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ORIGINAL ARTICLE

Effectiveness of a high fiber diet in improving constipation in patients with defecatory dyssynergy under treatment with anorrectal biofeedback. Exploratory, randomized clinical trial

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KEYWORDS
Functional constipation;
Defecatory dyssynergy;
Anorrectal biofeedback;
Fiber diet

Abstract
Introduction: fiber is the initial treatment in chronic functional constipation. However, its role in the group of patients with defecatory dyssynergy is not well established. The objective of the study is to evaluate the efficacy and safety of a high fiber diet in patients with defecatory dyssynergy in the treatment with anorectal biofeedback.
Patients and methods: An exploratory, randomized (1:1), double-blind, controlled "add-on" clinical trial was carried out in a reference center in Spain in patients with functional constipation and defecatory dyssynergy according to the ROME IV criteria. Control group: treatment with biofeedback and low-fiber diet (15—20 g/day). Experimental group: treatment with biofeedback and high fiber diet (25—30 g/day). Analyzed: responder (primary endpoint), patient whose defecatory dyssynergy had been corrected (>20% reduction in anal pressure during the defecation maneuver and normal balloon expulsion test); anorectal parameters (anal relaxation, reduced straining); safety (abdominal symptoms: flatulence, pain, borborygmus, bloating).

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Results: A total of 44 patients were randomized: 22 per group. The percentage of responders was 75% (15/20, 95% CI: 53 89%) control group and 70% (14/20, 95% CI: 48–85%) experimental group, p value: 0.225. Differences in favor of the control group were only observed in abdominal symptoms: flatulence (p-value: 0.028), abdominal distension (p-value: 0.041) and digestive comfort (p value: 0.043).
Conclusions: In patients with defecatory dyssynergy, a high-fiber diet not only does not improve the efficacy of anorectal biofeedback but is associated with a loss of improvement in abdominal symptoms.

PALABRAS CLAVE
Estreñimiento funcional;
Disnergia defecatoria;
Biofeedback anorrectal;
Dieta con fibra

Eficacia de la dieta alta en fibra en la mejora del estreñimiento en pacientes con disinergia defecatoria en tratamiento con *biofeedback* anorrectal. Ensayo clínico exploratorio, aleatorizado

Resumen
Introducción: La fibra es el tratamiento inicial en el estreñimiento crónico funcional. Sin embargo, su papel en el grupo de pacientes con disinergia defecatoria no está bien establecida. El objetivo del estudio es evaluar la eficacia y seguridad de la dieta alta en fibra en pacientes con disinergia defecatoria en el tratamiento con *biofeedback* anorrectal.
Material y métodos: Se realizó un ensayo clínico exploratorio, aleatorizado (1:1), doble ciego, controlado ''add-on'', en un centro de referencia en España en pacientes con estreñimiento funcional y disinergia defecatoria de acuerdo con criterios de ROMA IV. Grupo control: tratamiento con *biofeedback* y dieta baja en fibra (15—20 g/día). Grupo experimental: tratamiento con *biofeedback* y dieta alta en fibra (25—30 g/día). Se analizó: respondedor (variable principal), paciente que la disinergia defecatoria se había corregido (>20% de reducción de la presión anal durante la maniobra defecatoria y prueba de expulsión del balón normal); parámetros anorrectales (relajación anal, reducción del esfuerzo); seguridad (síntomas abdominales: flatulencia, dolor, borborigmo, distensión).
Resultados: Un total de 44 pacientes fueron aleatorizados: 22 por grupo. El porcentaje de respondedores fue 75% (15/20, IC95%: 53–89%) grupo control y 70% (14/20, IC95%: 48–85%) grupo experimental, p-valor: 0.225. Sólo se observaron diferencias a favor del grupo control en síntomas abdominales: flatulencias (p-valor: 0.028), distensión abdominal (p-valor: 0.041) y bienestar digestivo (p-valor: 0.043).
Conclusión: En pacientes con disinergia defecatoria, la dieta alta en fibra no sólo no mejora la eficacia del *biofeedback* anorrectal, sino que se asocia a una pérdida de la mejoría de los síntomas abdominals.

Introduction

Chronic functional constipation is a common reason for consultation in primary care and gastroenterology. It takes up a considerable share of healthcare resources and significantly affects patients' quality of life.[1]

A high-fibre diet is the initial therapeutic measure for chronic functional constipation recommended by most scientific societies.[2,3] In general, a gradual increase in fibre intake, included in the diet or as supplements, from 10—15 g (the amount consumed in the Western world) to 25—30 g of fibre per day is recommended.[4] A high-fibre diet is associated with abdominal distension and flatulence in more than 50%.[5]

The role of fibre has not been established in the group of patients with chronic functional constipation and defecation disorders (DD), also called constipation due to dyssynergic defecation.[6] Functional and DD-related constipation, unlike constipation associated with irritable bowel syndrome (IBS-C), where the predominant symptom is abdominal pain, is primarily due to impairment in the coordinated physiological mechanisms of defecation.[6]

The treatment of functional and DD constipation is well established and is performed using the anorectal biofeedback technique.[6] It is based on operant conditioning techniques and uses instruments such as electromyography (EMG) sensors, balloons and anorectal manometry to guide the patient to increase intra-abdominal pressure effectively and to relax the pelvic floor and anal sphincters in a coordinated way during defecation.[7]

Our working hypothesis is that a high-fibre diet is an effective treatment in patients with chronic functional

constipation and DD having treatment with the anorectal *biofeedback* technique. Therefore, the aim of this clinical trial is to study the efficacy and safety of a high-fibre diet (HFD) in these patients.

