

Effect of a Fructose and Lactose Elimination Diet in Patients with Irritable Bowel Syndrome: A Randomized Double-Blind Placebo-Controlled Study

Katharina Moritz, Wolfgang Hemmer, Peter Jung, Gabriele Sesztak-Greinecker, Manfred Götz, Reinhart Jarisch, Felix Wantke

Katharina Moritz, Wolfgang Hemmer, Peter Jung, Gabriele Sesztak-Greinecker, Manfred Götz, Reinhart Jarisch, Felix Wantke, Floridsdorf Allergy Centre, Franz Jonas Platz 8/6, A-1210 Vienna, Austria.

Correspondence to: Felix Wantke, MD, Floridsdorf Allergy Centre, Franz Jonas Platz 8/6, A-1210 Vienna,

Austria. wantke@faz.at

Telephone: +43-1-2702542

Fax: +43-1-270254278

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ABSTRACT

AIM: Current data on the impact of carbohydrate maldigestion on symptoms in patients with irritable bowel syndrome (IBS) are conflicting. The aim of the present study was to investigate in a randomized double-blind placebo-controlled manner whether a lactose or fructose elimination diet can improve symptoms of IBS.

METHODS: 320 patients with IBS were first randomized to a fructose or lactose-free diet for 3 weeks. Stool frequency and consistency and gastrointestinal complaints were recorded before and after the diet phase using a standardized questionnaire including visual analogue scales for severity of abdominal pain, number of days with abdominal pain, bloating and flatulence, contentment and impairment in quality of life. Subsequent to the diet phase, patients were examined for fructose or lactose malabsorption by H₂ breath testing.

RESULTS: Of 221 patients completing the study (40 males, 181 females), 111 had a positive breath test to fructose (group 1), 12 to lactose (group 2), 72 to both fructose and lactose (group 3), and 26 patients were negative in both tests (group 4). In group 1, the mean symptom score decreased from 313±69 before the diet to 178±100 after the diet (-135±100, $p<0.0001$) under fructose-free diet (verum), and from 326±65 to 197±104 (-129±111, $p<0.0001$) under lactose-free diet (placebo). Also in the other groups (including patients with a negative breath test to both carbohydrates), both diets lead to a comparable decrease in total symptom scores (mean drop -40±10%, $p<0.05$ to $p<0.0001$) without significant differences between fructose- and lactose-free diet.

CONCLUSION: Although a great proportion of IBS patients show

impaired absorption of fructose or lactose in H₂ breath tests, the clinical effect of the corresponding verum diets was not superior to that of placebo diets. The results suggest that clinical improvement in IBS patients following elimination diets is largely due to placebo effects.

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Key words: Irritable bowel syndrome; Fructose malabsorption; Lactose malabsorption; Placebo effect

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INTRODUCTION

Irritable bowel syndrome (IBS) is a frequent gastrointestinal motility disorder that has a wide clinical spectrum and affects 10-20% of people worldwide^[1,2,3,4]. IBS cannot be defined by definitive biochemical, structural or serological abnormalities, and a unifying hypothesis regarding the pathophysiology of IBS is still lacking^[3,4,5]. Numerous etiologic factors are involved in this multifaceted disorder, including environmental factors^[6], genetic links^[7], preceding infection^[8], abnormal serotonergic signaling in the gastrointestinal tract^[9] or food intolerance^[10,11,12,13].

Malabsorption of fructose and lactose is characterized by the inability of the gut to take up these carbohydrates efficiently. Non-absorbed saccharides reaching the colon get metabolized by bacteria to H₂, CO₂, CH₄ and short fatty acids^[11,14,15]. The symptoms include abdominal pain and distension, bloating, excessive flatulence and diarrhea or sometimes constipation, which is associated with methanogenesis^[16]. The clinical picture of carbohydrate malabsorption syndromes shows a considerable overlap with those of irritable bowel disease. Although there are a number of studies by now dealing with the correlation between IBS and food intolerance^[10,17-25], this link is not well established yet. Furthermore, the usefulness of elimination diets is still controversial.

