XYLOGLUCAN FOR THE TREATMENT OF ACUTE DIARRHEA: RESULTS OF A RANDOMIZED, CONTROLLED, OPEN-LABEL, PARALLEL GROUP, MULTICENTRE, NATIONAL CLINICAL TRIAL
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Introduction: There is a strong rationale for the use of agents with film-forming protective properties, like xyloglucan, for the treatment of acute diarrhea. However, few data from clinical trials are available.

Aims & Methods: To assess the efficacy, safety and time of onset of the antidiarrheal effect of xyloglucan (Xilaplus®), in comparison with two widely used anti-diarrheal agents, the yeast probiotic Saccharomyces boulardii (Ultra-Levura®), and diosmectite (Smecta®), an absorbent activated natural aluminosilicate clay.

This randomized, controlled, open-label, parallel group, multicentre, clinical trial included adult patients with acute diarrhea due to different causes.

Patients were randomized to receive a 3-day treatment (4 capsules/6 h of Xilaplus®, 3 sachets/day of Smecta® and 2 capsules/day of Ultra-Levura®), being the first dose administered at visit 1. Presence of symptoms (stools type 6 and 7 on Bristol Scale, nausea, vomiting, abdominal pain and flatulence) was assessed by a self-administered ad-hoc questionnaire at 1, 3, 6, 12, 24, 48 and 72 h after the first dose administration. Adverse events were recorded.

Results: 150 patients (69.3% women, mean age 47.3 ± 14.7 years) were included (n = 50 in each group). A faster onset of action was observed in the xyloglucan group compared with diosmectite group, in terms of absolute and mean number of stools (p<0.05) during the first 24 h. In the xyloglucan group the highest reduction of the number of type 6 and 7 stools was observed at 6 h with an effect that was statistically significant compared with diosmectite (p = 0.031). A higher efficacy was also observed with xyloglucan compared to S. bouliardii at 12 and 24 h.

Xyloglucan was the most efficient treatment in reducing nausea throughout the study, particularly during the first hours (from 26% at baseline to 4% after 6 and 12 h).

An important improvement of vomiting was observed in all three treatment groups, with null percentages at 6 and 12 h.

Xyloglucan was more effective than diosmectite and S. bouliardii in reducing abdominal pain, with a constant improvement observed throughout the study. At visit 2, the lowest percentage of patients with abdominal pain was recorded in the xyloglucan group (10%), in comparison with diosmectite (22%) and S. bouliardii (12%).

The clinical evolution of flatulence followed similar patterns in the 3 groups, with continuous improvement of the symptom. The greatest improvement was shown in the xyloglucan group, with 10% of patients with flatulence at visit 2, compared with diosmectite (30%) and S. bouliardii (18%).

All 3 treatments were well tolerated, without adverse events.

Conclusion: Xyloglucan is a fast, efficacious and safe option for the treatment of acute diarrhea, with a rapid onset of action in reducing diarrheal symptoms.
I confirm having declared any potential Conflict of Interest for ALL authors listed on this abstract: Yes

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