Patients and methods

Study design

An exploratory, randomised, double-blind, add-on controlled, parallel, single-centre (tertiary hospital) clinical trial was conducted in patients with chronic functional constipation and DD.

The study protocol was approved by the Research Ethics Committee (2018/23-DIG-HUGC) of the Hospital General Universitari de Catalunya, Universitat Internacional de Catalunya, and is registered in the Research Registry (research registry 8468). All patients gave their written informed consent to participate in the study. This clinical trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines (ICH E6). Patient confidentiality was guaranteed in accordance with current Spanish legislation (personal data protection law, LOPD 3/2018). This manuscript has been written in accordance with the CONSORT 2010 guideline.

Participants

Patients were recruited from the hospital outpatient clinic for the gastroenterology department. In accordance with our clinical practice, all patients with symptoms of functional constipation according to Rome IV criteria underwent anorectal manometry and a rectal balloon expulsion test. Those who had a defecation disorder (dyssynergic defecation) according to Rome IV criteria, defined as abnormal anorectal voiding pattern by manometry (<20% reduction in anal pressure during the defecation manoeuvre) and abnormal rectal balloon expulsion test, had the study explained to them and were offered the chance to take part.

Inclusion criteria were patients: $\geq$18 years old; male or female; with a diagnosis of functional constipation and dyssynergic defecation according to Rome IV criteria; and who agreed to take part (signing the informed consent form). Exclusion criteria: patient deemed by the investigator to be unable to meet the requirements of the study.

Study procedure

Fig. 1 shows the procedure followed in the clinical trial. Three visits were conducted: visit 1 or patient enrolment visit; visit 2 or randomisation visit or treatment initiation visit, 7 days after time 0 of visit 1; and visit 3 or end of study, 10 weeks after visit 1.

Visit 1. At this visit the patient signed the informed consent form. Once signed: (a) information was collected on abdominal and defecation symptoms with a "symptom questionnaire"[8]; this questionnaire was completed every day for the first week of the clinical trial; (b) anorectal manometry and a rectal balloon expulsion test were performed (these procedures were the same as those used at diagnosis); and (c) colonic transit time (CTT) was studied.

After completion of tests (b) and (c) (time 0) the *pretreatment period* of one week began. During this first week of the study, patients had to eat their usual diet and fill in a diary provided by a dietician recording the food they consumed.

Visit 2 (7 days - week 1 - after visit 1). The patient was visited by the dietician, to whom they had to hand in the diary with the record of the food consumed during the first week and the "symptom questionnaire".[8] The approximate daily fibre intake was calculated. The patient was randomised according to the randomisation list to either a low-fibre diet (LFD) or a high-fibre diet (HFD). The 9-week *treatment period* then began.

Visit 3 (10 weeks after visit 1). a) The "symptom questionnaire"[8] was collected in; this questionnaire was to be completed every day for the week prior to visit 3; (b) anorectal manometry and a rectal balloon expulsion test were performed; and (c) CTT was studied.

The anorectal tests - anorectal manometry and rectal balloon expulsion test - were repeated after anorectal biofeedback therapy to identify patients in whom dyssynergic defecation had been corrected (>20% reduction in anal pressure during bowel movements and normal balloon expulsion test).[9]

Randomisation and blinding

The computer-generated randomisation list was created by an external statistical consultant prior to the start of the study. Patients were randomised in blocks of 10. Once the patients who met the inclusion criteria and none of the exclusion criteria had signed the informed consent form, they were randomised (1:1) to one of two study groups: (1) control group: patients treated with anorectal biofeedback and a low-fibre diet (1520 g/day); or (2) experimental group: patients treated with anorectal biofeedback and a high-fibre diet (25−30 g/day).

The study participants were informed by the investigating physician responsible for each patient. It was explained to them that the treatment consisted of either a low-fibre diet or a high-fibre diet; that they would not be informed which of the two diets they had been allocated at randomisation; and that they would not be informed of the end-of-study manometry result and whether they had responded to the treatment (anorectal biofeedback and diet) until the clinical trial had been completed and analysed. The investigating physician responsible for each patient provided the informed consent form for signing and conducted visits 1 and 3, unaware of (blinded to) which type of diet each patient had been assigned. The investigating physician was therefore blind to the diet when assessing the efficacy (anorectal manometry and balloon expulsion test), abdominal and defecation symptoms and CTT.