The aim of our study was to investigate whether a lactose or fructose elimination diet can improve symptoms in patients with IBS. To ensure a strict double-blind placebo-controlled study design, patients were first randomized to follow either a lactose or a fructose-free diet for three weeks while testing for possible carbohydrate malabsorption was performed only after completion of the clinical observation period. In doing so, lactose diet acted as a placebo diet in patients with a final diagnosis of fructose maldigestion, and inversely fructose diet as a placebo diet in those with a final diagnosis of lactose maldigestion.

METHODS

Participants

742 adult patients attending our outpatient clinic (Floridsdorf Allergy Center) and complaining of recurrent abdominal pain, cramps, bloating, distensions, diarrhea or constipation were screened. Among patients fulfilling the ROME II criteria of IBS^[27], 320 volunteered to participate in the study. The mean age was 34.3 years (range 19-78 years). The range of BMI was 16.5-43.2 (mean 23.6). In accordance with the exclusion criteria, none of the patients had a history of rectal bleeding, major loss of weight, history of colon cancer, inflammatory bowel diseases or diverticulitis, and all showed negative serological screening for celiac disease (normal anti-tissue transglutaminase IgA/IgG and anti-gliadin IgA/IgG) and food allergy (fx5, Phadia ImmunoCAP, Thermo Fisher, Uppsala, Sweden). Pregnancy was ruled out by using the “quick and early pregnancy test” (ATT Drogerievertriebs GmbH, Seekirchen, Austria). Local ethics committee approval was given (EK 06-039-0406) and written informed consent to participation was obtained throughout. All data were collected at Floridsdorf Allergy Center.

Trial design and interventions

The study was performed as a randomized double-blind placebo-controlled parallel group trial. After evaluating the baseline symptom score, patients were randomized in a ratio of 1:1 to follow either a fructose elimination diet or a lactose elimination diet for a period of three weeks. Fructose elimination included exclusion of all kinds of fruit, fruit juices, vegetables (including legumes) and sweets. Lactose elimination diet concerned all kinds of dairy products. After the three week diet phase patients had to fill in the same visual analogue scale again to evaluate the total symptom score. Only thereafter patients underwent fructose and lactose H₂ breath tests to detect or exclude carbohydrate maldigestion.

Depending on breath test results, patients were finally divided into four groups: Group 1: patients with a positive breath test to fructose (fructose malabsorption); Group 2: patients with a positive breath test to lactose (lactose malabsorption); Group 3: patients with a double-positive breath test to fructose and lactose (fructose and lactose malabsorption); Group 4: patients with a negative breath test to both carbohydrates (double-negative).

This unconventional experimental design made possible a strict double-blind placebo-controlled dietary intervention study which is otherwise difficult to conduct. The study was placebo-controlled inasmuch as the fructose-free diet acted as a verum diet in those with finally proven fructose malabsorption (group 1), and as a placebo diet in those with finally proven lactose malabsorption (group 2). Vice versa, the lactose-free diet was a verum diet for those with lactose malabsorption (group 2), and a placebo diet for those with fructose malabsorption (group 1). The study was truly double-blind, because breath tests were done only after completion of the dietary intervention phase implying that neither investigators nor patients

were aware of which of the two diets will turn out verum or placebo in the end. The accepted disadvantage of the chosen study design is that patients with double-positive breath test results to fructose and lactose (group 3) are not eligible for primary analysis, since both of the diets they were randomized to may be seen as a verum diet. In patients with a double-negative breath test, both diets may be considered placebo diets.

Symptom scores and IBS subtype classification

A standardized questionnaire was used to evaluate the baseline symptom score. Visual analogue scales including five graphic ratings for (1) severity of abdominal pain; (2) number of days with abdominal pain; (3) bloating and flatulence; (4) contentment and (5) impairment in quality of life graded from 0 (no perception) to 100 (very strong perception) were used to calculate the total symptom score^[27]. In addition, stool frequency and stool consistency was recorded.

According to ROME criteria, patients suffering predominantly from diarrhea were classified as IBS type 0 (IBS-D), those predominantly suffering from constipation were classified IBS type 1 (IBS-C) and in case of alternating constipation and diarrhea were classified IBS type 2 (IBS-M).

Primary and secondary Outcomes

The primary read-out parameter was the change in total symptom score after the three-week elimination diet period. Secondary outcome measures were change in single symptom scores, change in stool frequency and stool consistency, correlation between change in symptom score and H₂ increase during breath testing, and correlation between improvement and patient compliance.

