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# Albendazole: a new single dose anthelmintic

## Study in 1455 patients

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## Summary

Albendazole has been tested in an open trial conducted in France, seven countries of West-Africa, Martinique and the People's Republic of China in a total of 1455 patients harboring single or mixed infections caused by roundworms, pinworms, hookworms and whipworms. All patients were closely observed before and after treatment for clinical side effects and hematology and clinical chemistry values were done in about 5% of the cases. Fecal samples obtained before and approximately 15, 16 and 17 days after treatment were examined using the Kato test, and when negative, a concentration technic. In case of ancylostomiasis, a coproculture was carried out for species identification. Following a single oral dose, albendazole was highly effective in enterobiasis (100%), ascariasis (89%), ancylostomiasis caused by *Necator americanus* (88%) and trichuriasis (70%). The drug did not procedure any significant adverse reactions or modifications of the hematological and clinical blood chemistry values and only 6% of the 1455 patients reported minor side effects.

**Key words:** albendazole; roundworms; side effects.

## Introduction

Albendazole is methyl-5 propylthio-1-H benzimidazol-2-yl carbamate with the following structural formula:

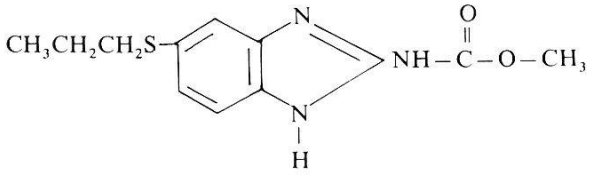


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Table 1. Number, age and sex of patients

| Age (years) | Males | Females | Total |
|---|---|---|---|
| 2–12 | 225 | 237 | 462 |
| 13–19 | 231 | 133 | 364 |
| 20–29 | 183 | 81 | 264 |
| 30–39 | 129 | 73 | 202 |
| 40–49 | 56 | 36 | 92 |
| More than 49 | 47 | 24 | 71 |
| Total | 871 | 584 | 1455 |

It has been reported to be a safe and effective broad spectrum nematocidal drug in the treatment of ascariasis, ancylostomiasis caused by *Necator americanus* and *Ancylostoma duodenale*, trichuriasis and strongyloidiasis (Pene et al., 1982). The objective of this multicenter open clinical trial was to confirm the effectiveness of a single 400 mg dose against the major intestinal nematodes.

**Patients, Material and Methods**

*Sites.* The study was conducted in Paris, France, in Martinique, in seven countries of West-Africa: Mali, Senegal, Niger, Guinea, Ivory Coast, Cameroon and Central African Republic, and in two provinces of the People's Republic of China: Inner Mongolia and Xinjiang.

*Patients.* A total of 1455 patients, mainly black African, and some 171 Chinese harboring a broad spectrum of nematodes was included. They remained outpatients of hospitals or dispensaries throughout the course of the study. Those patients who were receiving or who had received anthelmintics for 7 days prior to initiation of the study were excluded, as well as those with an acute illness (with or without fever), pregnant females, nursing mothers, children under three years, epilepsy cases and those with generalized active skin conditions. In general, patients who experienced high sensitivity to any drug or those receiving long-term therapy or those having chronic illnesses or proteinuria were excluded. Among 1455 patients, 871 were males and 584 females. There were 462 children under 12 years old, 225 boys and 237 girls. Number, age and sex distribution is shown in Table 1.

*Methods.* Each patient underwent a complete physical examination, including a fecal examination on a single stool specimen using the Kato technique (Kato and Miura, 1954; Katz et al. 1972). A Graham scotch test was also performed for suspected pinworm infections. In case of ancylostomiasis, a coproculture using the Harada-Mori technique (WHO, 1963) was carried out for species identification. At the same time, a pregnancy test was performed in all females of child-bearing potential and in 75 patients, haematology (CBC) and clinical chemistry values (BUN, SGOT, SGPT, proteinuria, glycosuria) were also obtained.

Albendazole was made available as a 200 mg tablet or 2% suspension. Treatments were administered as a single 400 mg dose *(2 tablets or 20 ml of suspension)* in the presence of the physician and the mouth was inspected after dosing. No fasting was required.

The same physical examination was carried out 24 to 72 hours after treatment and each patient was carefully questioned about clinical side effects and again in the 75 patient group, haematological and clinical chemistry values were determined.