The investigating team's dietician randomised and provided the study diets and instructions to the patients at visit 2 and also assessed the amount of fibre in the diet (pretreatment period). The dietician undertook not to reveal which type of diet had been assigned to the rest of the investigating team.

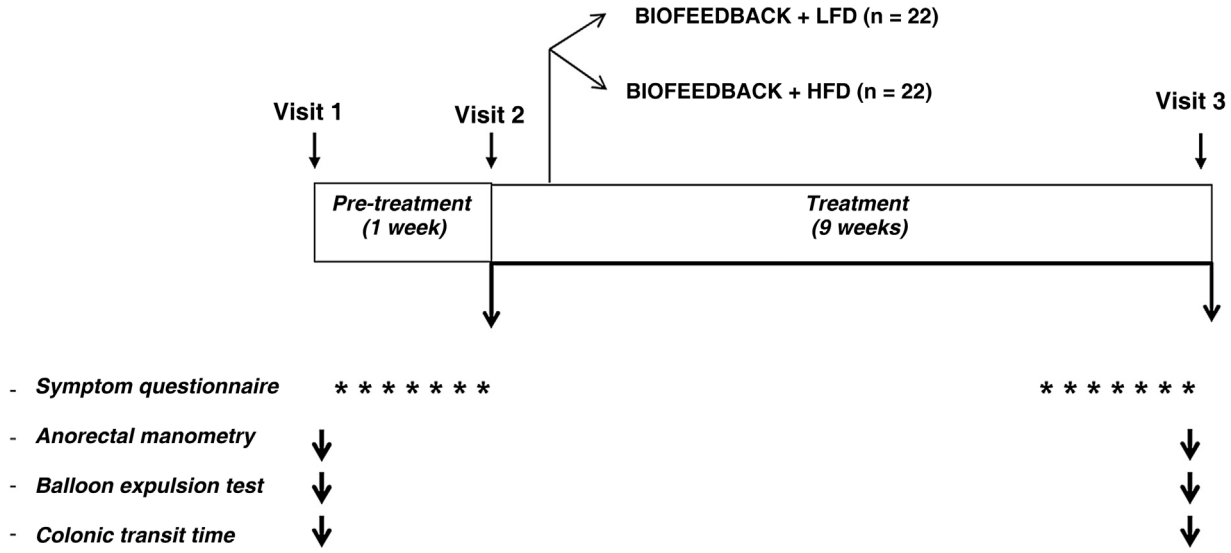

Figure 1 Experimental design.
HFD: high-fibre diet; LFD: low-fibre diet.

Treatments to be studied

Anorectal biofeedback. All patients included in the clinical trial were treated with anorectal biofeedback. During the treatment period, three standard biofeedback sessions were conducted in our laboratory.

In addition, the patient had to perform exercises at home every day according to the instructions given by the rehabilitation nurse. The patient watched the intrarectal and anal manometry recordings on the monitor continuously so they could observe what happened when they tried to move their bowels. They could then be shown how to do it correctly by watching the change in pressures.[8] The sessions each lasted 30—45 min and a total of three sessions were held; at weeks 2, 5 and 8 after visit 1, during the treatment period.

High-fibre diet (25—30 g fibre per day): experimental group. This diet consisted of:

- Breakfast: wholemeal bread rusks or biscuits.
- Lunch: portion of vegetables or pulses (broccoli, mixed vegetables, artichokes, peas, beans, lentils and chick-peas) + wholemeal bread on the side, accompanied by meat of choice, and fruit for dessert (apple, pear, orange or mandarins).
- Evening meal: vegetable soup (spinach, carrot and leek, courgette, aubergine) + wholemeal bread on the side, accompanied by meat of choice, and fruit for dessert (apple, pear, orange or mandarins).

Low-fibre diet (15—20 g fibre per day): control group. This diet, with a similar amount of fibre to that consumed in a standard diet in the Western world, consisted of:

- Breakfast: non-wholemeal cereals or bread rusks; optional white bread sandwich with cold meat or cheese plus black coffee/coffee with milk or some type of tea.
- Lunch: portion of vegetables or pulses (broccoli, mixed vegetables, artichokes, peas, beans, lentils and chick-peas) + white bread on the side, accompanied by meat of choice, and fruit for dessert (apple, pear, orange or mandarin).
- Evening meal: pasta, rice, soup or salad accompanied by meat of choice and fruit for dessert (apple, pear, orange or mandarins).