Case number calculation

Sample size calculation was done with special emphasis on patients with monovalent fructose malabsorption (group 1) since this group was expected to comprise approximately 50% of all study patients (based on a pre-study analysis of test results from IBS patients having previously undergone routine breath testing for carbohydrate malabsorption at our center).

The sample size of 2 times 160 participants was estimated for a 2-way analysis of variance assuming a significance level of 0.05 and a reduction of 40% (i.e. an effect size of 128) in the symptom score. Furthermore a drop-out rate of 30% and a within-standard-deviation of the mean symptom score in the subgroups of ± 100 were assumed. This design resulted in a power of 83.8%.

Randomization

The randomization sequence was generated by the Unit of Medical Statistics, Medical University of Vienna, as a balanced block randomization sequence using variable block sizes and provided as sequentially numbered containers. Such the balancing of the group sizes of 2 times 160 participants was achieved at the end of the recruitment process. Patients were assigned to the randomized diets strictly in the order of entering the study.

H₂ breath tests

Breath tests for lactose and fructose maldigestion followed standard procedures. After an overnight fast of 12 hours, a dose of 50 g lactose suspended in 250 mL of water was administered to the patient. A baseline breath sample was taken before drinking the lactose solution. H₂ concentrations were measured with the H₂ gastrolyzer (Gastrolyzer H₂ Atemtestgerät, Bedfont, UK) at 30 minute intervals from the

time of ingestion for a total of 3 hours. In patients with a baseline H₂ exceeding 20 ppm, tests were repeated on a different day. An increase in breath hydrogen concentration of more than 20 ppm over baseline was classified as positive and patients were scored as carbohydrate malabsorbers. Subjects whose hydrogen concentration increased less than 20 ppm over baseline were termed as regular carbohydrate absorbers.

Fructose malabsorption tests were performed in the same way using 50 g fructose as recommended at the time the study was performed (2008). We are well aware that testing is nowadays performed with 25 g of fructose to reduce the number of false-positive results^[28,29].

Statistical Analysis

An analysis of variance was done to evaluate influence of diets on the improvement of the symptom score. The target variable was the symptom score after the diet and independent variables were type of diet, group of malabsorption status, group of malabsorption status and diet interaction, symptom score before the diet, compliance, age, sex, BMI and IBS type.

Additionally, the Kendall Tau correlation coefficient was computed to assess the correlation between H₂ increase, improvement of symptom score and other measurements for success of therapy. Statistical analysis was performed using PROC GLM and PROC CORR from SAS 9.1 for Windows (SAS statistical software, SAS Institute, Cary, NC, USA).

RESULTS

Out of 742 patients screened, 320 patients were included in the study on the basis of fulfilling the ROME II criteria. 221 patients (40 male, 181 female) finished the study (Figure 1, Table 1). Out of these, 105 suffered from diarrhea-predominant IBS (IBS type 0; IBS-D), 28 from constipation-predominant IBS (IBS type 1; IBS-C), and 88 from alternating constipation and diarrhea-predominant IBS (IBS type 2; IBS-M).

Randomization of patients to lactose or fructose elimination diet in the different subgroups is summarized in table 1.

Table 1 Descriptive data of the study.

	<i>n</i>	randomized to fructose-free diet	randomized to lactose-free diet
Screened (suspected IBS)	742		
Entered the study (ROME II +)	320	160	160
Dropouts	99	46	53
Finished the study	221	114	107
Breath test results:			
Fructose malabsorption	111	53	58
Lactose malabsorption	12	6	6
Fructose & lactose malabsorption	72	43	29
H ₂ negative group	26	12	14

H₂ testing

According to breath test results, 111/221 patients (50.2%) had fructose malabsorption, 12/221 (5.4%) had lactose malabsorption, 72/221 (32.6%) had fructose and lactose malabsorption, and in 26/221 patients (11.8%) both breath tests were negative (Table 1).

