Tolerability of FODMAP – reduced diet in irritable bowel syndrome – efficacy, adherence, and body weight course

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Tolerability of FODMAP – reduced diet in irritable bowel syndrome – efficacy, adherence, and body weight course

Toleranz einer FODMAP – reduzierten Diät beim Reizdarmsyndrom – Effektivität, Adhärenz und Gewichtsentwicklung

Authors
Thomas Frieling, Jürgen Heise, Britta Krummen, Corinna Hundorf, Sigrid Kalde

Affiliation
Department of Internal Medicine and Gastroenterology, Helios Klinikum Krefeld, Krefeld, Germany

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Correspondence
Thomas Frieling, MD
Department of Internal Medicine and Gastroenterology
Helios Klinikum Krefeld, Lutherplatz 40, 47805 Krefeld, Germany
Tel.: ++ 49/21 51/32 27 07
Fax: ++ 49/21 51/32 20 78
thomas.frieling@helios-gesundheit.de

ZUSAMMENFASSUNG

Hintergrund Die FODMAP-reduzierte Kost (fermentierbare Oligo-, Di-, Monosaccharide und Polyole) gehört zur etablierten Therapiestrategie beim Reizdarmsyndrom (IBS). Die Nachteile dieser Diät sind allerdings gravierend und können zum Gewichtsverlust und zur mangelnden Patientenadhärenz führen. Zahlen in Deutschland liegen allerdings hierüber nicht vor.
Patienten und Methoden In einer prospektiven Studie wurden 93 Patienten mit IBS nach Rom-III-Kriterien untersucht. 63 Patienten konnten für die Studie rekrutiert werden. Es wurde eine standardisierte Untersuchung, Aufklärung und FODMAP-Ernährungsberatung mit schriftlichem Informationsmaterial durchgeführt. Die Beschwerden wurden anhand validierter Fragebögen und einer standardisierten Lickert-Skala vor und 8 Wochen nach Beginn der Ernährungstherapie erfasst. Die Stuhleigenschaften wurden anhand der Bristol-stool-form-Skala dokumentiert.
Ergebnisse Die Patientenadhärenz war gering, da 30 Patienten (47 %) die Therapie frühzeitig beendeten. Von den 33 verbliebenen Patienten entwickelten 36 % (n = 12) einen signifikanten Gewichtsverlust unter FODMAP-Diät. Die Patienten gaben in 79 % eine signifikante globale Besserung ihrer Beschwerden (Bauchschmerzen 85 %, Blähungen 73 %, Flatulenz 69 %, Borbogymi 69 %, Übelkeit 46 %, Fatigue 69 %) an. Ebenfalls war die Schwere der Symptome signifikant reduziert. 14 Patienten entwickelten eine Veränderung ihres Stuhlverhaltens mit einer Verbesserung der durchfälligen Stühle bei 11 Patienten und der Verstopfung in 3 Fällen.
Schlussfolgerung Die FODMAP-reduzierte Kost ist eine effektive Therapie bei IBS. Allerdings ist die Patientenadhärenz gering und die Therapie kann einen signifikanten Gewichtsverlust erzeugen.

ABSTRACT

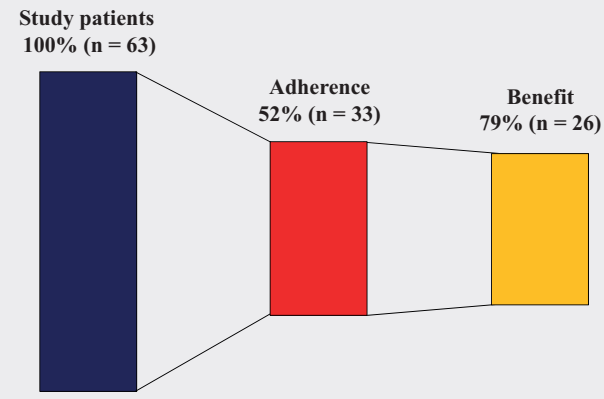
Background FODMAP reduced diet (fermentable oligo-, di-, monosaccharide, and polyols) belongs to the established therapy strategies in irritable bowel syndrome (IBS). However, disadvantages of this diet are significant and may lead to weight loss and insufficient patient adherence. Reports from Germany are not available yet.
Material and methods In a prospective study, 93 patients with IBS according to Rom III were investigated. Sixty-three patients were recruited for the study and received standardized investigation, informed consent, and structured dietary instructions about the FODMAP reduced diet. Patients complaints were documented by a validated questionnaire and a standardized Lickert scale before and 8 weeks after the start of the diet. Stool characteristics were documented by the Bristol stool form scale.
Results Patients adherence was low because 30 patients (47 %) stopped the diet. Of the remaining 33 patients, 36 % (n = 12) developed significant weight loss during the FODMAP therapy. Patients completing the study reported significant global improvement of symptoms in 79 % of cases (abdominal pain 85 %, meteorism 79 %, flatulence 69 %, borbogymi 69 %, nausea 46 %, fatigue 69 %). In addition, the severity of symptoms was significantly reduced. Fourteen patients developed changes of their stool characteristics according to the Bristol stool form scale, 11 of whom improved diarrhea and 3 improved constipation.
Conclusion FODMAP reduced diet is an efficient therapy in IBS. However, adherence of the patients is poor and the therapy bears the risk of significant weight loss.