During the nine-week treatment period, patients were not allowed to consume any fermented milk products or food supplements containing prebiotics or probiotics. A dietician provided dietary instructions and checked adherence to the diets using structured intake questionnaires.[10]

Study variables

Primary efficacy endpoint: anorectal manometry. The defecation pattern was assessed by manometry, using a five-lumen polyvinyl catheter (outer diameter 4.8 mm; ARM, Arndorfer, WI) with four manometry sensors spaced 1 cm apart and a latex balloon at the distal tip located 5 mm from the distal sensor. With the sensors placed in the anal canal and the balloon inflated with 25 ml of air in the rectum, patients were asked to go through their usual process for trying to move their bowels; normally, abdominal compression during straining (increased rectal pressure) is associated with anal relaxation (drop in anal pressure). Both rectal pressure and the change in anal pressure during the bowel movement were measured.

Balloon expulsion test. The expulsion capacity was measured by this test following the standard procedure in our laboratory. Abnormal evacuation was defined as the inability to evacuate a rectal balloon filled with 60 ml of water in less than one minute.[11]

A responder was defined as a patient whose anorectal manometry after biofeedback therapy showed that the dyssynergic defecation had been corrected (>20% reduction in anal pressure during the bowel movement and normal balloon expulsion test).[9]

Secondary efficacy variables: abdominal and defecation symptoms, and CTT.

- *Abdominal and defecation symptoms questionnaire*. Participants were instructed to complete symptom questionnaires every day for one week at two points during the clinical trial. The first time point corresponded to the pre-treatment period (week 1 of the clinical trial, days 1–7) and the second time point corresponded to the last week of the diet treatment period (week 10 of the clinical trial, days 64–70).

The questionnaire included the following parameters: a) subjective sensation of flatulence, abdominal pain, borborygmi and abdominal distension with analogue scales from 0 to 10; b) digestive well-being using a 10-point numerical scale ranging from +5 (extremely comfortable/satisfied) to -5 (extremely uncomfortable/dissatisfied), and mood with 10-point numerical scale ranging from +5 (very positive) to -5 (very negative); c) number of bowel movements per week; d) straining to defecate, incomplete evacuation and digital evacuation in yes/no response; and e) stool consistency using the Bristol scale.

This questionnaire has been used in previous studies and has been shown to be sensitive enough to detect the effects of dietary interventions in different populations.[12,13]

- *Colonic transit time*. CTT was determined by the Chaussade and Metcalf method,[14] protocolised by the Grupo Español para el Estudio de la Motilidad Digestiva [Spanish Group for the Study of Gastrointestinal Motility],[15] consisting of the daily ingestion in the morning of two gelatin capsules, which each contain ten radiopaque markers (Portex®), for three successive days. In total the patient swallowed 60 markers. On day four, a plain panoramic X-ray of the abdomen was performed with a high kilovoltage technique and low exposure time. On day seven, another X-ray was taken using the same technique as described above. For the days of the study, the patient was not to take laxative medication. Instructions were given in writing to patients or their relatives. To facilitate follow-up, markers were administered on Saturday, Sunday and Monday, with X-rays being taken on the following Tuesday and Friday.

The total CTT was calculated by counting the number of markers on the two radiographs and multiplying by the constant 1.2. The right, left and rectosigmoid segmental CTT were determined by dividing the radiographs by three preset lines, counting the markers in each area and multiplying by 1.2.[15]

Safety variables. The abdominal and defecation symptoms questionnaire was also used as an instrument to assess the safety of the diets. We also recorded all adverse events which occurred or were reported by patients throughout the clinical trial.

Statistical analysis

Sample size calculation. Of patients with chronic primary DD constipation, 70% correct dyssynergic defecation after being treated with anorectal biofeedback (unpublished internal data). To detect differences in the contrast of the null hypothesis (H_0:p1 = p2) using a bilateral chi-square test for two independent samples with a power of 80%, taking into account a significance level of 5% and a distribution between groups of 1:1, and assuming that dyssynergic defecation will be corrected in 70% of the control group and 90% of the experimental group, it will be necessary to include 62 patients in each study group, totalling 124 patients. An interim futility analysis was scheduled for when at least 40 patients had completed the study. A "data and safety monitoring committee" was set up to evaluate this interim analysis and recommend stopping or continuing the clinical trial.

A descriptive analysis of the different study variables was performed. Continuous variables were described as mean and standard deviation (SD) and categorical variables as absolute frequencies and percentages. Fisher's or chi-square test for nominal variables, Student's t-test for continuous variables and Mann–Whitney U-test for ordinal variables and for continuous non-Gaussian variables were used to study the relationship between variables. The 95% confidence intervals (95% CI) were calculated.

The main analysis population was by intention-to-treat. A p-value $\leq$0.05 was considered statistically significant. Statistical analysis was performed using Stata for Windows version 15 software (StataCorp, College Station, TX, USA).

Results

This clinical trial was stopped before achieving the planned sample size, following the recommendations of the data and safety monitoring committee, after the interim futility (lack of efficacy) analysis meeting planned in the study protocol.

