

SIMPÓSIO INTERNACIONAL comemorativo do CENTENÁRIO da descoberta da DOENÇA DE CHAGAS 1909 • 2009



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Trabalhos Científicos

BENZONIDAZOLE ADVERSE EVENTS IN PATIENTS WITH CHRONIC CHAGAS DISEASE TREATED AT THE INSTITUTO DE PESQUISA CLÍNICA EVANDRO CHAGAS / IPEC / FIOCRUZ: PRELIMINARY ANALYSIS.

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Eixo Temático:

Terapia

Introduction: Chagas disease is classified as a neglected disease. One of its the main reason is a very long period with lack of investments in developing new therapies. Clear evidence about this issue is the uncertainty about the benefit of Chagas disease treatment in the chronic phase after all these years. Benzonidazole is given to most of Chagas disease chronic patients that should receive trypanocidal therapy, an imidazole derivate with approximately 60 years old, whose effect has always been questioned and with considerable adverse effects rates. It was described previously that about one third of all subjects treated do not complete therapy due to any kind of intolerance.

Objective: To describe adverse events rates during benzonidazole trypanocidal therapy in patients with chronic Chagas disease.

Methods: This was a retrospective observational follow-up study with active search in medical registers. Medical charts of all patients with Chagas disease that started follow-up or were treated with benzonidazole between April 2000 and August 2004 were checked. Data regarding trypanocidal therapy adverse events were recorded on clinical research forms. Each event was classified for its causality with the Naranjo algorithm and intensity with the NIH recommendations.

Results: Three hundred and twelve medical charts were initially screened, and 42 patients received benzonidazole, all of them were patients with chronic Chagas disease. Male patients are 52.38% of the sample, median age of 28 and age range from 5 to 50 years, quartiles of 24 and 30 (25% and 75% respectively). Only 2 (4.76%) had record of any drug allergy before treatment. All patients used 200mg/day of oral benzonidazole. The treatments lasted between 4 and 90 days, with a median of 42 days. Only 6 (14.28%) patients completed 60 days therapy, 1 completed 90 days, 3 discontinued because of suspected pregnancy and 22 discontinued because of a event, that is, 70.96% of the events justified therapy interruption. From those who discontinued treatment, 2 patients resumed and finished at the time recommended by their doctors and 1 dosage was changed to a smaller dose. There was no hospitalization because of events and all patients recovered without sequel. Only seven patients used other



medications during benzonidazole therapy.

There were records of 31 events in 42 treatments. Five patients had three or four events, one patient had two events (this one was coinfecting with HIV) and in the remainder only one event was recorded. The crude incidence of therapies with any adverse events was 42.86%.

&tabela

Adverse events reported during treatment are presented in the table. The most common were: rash (32%), nausea (19%), vomiting and headache (9.7%).

Applying the causality Naranjo algorithm, 20 (64.52%) events were classified as probable and 11 (35.48%) as possible. Regarding intensity, 2 (6.45%) were classified as severe, 13 (41.94%) as moderate and 16 (51.61%) as mild. Only three treatments interrupted by suspected pregnancy were classified as serious.

Conclusion: Almost half of the patients had at least one event. Most of the events justified therapy interruption, although they were not classified as severe and did not lead to sequel or hospital admission. These benzonidazole unwanted characteristics are similar or worse than other old drugs such as anphotericin and erythromycin. If benzonidazole was a new product in a research process at present time, certainly it would not pass through the preliminary phases. Even so, it is still widely used due to lack of alternatives to trypanocidal therapy. Dosage with lower daily doses and for prolonged periods, or combined with other drugs could, theoretically, reduce the incidence of benzonidazole adverse events and could be easily tested in controlled research settings. However, benzonidazole effect would remain uncertain.

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