Symptom score, success of treatment and compliance

Irrespective of the diagnosis, the total symptom score decreased significantly and to a comparable degree after the dietary intervention in all patients groups and with either diet ($p < 0.05$ to $p < 0.0001$) (Table 2). Only in patients with monovalent lactose malabsorption ($n = 12$), the improvement under verum (lactose-free diet) was numerically visibly higher than under placebo (fructose-free diet), though the difference was not statistically significant. Due to the small sample size of this group, these numerical differences have to be interpreted with caution. In all other groups both diets lead to a comparable decrease in total symptom scores (mean decrease 127 points, range 100-156). In all, there was a weak tendency of greater improvement with the fructose-free diet as compared with the lactose-free diet.

The compliance to the diet as assessed by visual analog score was very good with a mean of 87% (range 31 to 100%, median 90.5%). 199/221 patients had a compliance $> 70\%$. The higher the compliance, the lower the symptom score after the intervention ($p < 0.05$).

Influence of diets in different IBS types

A significant drop in total symptom scores could be observed in both

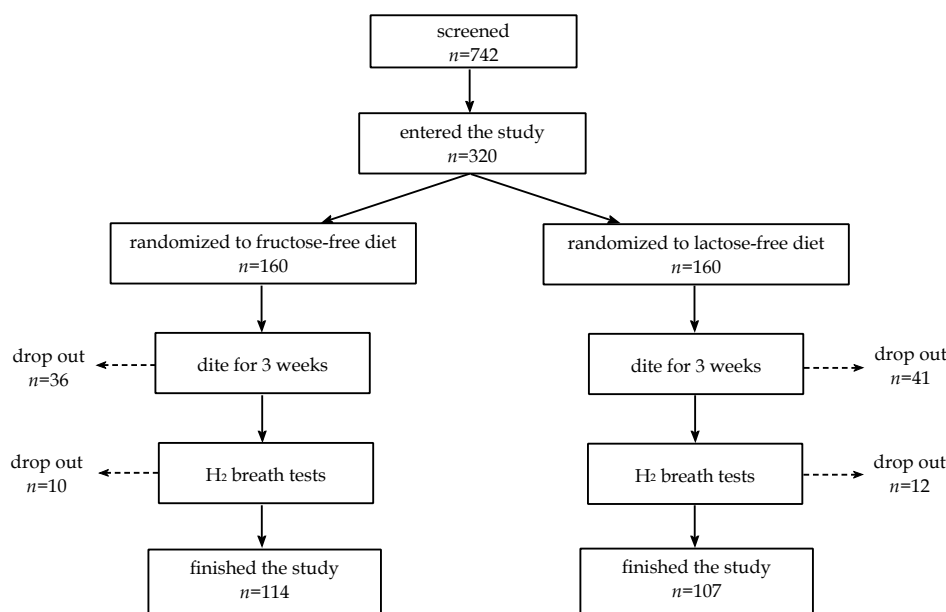


Figure 1 Number of patients screened, included and randomized in the study.

diarrhea-predominant and constipation-predominant IBS (Table 3). Improvement appears to be greater on average in patients with diarrhea-predominant IBS, however, the limited number of subjects with constipation-predominant IBS in our study population does not allow final conclusions.

The analysis of total symptom scores and individual scores for intestinal complaints revealed that clinical improvement in IBS patients with diarrhea was determined to a similar degree by the reduction in meteorism, reduction in stool frequency, and improvement in stool consistency. Mean stool frequency per day and per week consistently decreased in all groups with either diet (Table 4). In contrast, clinical improvement in IBS patients with constipation strongly correlated with the reduction in meteorism and flatulence whereas stool frequency and stool consistency were of little importance. There was no consistent change in the mean number of stools per day and per week by the diets in constipation-predominant IBS patients in any group (Table 4).

Drop out rate

99 patients (30.9%) did not finish the study. Of these patients, a similar number has been randomized to the fructose elimination diet (*n*=46) and the lactose elimination diet (*n*=53), respectively, making unlikely an influence of a particular diet on drop-out rate. According to subsequent telephone inquiries about the reasons for withdrawal, 77 patients (78%) did not start the diet at all or discontinued during the diet phase, and 22 (22%) patients completed the diet phase but refused or did not complete final breath tests.

DISCUSSION

The most striking finding of this study is that nearly all IBS patients improved under a carbohydrate elimination diet irrespective of the outcome of H₂ breath tests. This may be explained, at least in part, as a placebo effect which plays an essential role in dealing with IBS. Psychological factors have to be considered in this disease knowing that psychotherapy works excellently in patients with severe irritable

Table 2 Symptom scores before and after diets.