Introduction

According to Rom III consensus, patients with irritable bowel syndrome (IBS) are characterized by abdominal pain and/or discomfort associated with bowel movement without organic findings following clinical routine investigation [1]. It is now established that IBS represents subgroups of patients with different organic abnormalities within and/or outside the gut wall suspicious for the individual pathophysiology of IBS patients [2, 3]. However, management of IBS in daily practice is ambiguous because of the lack of biomarkers that characterize these subgroups for specific therapies in clinical practice [4, 5]. One characteristic of IBS is that many patients report about affection of their symptoms by daily food intake. In fact, compared to normals, up to 70 % of patients with IBS report about food-related complaints [6 – 10]. It is, therefore, rational to look for dietary therapy strategies to improve the symptoms of IBS. The FODMAP (fermentable oligo-, di-, monosaccharide, and polyols) reduced diet is one of the key dietary strategies that has been developed recently. The majority of studies illustrate positive effects of low FODMAP on IBS symptoms, particularly on bloating and abdominal pain [11 – 27]. However, the role of FODMAP reduced diet in the treatment of IBS is still under debate because of the heterogeneous quality of studies found in the literature. This has been illustrated in numerous systematic reviews [15, 18, 19, 21 – 24, 27] with 5 meta-analyses [15, 19, 21, 22, 24]. In addition, the FODMAP diet appears to be not superior to traditional remedies for IBS [10, 25, 26]. Because the low-FODMAP diet imposes an important restriction of dietary choices, it may lead to malnutrition and weight loss [28, 29]. Furthermore, this restrictive diet may have an impact on quality of life and adherence of the patients [30, 31]. We therefore report on 63 patients with IBS according to Rom III that received standardized investigation, informed consent, and structured dietary instructions about the FODMAP reduced diet to improve their symptoms. Preliminary data were published in abstract form [32].

Material and methods

In a prospective study, we investigated 93 patients with IBS according to Rom III consensus. Sixty-three patients could be recruited for the study. Patients received standardized investigation with exclusion of other organic diseases such as neoplasia, vascular diseases, inflammation, celiac disease, intolerance for lactose, fructose and/or sorbit. Patients' symptoms such as abdominal pain, meteorism, flatulence, borborgymi, nausea, and fatigue were documented by a structured history. Severity of symptoms was categorized by a standardized Lickert scale (0 = none, 1 = moderate, 2 = medium, 3 = severe complaint) before and 8 weeks after starting the low FODMAP diet. Stool characteristics were analyzed by the Bristol stool form scale [33] before and 8 weeks following the FODMAP diet by structured history. Diarrhea was defined as Bristol stool form scale 6 – 7 and constipation as 1 – 2. Improvement of stool behavior was defined as a change to Bristol stool form scale of 3 – 5 according to patients' reports. Stool frequency was not evaluated. Responders to the FODMAP reduced diet were defined as patients who reported subjective global improvement of their symptoms. Subjective global improvement was defined as the feeling of the patients being satisfied by the FODMAP diet due to symptom improvement.



▶ **Fig. 1** Patients adherence and clinical benefit.

Information about the FODMAP reduced diet was transmitted according to nutritional guidance by a trained dietician and handed to the patients by structured documents. The standardized FODMAP diet was applied according to the recommendation in the literature [34]. Data were expressed as mean ± standard deviation (SD). Statistical significance was measured by the Student's t-test. The level of significance was set at $p < 0.05$.