Cure rate was based on repeated fecal examinations using the Kato technique and a concentration technique (Junod) when Kato was found negative. They were generally conducted on days

Table 2. Efficacy of albendazole treatment

| Parasite | No. of cases | Mean egg count (eggs/g feces) | Cure rate | Mean egg reduction Non-cured patients |
|---|---|---|---|---|
| *E. vermicularis* ... | 141 | – | 100% | – |
| *A. lumbricoides* ... | 502 | 2527 | 92% | 99% |
| *N. americanus* .... | 743 | 612 | 90% | 98% |
| *T. trichiura* ..... | 430 | 590 | 70% | 99% |

Table 3. Albendazole efficacy per intensity of infection

| Egg count class | No. of cases** | Mean egg count (egg/g feces) | % cured | Mean egg reduction |
|---|---|---|---|---|
| *A. lumbricoides* | | | | |
| Light infections* ..... | 276 | 521 | 96.3 | 38.4 |
| Moderate infections* ..... | 206 | 3,655 | 84.9 | 80.2 |
| Heavy infections* ..... | 20 | 51,839 | 100.0 | – |
| *N. americanus* | | | | |
| Light infections* ..... | 694 | 330 | 91.3 | 71.8 |
| Moderate infections* ..... | 46 | 3,902 | 70.0 | 66.3 |
| Heavy infections* ..... | 3 | 15,338 | 67.0 | 64.0 |
| *T. trichiura* | | | | |
| Light infections* ..... | 390 | 367 | 73.0 | 81.2 |
| Moderate infections* ..... | 39 | 2,839 | 46.1 | 71.2 |

* *Light infections:* less than 2,000 eggs per gram of feces. *Moderate infections:* from 2,000 to 10,000 eggs per gram of feces. *Heavy infections:* more than 10,000 eggs per gram of feces

** Multiple infections included

Table 4. Side effects of albendazole treatment

| Clinical signs | Number of cases |
|---|---|
| Epigastric pains ..... | 33 (2.2%) |
| Nausea ..... | 4 (0.2%) |
| Headache ..... | 16 (1.0%) |
| Vomiting ..... | 1 (0.1%) |
| Dizziness ..... | 2 (0.1%) |
| Diarrhea ..... | 29 (1.9%) |
| Constipation ..... | 1 (0.1%) |
| Pruritus ani ..... | 1 (0.1%) |
| Dry mouth ..... | 1 (0.1%) |
| Total | 88 (6.0%) |

15, 16 and 17 after treatment and three negative fecal examinations were necessary to consider the patient cured. In cases of diagnosed enterobiasis, a Graham scotch test was also done on the same days.

## Results

Out of 1455 patients, 1104 (75.8%) had single infections, 283 (19.4%) had mixed infections involving two parasites, 67 (4.6%) had three parasites, and only one four different organisms.

The drug was highly effective against *Ascaris lumbricoides, Enterobius vermicularis, Necator americanus* and *Trichuris trichiura* (Table 2).

In 28 patients harboring the cestode *Hymenolepis nana*, a cure rate of only 42% was recorded following the single 400 mg dose. Eleven patients had *Taenia saginata* and were followed up for only a maximum of 3 weeks. Twenty-one days is generally considered as inadequate to evaluate cure in such an indication. *Strongyloides stercoralis* was only found in 5 cases, an insufficient number for evaluation.

Albendazole efficacy per intensity of infection for each parasite is shown in Table 3.

A total of 88 clinical side effects were reported by the 1455 patients (Table 4). These side effects, observed in 6% of the patients, were minimal and generally disappeared within 48 hours. Haematology and clinical chemistry values obtained from 75 patients before and after treatment always remained within the normal limits.

## Discussion and Conclusions

The results of this multi-center open trial conducted in a large number of patients (1455) are very consistant with those reported in our previous experiment carried ou against a placebo (Pene et al., 1982). The drug administered as a single 400 mg dose both in adults and children is extremely well tolerated and highly effective against the four major species of intestinal nematodes: pinworms, roundworms, hookworms and whipworms. These results are suggesting that mass treatment could be considered for evaluating the drug in the control of intestinal nematode infections.

Kato K., Miura M.: Comparative examination. Jap. J. Parasit. *3*, 35 (1954).

Katz N., Chaves A., Pellegrino J.: A simple device for quantitative stool thick-smear technique in schistosomiasis mansoni. Rev. Inst. Med. trop. S. Paulo *14*, 397–400 (1972).

Pene P., Monjon M., Garin J. P., Coulaud J. P., Rossignol J. F.: Albendazole a new broad spectrum anthelmintic. Double-blind multicenter clinical trial. Amer. J. trop. Med. Hyg. *31*, 263–266 (1982).

World Health Organization: CCTA/WHO African Conference on Ancylostomiasis, Brazzaville, 22–29 August 1961. WHO Techn. Rep. Ser. No. 255 (1963).