	<i>n</i>	Before diet	After diet	Δ	<i>p</i> -value
Fructose malabsorption (<i>n</i>=111)					
Fructose free diet	53	313±69	178±100	-135±100	<0.0001
Lactose free diet	58	326±65	197±104	-129±111	<0.0001
Lactose malabsorption (<i>n</i>=12)					
Fructose free diet	6	335±103	298±103	-37±26	<0.05
Lactose free diet	6	316±63	134±103	-182±156	<0.05
Fructose & lactose malabsorption (<i>n</i>=72)					
Fructose free diet	43	323±74	192±90	-131±103	<0.0001
Lactose free diet	29	291±65	191±93	-100±100	<0.0001
H₂ negative group (<i>n</i>=26)					
Fructose free diet	12	330±81	174±116	-156±150	<0.005
Lactose free diet	14	325±91	198±105	-127±90	<0.0001
Total	221	318±71	191±101	-128±107	<0.0001

Table 3 Change in total symptom score in IBS type 0 (diarrhea predominant) and type 1 (constipation predominant). Data for IBS type 2 are not shown.

	IBS type 0 (diarrhea predominant)					IBS type 1 (constipation predominant)				
	<i>n</i>	Before diet	After diet	Δ	<i>p</i>	<i>n</i>	before diet	after diet	Δ	<i>p</i>
FM										
Fructose-free diet	25	315±75	171±112	-144	<0.0001	9	344 ± 64	212 ± 90	-132	<0.01
Lactose-free diet	26	336±66	182±80	-154	<0.0001	10	340 ± 54	237 ± 142	-103	0.05
LM										
Fructose-free diet	4	379±91	339±104	-40		0	-	-	-	
Lactose-free diet	1	290	281	-9		2	375 ± 39	336 ± 89	-39	
FM+LM										
Fructose-free diet	23	338±68	211±88	-137	<0.0001	2	347 ± 171	136 ± 74	-211	
Lactose-free diet	12	310±44	200±111	-110	<0.01	2	244 ± 13	292 ± 59	+48	
Non-FM-LM										
Fructose-free diet	7	318±74	130±83	-188	<0.001	1	374	10	-264	
Lactose-free diet	7	353±95	199±115	-154	<0.05	2	362 ± 15	253 ± 133	-109	

Table 4 Dynamics of mean stool frequency per week before and after the diet in IBS type 0 (diarrhea predominant) and type 1 (constipation predominant). Data for IBS type 2 are not shown. n.s. not significant.

	IBS type 0 (diarrhea predominant)				IBS type 1 (constipation predominant)			
	<i>n</i>	before diet	after diet	<i>p</i>	<i>n</i>	Before diet	After diet	<i>p</i>
FM								
Fructose-free diet	25	19.7±10.9	12.7±7.4	0.01	9	2.9±1.9	2.7±1.5	ns
Lactose-free diet	26	14.1±5.2	10.7±5.1	0.02	10	4.1±1.7	3.9±1.9	ns
LM								
Fructose-free diet	4	21.9±9.2	20.1±7.8	n.s.	0	-	-	
Lactose-free diet	1	14.0	14.0		2	5.0±0.0	7.8±3.9	
FM+LM								
Fructose-free diet	23	16.0±7.5	12.2±7.4	0.09	2	5.0±0.0	5.3±2.5	
Lactose-free diet	12	13.1±6.2	9.6±6.6	n.s.	2	6.3±6.0	3.3±1.1	
Non-FM-LM								
Fructose-free diet	7	14.0±6.7	10.5±4.0	n.s.	1	3.0	3.0	
Lactose-free diet	7	16.0±6.7	9.5±3.3	<0.05	2	5.0±2.8	3.5±0.7	

