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Comparison of metronidazole vs paramomycin in the treatment of *D. fragilis* infection

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Background: : *Dientamoeba fragilis* is a pathogenic protozoan of the human gastrointestinal tract with a worldwide distribution. Drugs as metronidazole and paramomycin have been used in its treatment. This study compares the results of the treatment with metronidazole versus paramomycin in a group of patients with *D. fragilis* infection.

Material/methods: We perform a descriptive study in all patients diagnosed with *D. fragilis* infection. Each patient's clinical history was collected. Blood tests and biochemical analyses were performed for all patients. Three stool samples per patient were concentrated stained with lugol and screened under a light microscope with a low magnification. *D. fragilis* was detected using a PCR assay. A pinworm test was performed in stool samples of all patients. Parasitological controls were performed at 4 and 8 weeks after the end of treatment in all patients. All patients were treated with metronidazole 500 mg/8 h or paramomycin 250 mg/8 h. Patients with *E. vermicularis* co-infection and/or an *E. vermicularis*-positive case in the family were treated with mebendazole 100 mg/12 h for 3 days.

Results: 103 patients (51,4% male, mean age 34[20]) were studied. Most of them were from Spain (60%), followed by those who came from Equatorial Guinea (12.6%), Colombia (8.7%), Ecuador (6%), Pakistan (4%) and others countries (8.7%). Forty-seven patients (44.8%) were asymptomatic. The most frequent symptoms reported by the remaining patients were abdominal pain abdominal pain (32 patients) and diarrhea (14 patients). The mean level of eosinophilia was $1.361 \pm 1.676 \times 10^9$ cells/l. Five patients had hypereosinophilia in the blood. Eighty-seven patients were treated with metronidazole and 16 with paramomycin. There were no *statistically significant differences* in sex, age, origin, or symptoms between both groups. A co-infection with *E. vermicularis* was found in 32 patients (31 from metronizadole group, $p = 0.014$) and at least one episode of *E. vermicularis* in the family was

reported in 44 patients (41 from metronidazole group, $p=0.030$). Of the 90 patients, who were cured, 74 (83.9%) were included in metronidazole group and 16 (100%) in paramomicin group. Although all patients treated with paramomicin cured, there is no significant differences ($p=0.093$). *D. fragilis* was detected in stool samples taken 4 weeks after the treatment of the 13 remaining patients. Treatment failure was associated to coinfection by *E. vermicularis* (9 vs 4 $p=0.003$ [0.043-0.543]) or detection of *E. vermicularis* in a family member (10 vs 3, $p=0.009$, OR 0.182[0.047-0.709]) but not with the metronidazole treatment ($p=0.255$). Multivariable analysis confirmed the influence of *E. vermicularis* ($p=0.009$), but not the metronidazole treatment ($p=0.252$).

Conclusions: Metronidazole is a safe and secure treatment for *D. fragilis* infection with no *E. vermicularis* coinfection. The presence of *E. vermicularis* should be discarded previously to the beginning the treatment.