Baseline characteristics

Forty-four patients were included in the study and randomised. All randomised patients had abnormal voiding parameters on manometry (dyssynergic defecation), meaning that all patients had impaired (<20%) anal relaxation while trying to move their bowels and an abnormal balloon expulsion test. In addition, during the pre-treatment period (first week of the study), when patients were on their usual diet, they reported bloating, abdominal pain, flatulence, excessive straining to defecate and a feeling of incomplete evacuation. No differences in daily fibre intake were found between the study groups. The baseline characteristics for each study group are shown in Table 1. No differences were found between groups in demographic data, anorectal manometry parameters or abdominal and defecation symptoms. Fig. 2 shows the algorithm for recruiting the patients in the study.

Effectiveness of the diet

Primary variable. Anorectal manometry performed after biofeedback therapy (visit 3) showed that dyssynergic defecation was corrected (responder) in 75% (15/20; 95% CI 53–89%) of patients in the low-fibre diet group (control

Table 1 Characteristics of the study population.

	Diet		
		Low fibre; control group (n = 22)	High fibre; experimental group (n = 22)
Demographic data			
Age, years	Median (range)	45 (32—72)	48 (23—59)
Gender, M/F	n (%)/n (%)	1 (5)/21 (95)	1 (5)/21 (95)
Bowel habit (n/week)	Mean (SD)	5.5 (0.5)	5.2 (0.6)
Stool consistency (Bristol scale)	Mean (SD)	3.4 (0.4)	2.9 (0.3)
Symptom scale[a]			
Abdominal distension	Mean (SD)	3.7 (0.7)	4.2 (0.9)
Abdominal pain	Mean (SD)	2.8 (0.6)	3.4 (0.4)
Flatulence	Mean (SD)	2.8 (0.4)	3.8 (0.4)
Borborygmi	Mean (SD)	1.8 (0.4)	2.7 (0.4)
Straining to defecate (yes/no)	n (%)/n (%)	15 (68)/7 (32)	17 (77)/5 (23)
Feeling of incomplete evacuation (yes/no)	n (%)/n (%)	15 (68)/7 (32)	15 (68)/7 (32)
Bowel movements by manometry			
Rectal pressure (abdominal compression, mmHg)	Mean (SD)	56 (21)	62 (25)
Change in anal pressure[b] (%)	Mean (SD)	39 (38)[b]	62 (61)[b]

M: male; F: female.
[a] Daily measurements on a scale of 0–10, averaged over 7 days in the pre-treatment phase with the usual diet.
[b] Paradoxical contraction.

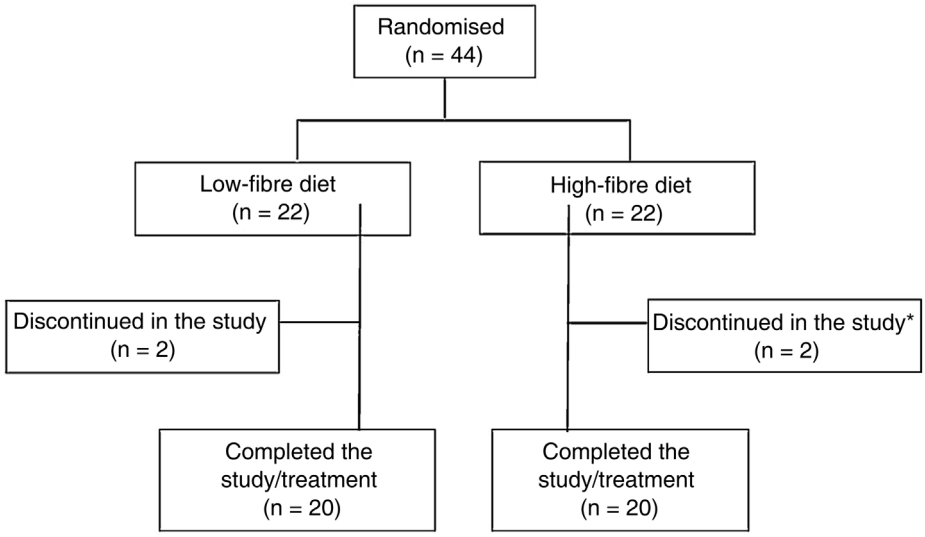

Figure 2 Algorithm for recruiting the study patients.
*Discontinued in the study for work reasons.

group) and in 70% (14/20; 95% CI 48–85%) of patients in the high-fibre diet group (experimental group), p = 0.205.

Regarding anorectal parameters, no differences were found between the two groups in the improvement of anal relaxation (p = 0.205), nor in the reduction of straining (p = 0.628).

In the *intra-group analysis* (only responders), with respect to anorectal parameters, in both groups studies, patients whose dyssynergic defecation was corrected had improved anal relaxation: increase (mean [SD]) in pressure in the *low-fibre diet group* (from 39 [8]% [i.e. paradoxical contraction] before treatment to 22 [10]% decrease [i.e. relaxation] after treatment; p < 0.0001); and *high-fibre diet group* (from 62 [14]% increase in pressure [i.e., paradoxical contraction] before treatment to 29 [9]% decrease [i.e. relaxation] after treatment; p < 0.0001). A reduction in rectal pressure was also observed in both groups: *low-fibre diet group* (from 56 [5] mmHg before to 33 [2] mmHg after treatment; p < 0.0001) and *high-fibre diet group* (from 62 [5] mmHg before to 36 [2] mmHg after treatment; p < 0.0001).

