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Clinical follow-up and tolerance of Chagas infected patients treated with benznidazole

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Background: The World Health Organization estimates that *Trypanosoma cruzi* infection affects 6-7 million people worldwide. There are two drugs available for this disease, benznidazole and nifurtimox, which can stop progression if administered in the acute phase of the infection. Benznidazole is the first choice drug to treat Chagas disease, but its efficacy is controversial in chronic infected patients. Moreover, bibliography suggests that around 40% of patients treated with this drug suffer any kind of adverse effects.

Material/methods: The aim of the study was to study the efficacy and safety of benznidazole treatment for Chagas' disease in real conditions, in a cohort of patients diagnosed in a non-endemic country and treated with a sequentially ascending dosage of the drug. Since September 2007, all patients aged more than 18, infected by *Trypanosoma cruzi* and diagnosed in a tertiary hospital's Tropical Diseases consultation were included. Treatment schedule consisted on a slowly increasing dose of 50 mg benznidazole every 2 days, up to the maximum dose of 5 mg/kg/day or 300 mg daily, continued during 60 days, and administered with 2 mg of dexclorpheniramine until day 21 after the maximum dose was reached. The patients were checked every 15 days, looking for adverse effects and analyzing blood count and liver function tests.

Results: In total 29 patients were included in the study, but only 22 reached the inclusion criteria. Most of them were women (77,3%), aged 40,4 years at diagnosis, and all except one Spanish patient coming from South America. Polymerase chain reaction (PCR) for diagnosis of Chagas disease was negative after treatment with benznidazole in all cases, whereas negative serology was only found in 3 patients. After 3 to 5 years of follow-up, electrocardiographic disorders were found in 32% of patients. 63,6% experienced at least one adverse reaction related to treatment, including general symptoms (18,2%) such as headache and asthenia, mild cutaneous disease (urticaria and erythema) in 9,1% of patients, gastrointestinal disorders only in one patient (4,5%), and hematological (22,7%) and biochemical (36,4%) alterations. None of them was serious, and they all resolved with symptomatic treatment and without benznidazole discontinuation.

Conclusions: Benznidazole is an effective treatment for Chagas disease in latent and chronic phases. Although the incidence of adverse effects observed, most were mild and all responded to symptomatic treatment, so it was not necessary to interrupt the treatment of any patient. Concomitant

administration of prophylactic treatment with antihistamines and sequentially ascending dosage reduced the occurrence and severity of skin reactions. Until a better treatment available for *Trypanosoma cruzi* becomes available, patients infected beneficiating from treatment with this drug should be closely monitored.