Xyloglucan for the treatment of acute diarrhea: results of a randomized, controlled, open-label, parallel group, multicentre clinical trial

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Background and aim

Currently, there is a strong rationale for the use of agents with film-forming protective properties, such as xyloglucan, which are able to form a protective mucoadhesive film in the intestine [1-3]. However, few data from clinical trials are available.

This randomized, controlled, open-label, parallel group, multicentre, clinical trial was performed to evaluate the efficacy and safety of xyloglucan (Tasectan Plus®, containing xyloglucan and gelatin of animal origin), in comparison with diosmectite (Smecta®) and *Sacharomyces boulardii* (Ultra-Levura®) in adult patients with acute diarrhea due to different causes.

Patients and Methods

Patients were randomized to receive a 3-day treatment (four capsules/6 hours in the case of Tasectan Plus®, three sachets/day in the case of Smecta® and 2 capsules/day in the case of Ultra-Levura®), in which the first dose was administered at visit 1 (baseline). Presence of symptoms (stools type 6 and 7 according to Bristol Stool 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 hours following the first dose administration. Occurrence of adverse events was also recorded. At visit 2, at day 3, approximately 72 hours after visit 1, the investigators reviewed the patient´s daily diary, regarding symptoms and adverse events recording.

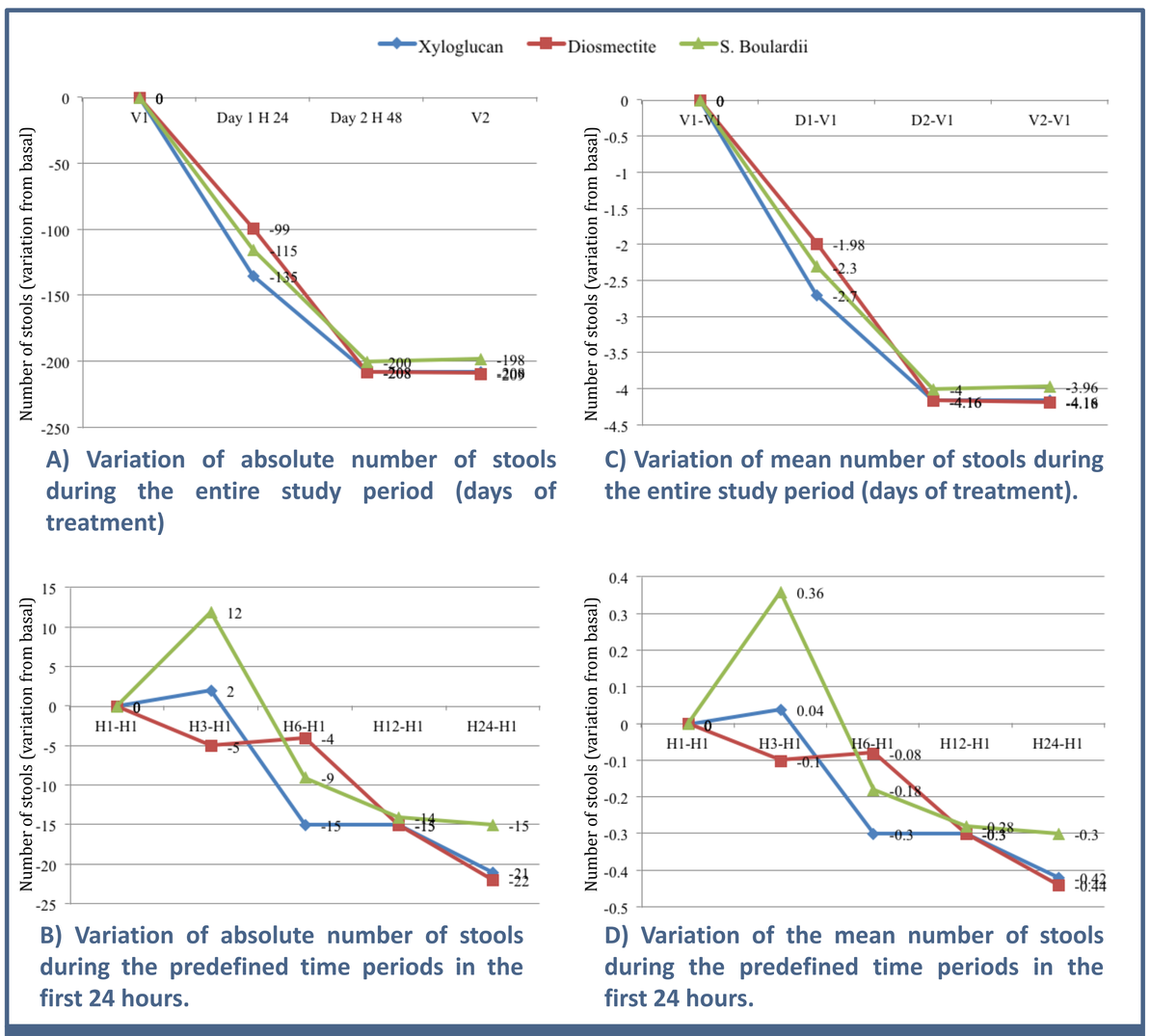
Results

A total of 150 patients were included in the study (50 in each group). Demographic characteristics were homogeneous among groups, with 69.3% of women and a mean age of 47.3 ± 14.7 years (Table 1).