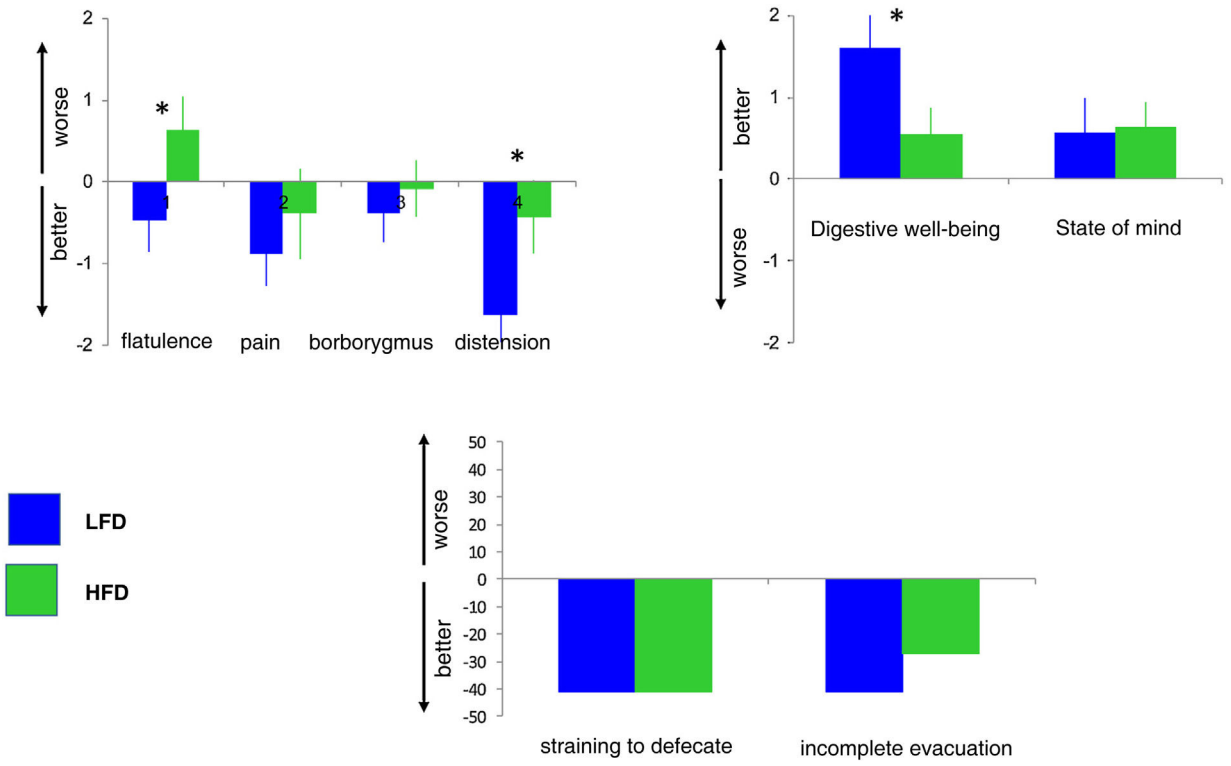

Figure 3 Comparison of treatment effect on abdominal symptoms and defecation symptoms between the two groups: low-fibre diet (LFD) and high-fibre diet (HFD).
Δ treatment period - pre-treatment period.

Secondary variables: abdominal and defecation symptoms, and CTT

Abdominal symptoms. At the end-of-study visit, statistically significant differences in favour of the low-fibre diet group compared to the high-fibre diet group were only found in subjective feelings of flatulence (p = 0.028), abdominal distension (p = 0.041) and overall digestive well-being (p = 0.043) (Fig. 3).

Defecation symptoms. No statistically significant differences were found between the two groups, despite correction of dyssynergic defecation: reduction of straining to defecate (p = 0.450); and sensation of incomplete evacuation (p = 0.340) (Fig. 3).

There were also no statistically significant differences between the two groups in the number of bowel movements per week (p = 0.118) or in the Bristol scale (p = 0.422).

Regarding the results of the *intra-group analysis* (only performed in responder patients) with respect to abdominal symptoms, patients whose dyssynergic defecation was corrected in the *low-fibre diet group* improved in symptoms such as abdominal pain (p = 0.034), abdominal distension (p = 0.004) and digestive well-being (p = 0.005); while in the *high-fibre diet group* there was no statistically significant improvement in any of the symptoms, despite correction of the dyssynergy (Fig. 4). In patients in both groups whose dyssynergic defecation was corrected, their defecation symptoms improved (straining and feeling of incomplete evacuation) (Fig. 5).

