the respective parasitic infections and to disclose discrete symptoms which could lead to exclusion from the trial. Symptoms discovered before treatment could thus be compared with symptoms after treatment, to exclude symptoms non attributable to treatment.

Treatment

Taenia solium et saginata cases received 5 mg/kg or 10 mg/kg as a single dose. Patients infected with *H. nana* received 10, 15, 20 or 25 mg/kg as a single dose. *Diphyllobothrium latum* patients were treated with 25 mg, *Diphyllobothrium pacificum* cases with 10 mg/kg, single dose. No laxatives should be administered. The patients received tablets with 400 mg, in some of the cases 150 mg tablets of Praziquantel. A dosage guide should enable the exact dosage mg/kg.

Results

In *Taenia saginata* infections 5 mg/kg were effective in 141/146 patients, 10 mg/kg in 256/267 patients. *Taenia solium* was difficult to find; accordingly only 9 patients were treated with 5 mg/kg, and 6/9 were cured. With 10 mg/kg, 33/33 patients could be cured. *Hymenolepsis nana* cases: 19/26 patients responded to 10 mg/kg, 286/323 patients to 15 mg/kg, 15/17 to 20 mg/kg and 351/380 to 25 mg/kg. *Diphyllobothrium latum* patients were cured in 52/54 cases by 25 mg/kg. In a field trial in Karelia, Finland, completed only recently, 151/159 patients were free of *D. latum* infection after 25 mg/kg Praziquantel

single-dose. *Diphyllobothrium pacificum* patients were cured by 10 mg/kg resulting in a 100% cure rate in 52/52 patients. These results confirm earlier reports already published or in print (see references).

Tolerance

The tolerance of the drug was good. Of totally 1046 patients treated with Praziquantel, 47 showed subjective symptoms. Headache, dizziness, abdominal discomfort and nausea were the main complaints, some of them by the same patients. Two skin rashes were observed within 24 h after treatment. Special medical care was not necessary for any of the reported adverse reactions. Laboratory examinations did not show any clinical relevant alterations from normal values. There were no clinical signs of interaction with other concomitant drugs given.

Discussion

Praziquantel, given as a single dose treatment, is clinically very effective in *Taenia, Hymenolepis* and *Diphyllobothrium* infections in humans. Tolerance of the drug was good. Occasionally complaints of abdominal discomfort, headache and dizziness were not of clinical importance. These symptoms persisted some minutes up to 3–4 h. The absence of objective side-effects apart from two skin-rashes, in over 1000 cases studied, showed that Praziquantel is practically safe. Proglottids were seldom observed in the faeces samples; only a few hours after treatment some patients reported that they saw proglottid-like parts of the cestode chain.

Although a comparative trial against Niclosamide was not performed the results of these multicentre investigations indicate that Praziquantel is comparable with Niclosamide in *Taenia* and *Diphyllobothrium* infections and superior to this drug in *Hymenolepis* infections.

Due to a relatively small patient material in Finland, lower dosages than 25 mg/kg were not given. Recommended dosages:
- in taeniasis: 5–10 mg/kg
- in hymenolepiasis 15 mg/kg
- in diphyllobothriasis (pacificum) 10 mg/kg
- in diphyllobothriasis (latum) 25 mg/kg

as a single-dose.

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