Table 1. Demographic characteristics among groups (F: female; M: male; SD: standard deviation).

	Statistic variable	Xyloglucan-gelatin	Diosmectite	*S. bouliardii*	Total
Gender (F/M)	n (%)	38 (76.0)/12 (24.0)	33 (66.0)/17 (34.0)	33 (66.0)/17 (34.0)	104 (69.3)/46 (30.7)
Age (years)	Mean (SD)	48.4 (14.5)	46.3 (16.9)	47.1 (12.5)	47.3 (14.7)

A faster onset of action was observed in the xyloglucan-gelatin group within the first 24 hours, with the highest reduction observed at 6 hours, in terms of absolute and mean number of type 6 and 7 stools, with statistically significant differences in comparison with diosmectite group (p = 0.031) (Figure 1).



A) Variation of absolute number of stools during the entire study period (days of treatment)

C) Variation of mean number of stools during the entire study period (days of treatment).

B) Variation of absolute number of stools during the predefined time periods in the first 24 hours.

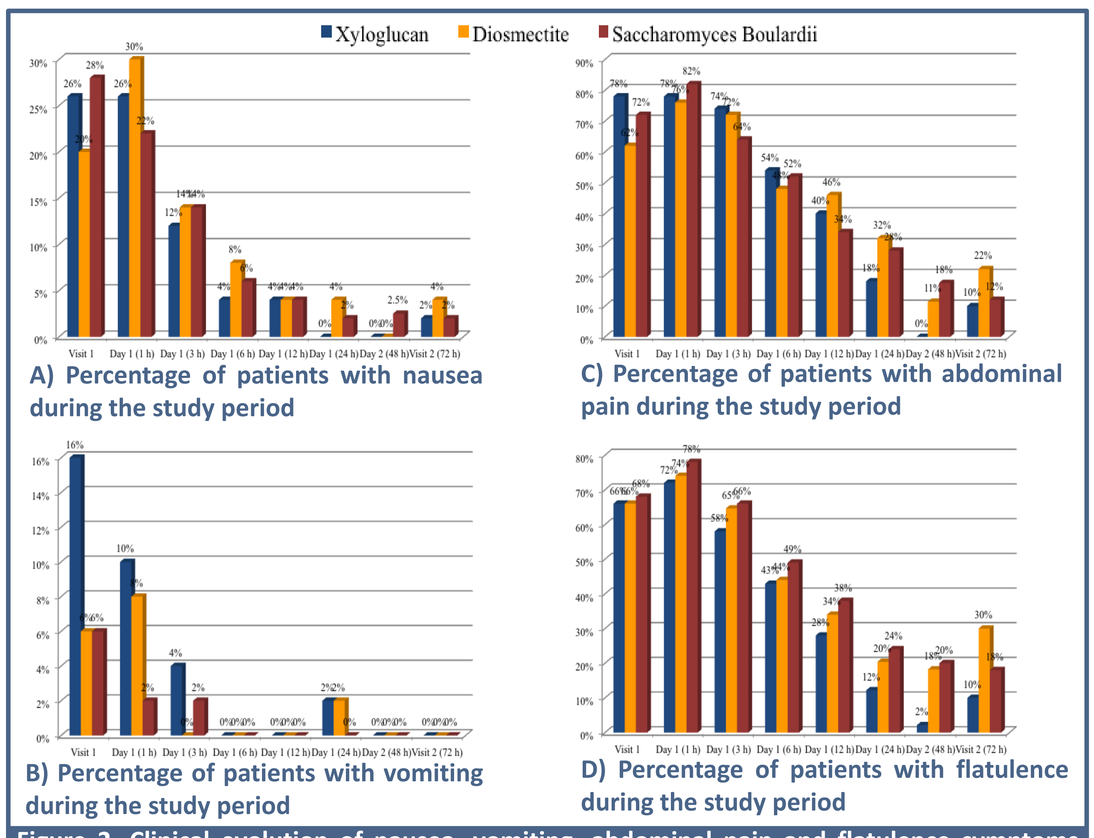
D) Variation of the mean number of stools during the predefined time periods in the first 24 hours.

Figure 1. Clinical evolution of diarrheal symptoms (number of stools) among groups.

All three treatments were safe and well tolerated, without any adverse event reported.

Xyloglucan was the most efficient treatment in reducing the percentage of patients with nausea throughout the study period, particularly during the first hours (from 26% at visit 1 and one hour after to 4% at 6 and 12 hours after visit 1) (Figure 2A). Regarding vomiting, an important improvement was observed in all three groups during treatment, with null percentages at 6 and 12 hours after visit 1 in all groups (Figure 2B).

Xyloglucan was more effective than diosmectite and *S. boulardii* in reducing abdominal pain, with a constant improvement observed throughout the study (Figure 2C). The clinical evolution of flatulence followed similar patterns in the three groups, with a slight worsening during the first hour after visit 1 and continuous improvement until visit 2 (Figure 2D).



A) Percentage of patients with nausea during the study period

C) Percentage of patients with abdominal pain during the study period

B) Percentage of patients with vomiting during the study period

D) Percentage of patients with flatulence during the study period

Figure 2. Clinical evolution of nausea, vomiting, abdominal pain and flatulence symptoms (percentage) among groups.

Conclusions

Xyloglucan is an efficacious and safe therapy for the treatment of acute diarrhea, with a rapid onset of action reducing diarrheal symptoms.

References

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