Colonic transit time. The CTT analysis was carried out in 23 patients: 13 in the low-fibre diet group and 10 in the high-fibre diet group. At visit 3 the total CTT (mean [SD]) was similar in both groups (72 [9] and 68 [9] hours respectively). Although a decrease in CTT was found among responders in the low-fibre diet group (intra-group analysis, p = 0.036), no statistically significant differences were found between the two groups (p = 0.379).

Figs. 4 and 5 show the diet-related symptoms reported with the abdominal symptoms questionnaire.

Discussion

To our knowledge, this is the first clinical trial evaluating the synergistic effect of a high-fibre diet in improving constipation in patients with chronic functional constipation and DD on anorectal biofeedback therapy. Our results show that a high-fibre diet does not improve the correction of dyssynergic defecation compared to a standard or low-fibre diet.

Our results show that the efficacy of biofeedback in the correction of constipation in patients with dyssynergic defecation is independent of fibre intake. The efficacy of anorectal biofeedback in correcting constipation in patients on a low-fibre diet was similar to that achieved in patients on a high-fibre diet. This overall efficacy is similar to that found in previous studies.[8,16,17] Objective parameters such as anal relaxation and effort reduction also improved significantly. However, in patients on the low-fibre diet, the improvement in constipation due to biofeedback therapy was also

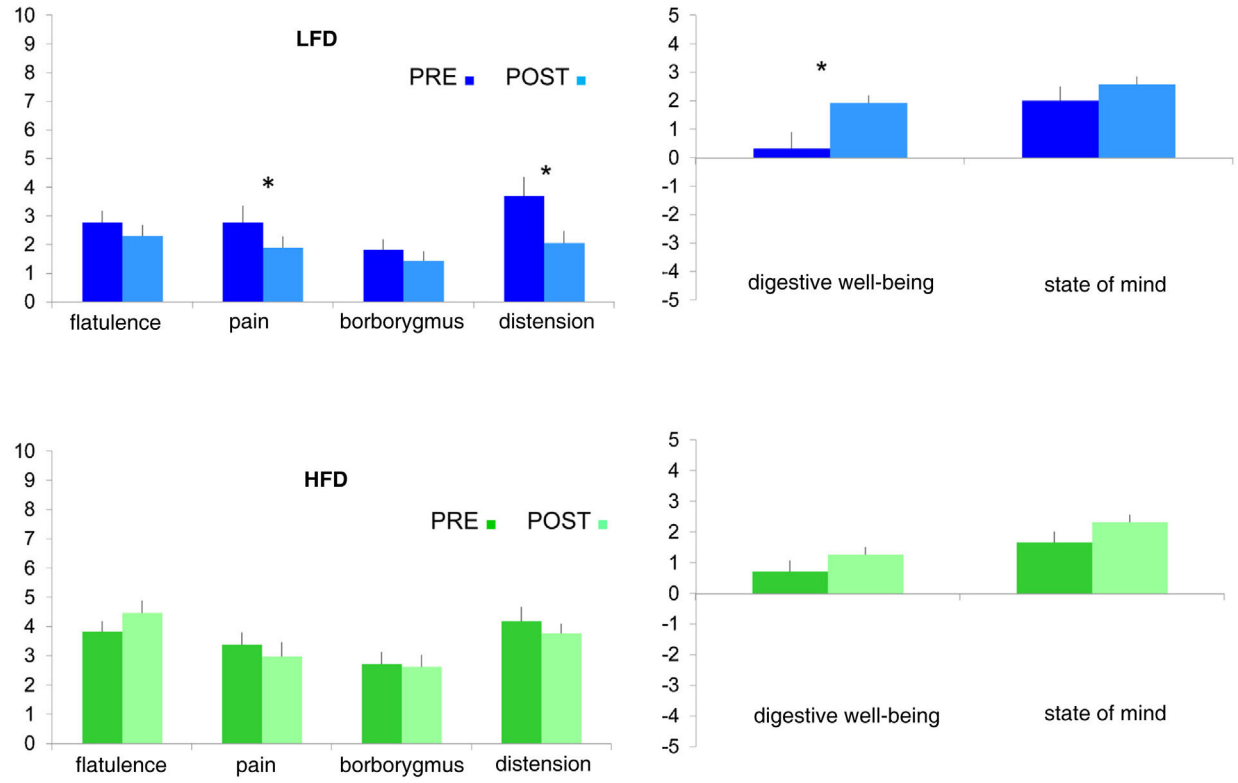

Figure 4 Effect of treatment on abdominal symptoms. Symptoms measured by daily questionnaires, pre-treatment period (week 1 of clinical trial) and treatment period (week 10 of clinical trial). Data are the mean of each 7-day period.
HFD: high-fibre diet; LFD: low-fibre diet.
*$p < 0.05$ pre-treatment vs treatment.

associated with an improvement in abdominal symptoms, compared to patients additionally treated with the high-fibre diet.