Results

We screened 93 patients with IBS according to Rom III consensus. All patients received standardized FODMAP guidance. However, 30 patients could not be recruited for the study because of loss of patient contact or unwillingness to participate in the study. Of these 63 patients (67 %) recruited, only 33 (52.4 %) adhered to the diet and completed the FODMAP dietary regime (12 men, 42 ± 19 years, body-mass index [BMI] 24.7 ± 5.3). The other 30 patients stopped the therapy within days (n = 19) or between 1 and 8 weeks (n = 11) because of ineffectiveness of the diet (n = 4) or nonadherence (n = 26). Nonadherence was caused because patients found the diet too complicated and too bothersome for their normal lives (▶ **Fig. 1**).

Patients who completed the therapy were 10 IBS-C, 9 IBS-D, 10 IBS-M, and 4 IBS-U. Twenty-six patients (78.8 %, 7 IBS-C, 8 IBS-D, 9 IBS-M, 2 IBS-U) responded to the FODMAP reduced diet and reported about subjective global improvement of their symptoms, with 3 patients (9.1 %, 1 IBS-C, 1 IBS-D, 1 IBS-M) symptom-free. The 7 non-responder were 3 IBS-C, 2 BS-U, 1 IBS-M, and 1 IBS-D. In the responder group, abdominal pain was reduced in 85 %, meteorism in 73 %, flatulence in 69 %, borborgymi in 69 %, fatigue in 69 %, and nausea in 46 % of patients. In addition, severity of symptoms was significantly ($p < 0.05$) reduced (▶ **Table 1**). ▶ **Table 1** shows the baseline characteristics and the effect of the

▶ **Table 1** Baseline characteristics and effect of the FODMAP reduced diet on specific symptoms in patients who responded to the diet and non-responders.

	responders (n = 26)		non-responders (n = 7)	
sex (men/women)	53 %/47 %		75 %/25 %	
age	44.3 ± 17		38.7 ± 15.9	
IBS-C	7		3	
IBS-D	8		1	
IBS-M	9		1	
IBS-U	2		2	
BMI (kg/m^2)	25.03 ± 5.56		23.47 ± 5.15	
weight loss (kg)	1.86 ± 2.97		0.42 ± 1.61	
symptoms	**before FODMAP**	**after FODMAP**	**before FODMAP**	**after FODMAP**
abdominal pain	2.20 ± 0.72	0.88 ± 0.65[1]	2.28 ± 1.11	2.14 ± 1.06
meterorism	2.57 ± 0.59	1.00 ± 0.56[1]	2.42 ± 1.13	2.28 ± 1.11
flatulence	2.38 ± 0.53	0.77 ± 0.71[1]	1.42 ± 0.97	1.14 ± 1.06
borborgymi	2.22 ± 0.78	0.83 ± 0.68[1]	1.85 ± 1.21	1.5 ± 1.27
nausea	2.25 ± 0.72	0.41 ± 0.49[1]	1.14 ± 1.21	1.14 ± 1.21
fatigue	2.45 ± 0.60	1.27 ± 1.06[1]	1.71 ± 0.95	1.71 ± 0.83

IBS-C: irritable bowel syndrome type constipation; IBS-D: irritable bowel syndrome type diarrhea; IBS-M: irritable bowel syndrome type mixed; IBS-U: irritable bowel syndrome with unaltered stool.
[1] $p < 0.05$.

FODMAP reduced diet on specific symptoms in responders and non-responders. The data did not show any significant differences of the baseline characteristics between responders and non-responders. However, non-responders tended to have lower baseline scores before the FODMAP reduced diet with regard to flatulence, borborgymi, nausea, fatigue, and weight loss.

Twelve patients (36.7 %, 4 IBS-C, 5 IBS-D, 2 IBS-M, 1 IBS-U) who completed the FODMAP diet developed significant weight loss of 4.29 ± 3.06 kg, whereas 3 patients (12.2 %, 2 IBS-D, 2 IBS-M) gained weight 3.50 ± 2.29 kg. Ten responders lost weight (38.46 %), whereas 2 responders (7.8 %) gained weight. The numbers for the non-responders were 2 patients with weight loss (28.57 %) and 1 patient (14.28 %) with increase of body weight. Fourteen patients (3 IBS-C, 6 IBS-D, 5 IBS-M) developed changes of their stool characteristics according to the Bristol stool form scale, 11 of whom improved diarrhea and 3 improved constipation.