bowel disease^[30-33]. In addition, complementary approaches of treatment also seem to be effective in IBS^[34]. Although their exact way of action is still unknown, placebo effects might significantly contribute. On the other hand, the recently recommended diet excluding bloating foodstuff, so called FODMAPs, comprising fermentable oligosaccharides (fructans and galactans), disaccharides (lactose), monosaccharides (fructose) as well as polyols, has been shown to be beneficial in IBS patients^[13,35,36]. This concept exceeds the rather narrow focus on lactose or fructose as causative agents of IBS. However, FODMAPs not only induce an H₂ increase even in healthy persons, giving evidence of fermentation in the colon, but also caused symptoms such as bloating. Because vegetables may contain, besides fructose, considerable amounts of other undigestible oligosaccharides (e.g. inulin in onions, stachyose in legumes), all patients randomized to a fructose-free diet in our study simultaneously reduced also intake of other relevant FODMAPs. This might explain the therapeutic benefit seen even in those with completely negative breath test results and thus argue against pure placebo effects by the dietary intervention. On the other hand, the fact that clinical improvement was equally good in breath test-negative patients set on a lactose elimination diet (not avoiding onions and legumes) again supports the view that placebo effects played a significant role in the positive response to the diets in all groups.

The evidence from studies investigating the clinical efficacy of particular diets is often limited since the performance of such studies in a truly placebo-controlled manner is difficult. Placebo responses to diets are well documented and may be substantial. The strength of the present study is that it was undertaken as a true randomized double-blind placebo-controlled study inasmuch as patients were first randomized to one of two carbohydrate elimination diets while carbohydrate malabsorption was assessed only after completion of the three-week diet period. The price we were willing to pay for this strategy is that a direct comparison of the efficacy of verum versus placebo diet can be done only in those patients with a single-positive breath test to either fructose or lactose. It must be mentioned again that the main focus of the present study was put on fructose single-positive patients (group 1) since pre-study analysis revealed that the number of subjects with a single-positive breath test to lactose will be too small to enable powerful statistical analysis. Anyhow, also the results from the breath test double-positive (group 3) and double-negative group (group 4), representing 44% of all patients, turned out to be of significant value, since unexpectedly improvement in these groups was fairly the same as in single-positive patients. Thus, the data from the double-positive and double-negative group substantially corroborate the view that placebo effects were important for inducing the positive responses to the diets in our IBS patients.

The clinical spectrum of IBS is very much the same like that of carbohydrate malabsorption syndromes. Intestinal gas production causing bloating and pain by intestinal distension seems to be the main clinical problem or inconvenience for the patient. According to the literature, 5 to 24% of people suffering from IBS may also have lactose intolerance^[37,38]. In our investigation lactose malabsorption was found in 38% of patients. Interestingly, only in patients with monovalent lactose malabsorption we could observe a clear numeric (though statistically not significant) difference between the effect of a lactose (verum) and a fructose (placebo) diet, potentially reflecting the value of a correct dietary treatment in this group. However, the number of patients in this group was too small to draw any final conclusions. In addition, considering diagnoses, lactose intolerance is a more clearly defined disease than fructose malabsorption, as the

pathologic threshold level for fructose is still controversial^[28,29,39].

According to our investigation carbohydrate malabsorption is very common in patients with IBS. 83% of patients had a positive provocation test to fructose. This high percentage might in part be due to using 50 g fructose for testing^[28,29] which was the recommended standard dose for provocation when the study was performed. However, by now it is known that 50 g of fructose can induce symptoms even in healthy people and therefore create false-positive results. While we can exclude false-negative results for sure in our study, we certainly would have found fewer reactors with 25 g of fructose which might have had a significant impact on our results. However, since the mean reduction in total symptom scores was similar by either diet in all four patients groups, it appears unlikely that the shift of some patients from fructose/lactose double-positive to lactose single-positive or from fructose single-positive to double-negative would have changed the results fundamentally. In this context, it is even more surprising that even in the H₂ breath test double-negative group ($n=26$) a significant reduction in symptoms could be achieved despite none of the diets was indicated by the breath test results. Therefore we are convinced that the unknown percentage of patients with false-positive H₂ test to fructose, although an inaccuracy of our study, does not significantly weaken the results overall.