Patients with constipation and dyssynergic defecation usually have excessive straining, a sensation of incomplete evacuation or the need for digital evacuation to aid defecation.[18] In our study, straining to defecate and the feeling of incomplete evacuation improved after correction of dyssynergic defecation,[19,20] in line with the results of previous studies. In addition, the amount of fibre in the diet did not influence the improvement in these symptoms, probably because the main causal mechanism for these symptoms is impaired anorectal coordination.[7] The number of bowel movements per week increased in both groups after correction of dyssynergic defecation, and we propose the same explanation, as there was no difference in the number between the two groups. However, non-significant differences in stool consistency according to the Bristol scale were found between the two groups, in line with the well-established effect of fibre on decreasing stool consistency.[21,22]

Abdominal symptoms are often associated with defecation disorders. In our study all patients had abdominal symptoms, but those with severe symptoms, for example severe abdominal pain or distension, were excluded as they would not meet the definition of functional constipation, but rather that of irritable bowel syndrome. In patients with irritable bowel syndrome, increased fibre intake has been associated with worsening abdominal symptoms, regardless of whether or not they have an associated defecation disorder.[23,24] Previous studies have reported an improvement in abdominal pain and distension after anorectal biofeedback therapy in patients with dyssynergic defecation.[17,25] Several mechanisms have been proposed to explain functional abdominal symptoms, including visceral hypersensitivity and abnormalities in gastrointestinal motility.[26] In addition, intestinal gas retention caused by obstruction of evacuation would cause more abdominal distension and pain than gas retention induced by inhibition of intestinal motility.[27,28] In our study there was only improvement in the low-fibre diet group; in abdominal distension, flatulence, and thus in digestive well-being. In contrast to other studies, we found no improvement in abdominal pain; one explanation could be that this symptom was not very severe at baseline and that abdominal pain is predominantly influenced by central control mechanisms of pain perception.[29] In the high fibre group, there was no improvement in any abdominal symptoms and no improvement in overall digestive well-being.

The efficacy of fibre as a first-line treatment for constipation is well established. However, the recommended high levels of 30 g of fibre per day are often associated with worsening abdominal symptoms associated with gas, distension and abdominal pain. As reported in previous studies,[30] this is because, as fibre contains non-absorbable and fermentable

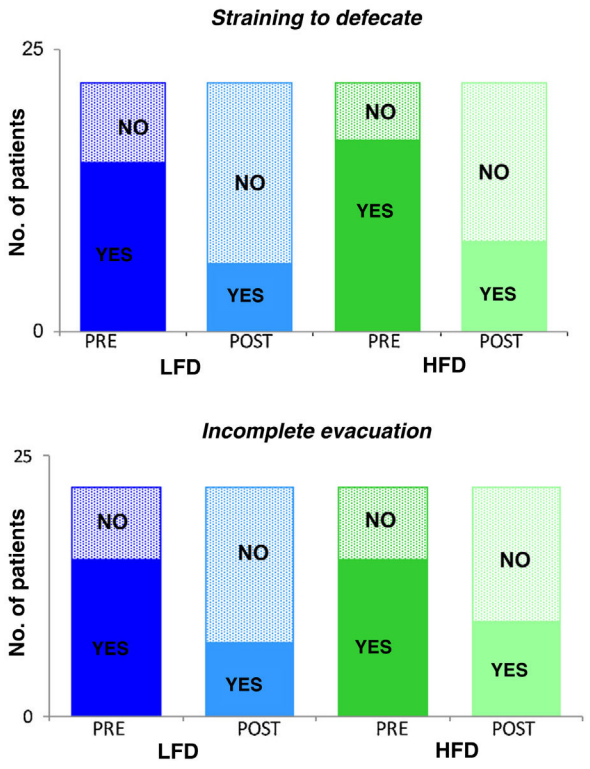

Figure 5 Effect of treatment on defecation symptoms. Presence or absence of symptoms, pre-treatment period (week 1 of clinical trial) and treatment period (week 10 of clinical trial). HFD: high-fibre diet; LFD: low-fibre diet.

residues, it is also used by the gut microbiota to increase gas production in the colon.

The limitations of our study include, firstly, the fact that it is a single-centre study. In addition, although patients were blinded to the type of diet, and adherence to the diet was monitored by the dietician, fibre intake cannot be accurately monitored because the diet was acquired by the patient and not administered by the investigators.

In conclusion, in patients with functional constipation and dyssynergic defecation, the high-fibre diet not only does not improve the efficacy of anorectal biofeedback therapy in the treatment of dyssynergic defecation, but is also associated with a loss of improvement in abdominal symptoms.

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Authors

Marianela Mego: study design, patient recruitment and data analysis and interpretation.

José Walter Huamán: study design, data analysis and interpretation and manuscript preparation.

Sebastián Videla: study design, data interpretation and correction of the manuscript.

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Conflicts of interest

None of the study authors reported any conflicts of interest.

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