Discussion

IBS represents a spectrum of organic diseases with different pathophysiologies located within the gut-brain axis [1 – 3]. Clinical management of IBS is ambiguous because several different therapeutic strategies may be successful in 1 single patient and have to be developed by a trial and error mode. This is because only few clinical biomarkers are available that allow the prediction of therapeutic modality and success [4, 5]. Interestingly, the majority of IBS patients report on the influence of their symptoms by food [6 – 10]. However, no biomarker is available to predict the response to food intervention. Therefore, in the context of an evidence-based IBS therapy, objective evidence for an adverse reaction to food can only be achieved by testing for lactose, fructose, and sorbit intolerances, small intestinal bacterial overgrowth, celiac disease, histamine intolerance syndrome, mast cell dysfunction, and food allergies. Ideally, potential symptom-inducing food products must be exposed to the patient via a randomized double-blind, placebo-controlled trial, which is not realistic in clinical practice. Therefore, evaluation of the clinical efficacy of therapeutic food intervention is highly dependent on the subjectivity of the patient and potential placebo effects. In this line, it is interesting to know that in a large study in over 3000 individuals, objective evidence for subjective feeling of food intolerance or allergy could be shown in only 3 % of cases [35].

In our study, we evaluated 93 patients and investigated 63 patients with IBS according to Rom III consensus. All patients reported affection of their symptoms by food. However, standardized evaluation did not detect a specific adverse reaction to food. Of these, 33 patients completed the low FODMAP regime. We chose the low FODMAP diet because several studies have shown significant symptom improvement by this diet [11 – 14]. In fact, recent studies suggested positive effects in approximately 70 % of IBS patients [6 – 10, 30], far more than the benefit achieved with pharmacological treatment. It is, therefore, not surprising that the low FODMAP diet is recommended in National Institute for Health and Clinical Excellence guidelines for IBS management

in primary care in the UK [36] and as second-line intervention by the British Dietetic Association guidelines [37]. FODMAP diet is recommended as second-line intervention because traditional remedies for IBS (first-line advice) are as effective as the low FODMAP diet [10, 38]. Our study confirms the positive findings in the literature because almost 80 % of the patients who hold out for the 8 weeks of dietary therapy reported about subjective global improvement of symptoms with complete symptom relief in 9 %. In addition, 46 – 85 % of the patients reported improvement of specific symptoms. This could be also shown by a significant reduction of symptom severity as measured by the validated Lickert scale. In addition, stool behavior as analyzed by the Bristol stool form scale improved in 14 patients. These effects of the FODMAP regime were independent of the various IBS subtypes such as IBS-C, IBS-D, IBS-M, or IBS-U. However, baseline analysis of responders and non-responders revealed that non-responders tended to have non-significant lower baseline scores before FODMAP reduced diet with regard to flatulence, borborgymi, nausea, and fatigue. In addition, weight loss tended to be lower in non-responders. Therefore, we cannot rule out that the non-responders did not benefit from the low FODMAP diet because of less symptom strength compared to the responders.

In addition to the positive effects of the low FODMAP diet, our findings also point to some negative aspects of this therapeutic regime. In our study, patient adherence was low because only 52 % of the patients completed the study. In addition, over one-third of the patients developed significant weight loss during the FODMAP reduced nutrition. These findings are of clinical significance and comparable to the literature [28 – 30] and suggest that the low FODMAP concept is not suitable for a longer time for most of the patients. This is because the diet is restrictive and may lead to malnutrition with the risk of reduced intake of fiber, calcium, iron, zinc, folate, vitamins B and D, and natural antioxidants, to weight loss with decrease in BMI and waist circumference, and to negative affection of quality of life [28 – 30]. These findings have to be taken into account when FODMAP reduced diet is thought to be indicated in IBS. However, this assumption is weakened by the fact that, in our study, we could not control patients with regard to the extent of their adherence to the FODMAP regime. Indeed, individual course of weight has been also demonstrated in other studies [28 – 30]. Evidence for this is that the weight course was variable with stable body weight in 11 patients and increase of body weight in 3 patients.

In summary, our study shows that the low FODMAP diet has a significant impact on various IBS symptoms and stool behavior. However, low patient adherence, weight loss, and the risk of malnutrition point to the limited clinical relevance of the low-FODMAP concept.

Conflict of Interest

The authors declare that they have no conflict of interest.

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