Taking together the unexpected effects of the diets and the somewhat puzzling results of breath tests, one may ask if testing for carbohydrate malabsorption should be performed at all. In our study, breath testing turned out to be of little value in the end since the diagnosis did not correlate with the clinical response to a certain diet, at least not during the three-week observation period. We can not comment on the long-term progress in our patients, considering that correct diagnosis of carbohydrate malabsorption has been claimed mandatory to achieve long-term benefit in patients by others^[18,19]. With reference to recent strategies recommending a diet low in all types of poorly digestible carbohydrates and polyols (FODMAPs) to every IBS patient, the justification of breath tests may consist in identifying those subjects with normal intestinal lactose and fructose resorption in order to individually alleviate the FODMAP diet rather than to specifically diagnose lactose or fructose malabsorption as the putative major cause of IBS. Breath tests would also prevent many patients from adhering to unnecessary dietary restrictions, especially with a view to the widespread occurrence of fructose in otherwise healthy foods such as fruits and vegetables. Furthermore, considering the apparent placebo effects exerted by both diets in this study, one might generally question the validity of overly rigorous and fussy adherence to any specific carbohydrate diet.

Although the number of patients with IBS suffering from lactose intolerance varies considerably from 25% up to about 70%^[18,19,37,38], the usefulness of a lactose elimination diet is highly controversial. On the one hand Goldstein *et al.*^[20] found that the number of symptoms decreased significantly after a carbohydrate-free diet excluding lactose, fructose or fructose-sorbitol, on the other hand there are data that only half of IBS patients improve on lactose free dietary regimes^[18,40,41]. To add to the confusion, Parker^[10] showed that 70% of IBS patients with a negative H₂ test to lactose improved to a lactose free diet despite only one third of them being intolerant to milk. Recently, in their evidence-based guidelines for the dietary management of IBS patients^[25], the British Dietetic Association recommends a lactose-free diet in IBS patients suffering from lactose intolerance. Although they found only moderate to weak evidence for this treatment, a lactose-free diet reduces short- and long-term abdominal symptoms^[25].

Even less is known about fructose malabsorption in IBS as illustrated by a current research in PubMed yielding only 34 papers on fructose malabsorption in IBS but 257 papers on lactose intolerance and IBS. Several papers reported that about one third of IBS patients IBS have fructose malabsorption and improve on a fructose-restricted diet^[12,20,42,43,44]. According to Corlew-Roath, carbohydrate maldigestion has a similar incidence in patients with and without IBS, but patients with IBS are less likely to improve when put on a diet^[15]. On the other hand, elimination of fructose is part of the FODMAP diet which is considered beneficial in IBS patients (recommendation grade B)^[25], at least in three out of four patients^[16]. It appears reasonable that, in patients intolerant to lactose or fructose, elimination of the relevant carbohydrate from the diet will lead to a reduction in symptoms. In comparison, patients with a double-positive breath test to fructose and lactose might be expected to show limited improvement if only one of the carbohydrates is withdrawn. Nevertheless, clinical improvement in double-positive patients was comparable to that in lactose or fructose monosensitive patients in our study. Finally, even patients negative in both H₂ breath tests improved to the same extent. In all, this underlines the proposed importance of placebo responses.

Nowadays a lactose-free diet put little strain on the patient, as lactose-free milk products are widely available at about the same price as regular dairy products. Therefore, a lactose-free diet can be considered safe without the risk of malnutrition or vitamin deficiency. In addition, moderate amounts of lactose (about 12 g) are tolerated even by lactose-intolerant patients^[46]. A fructose-free diet is less easily performed. However, simultaneous ingestion of glucose enhances intestinal fructose absorption and helps eating some fruit in everyday life^[46]. Till now, malnutrition or vitamin deficiencies due to keeping a diet low in FODMAPs is not described, even if some basic foodstuffs such as wheat are excluded.

CONCLUSION

In this randomized double-blind placebo-controlled study in IBS patients we could observe a significant clinical improvement after a three-week fructose or lactose elimination diet irrespective of whether or not patients had a positive H₂ breath test with one of the two carbohydrates. Accordingly, the positive response of IBS patients to carbohydrate elimination diets, as also indicated by previous papers, may be essentially due to placebo effects.

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- Peer reviewers:** Paolo Sossai, MD, AGAF, Chief Department of Medicine, General Hospital, Viale Comandino, 70, I - 61029 Urbino (Italy); Zhao-Xiang Bian, MD, PhD, Professor, School of Chinese Medicine, Hong Kong Baptist University, Kowloontong, Hong Kong, HKSAR, China.