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## Does a Low-FODMAP Diet Decrease Symptoms in Patients with IBS?

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**Does a Low-FODMAP Diet Decrease Symptoms in Patients with IBS?**

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A SELECTIVE EVIDENCE-BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
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## ABSTRACT

**Objective:** The objective of this evidence-based medicine analysis is to determine whether or not a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs), decreases overall symptoms in patients with irritable bowel syndrome (IBS).

**Study Design:** A systematic review including three randomized control trials (RCTs), which were conducted between the years 2014 and 2019.

**Data Sources:** The RCTs used were located through PubMed. All articles were selected from peer-reviewed journals that directly related to the clinical question and patient centered outcomes.

**Outcome Measured:** A reduction in symptoms related to IBS was measured using the IBS-Symptom Severity Scale (IBS-SSS) and the Visual Analog Scale (VAS). The IBS-SSS is based on a scale from 0-500 mm, while the VAS is scaled from 0-100 and 0-300 mm. Higher scores are correlated with more extreme IBS symptoms on both scales.

**Results:** Results reported by Bohn et al. revealed a decrease from baseline in the IBS-SSS of 78.0 (24%) in the low-FODMAP diet ( $p < 0.001$ ) and a decrease of 66.0 (22%) in the alternative IBS diet ( $p < 0.001$ ). In the RCT conducted by Patcharatrakul et al., a low-FODMAP diet decreased symptoms according to the VAS by 22.7 mm (37.1%) ( $p < 0.001$ ), whereas the control did not reach statistical significance ( $p = 0.30$ ). Halmos et al. reported an average decrease in symptom scores by 13.2 mm (36.67%) in the low-FODMAP diet ( $p < 0.001$ ), compared to an increase in symptoms on the control diet by 8.9 mm (24.72%) ( $p < 0.001$ ).

**Conclusions:** The studies reported statistically significant findings, proving the low-FODMAP diet decreased symptoms in patients with IBS, according to the IBS-SSS and VAS. With strong evidence to support the efficacy of the low-FODMAP diet, further studies should be conducted to modify, understand, and further improve the diet.

**Key Words:** Irritable bowel syndrome, symptoms, FODMAP, adult.

## INTRODUCTION

Irritable bowel syndrome (IBS) is defined by the manifestation of altered stooling, accompanied by gastrointestinal (GI) discomfort and pain. The main difference between IBS and most other GI disorders is the absence of any pathological disease or clinical evidence of disease, therefore termed a functional disorder.<sup>1</sup> IBS can be further classified into subcategories, by predominating symptoms of diarrhea, constipation, or a combination of both, known as IBS-D, IBS-C, or IBS-M respectively. IBS has an estimated prevalence of 10% to 23%, with females being affected one and a half to two times more frequently than males.<sup>2</sup> Symptoms are known to differ between men and women, with men reporting more diarrhea and women experiencing more abdominal pain and constipation.<sup>1</sup> More than half of the patients with IBS report experiencing their first symptoms prior to 35 years old, with a decreasing prevalence with age.<sup>3</sup>

In the United States, IBS is among the most frequently diagnosed GI disorder. The direct costs of IBS are estimated to be \$1.35 billion, while indirect costs are estimated to be \$205 million.<sup>4</sup> IBS is responsible for up to 50% of GI consults with an estimated 2.4 to 3.5 million annual physician visits per year in the United States.<sup>5,6</sup> Patients with IBS are hospitalized at a greater rate than other individuals, accounting for 25% to 30% of costs related to IBS.<sup>5</sup> These individuals undergo two to three times more cholecystectomies, double the amount of hysterectomies and appendectomies, and about half are known to receive an unnecessary ultrasound.<sup>5</sup> Therefore, these patients are at higher risk for enduring unnecessary testing during the diagnosis and treatment of IBS.

The diagnosis of IBS is based on the Rome III criteria, which deduces that symptoms should be present for six months before the diagnosis, with symptoms occurring during the last three months. Patients meet the criteria if they experience intermittent abdominal pain at the

minimum of one day per week for the past three months, with two or more of the additional components: symptoms related to stooling, associated with a change in stool consistency or frequency of stool.<sup>7</sup> Without pathological evidence of the disease, the diagnosis can be very difficult.

Though little supporting evidence exists regarding the causes of IBS, research suggests interactions between abnormal motility, brain-gut interaction, food intolerances, and psychosocial distress may be components of the disease.<sup>1</sup> The lack of understanding regarding the etiology and pathophysiology has compromised the ability to develop efficacious treatments. FDA-approved treatments of IBS include 5-HT<sub>3</sub> receptor antagonists such as ondansetron, rifaximin, and lubiprostone.<sup>8</sup> These treatments reveal minimal benefit over the placebo, placing emphasis on the need for future investigation of treatments for IBS.<sup>8</sup> Given that an estimated 66% of patients associated diet to an exacerbation in symptoms of IBS, a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) has been developed and increasingly utilized in the management of IBS.<sup>4</sup>

FODMAPs are poorly-absorbed small chains of carbohydrates that can increase the transit time for water and fermentable substances in the colon and intestines. This leads to excess formation of gas and distention of the GI lumen. Some examples of high-FODMAP foods include beans, apples, and garlic; while low-FODMAP foods include oranges, lactose-free milk, and gluten-free bread. The use of diet modification in the treatment of IBS can decrease adverse side effects that the use of pharmacotherapy could create, while decreasing the cost of treatment and the need for hospital visits and unnecessary testing.

**OBJECTIVE**

The objective of this evidence-based medicine analysis is to determine whether or not “a diet low in FODMAPs decreases the overall symptoms of IBS”.

**METHODS**

The randomized control trials (RCTs) systematically reviewed were selected based on credibility, correlation to the clinical question, and an emphasis on patient-oriented outcomes. All RCTs were obtained from PubMed using the keywords of “irritable bowel syndrome”, “symptoms”, “FODMAP”, and “adult”. Inclusion criteria was composed of articles published in the English language, peer-reviewed journals, publication within the last ten years, and an adult population. The exclusion criteria encompassed languages other than English, publication prior to 2011, secondary research, pediatric populations, inflammatory bowel disease (IBD), books, or documents. The results were reported via p-values and changes in scores from the IBS-SSS and VAS from baseline.

The sample population of the current review includes individuals diagnosed with IBS according to the Rome III criteria from selective populations ranging from 18 to 70 years old. A low-FODMAP diet was the intervention in all three studies. The controls included a traditionally recommended diet for IBS, a frequently recommended diet, and an Australian diet. Studies conducted by Bohn et al. and Patcharatrakul et al. were single-blinded RCTs, while the study conducted by Halmos et al. was also a single-blinded RCT with the addition of a cross-over trial. The demographics and characteristics regarding the RCTs is summarized in Table 1.

**OUTCOMES MEASURED**

All outcomes were assessing a decrease in patient-reported symptom severity during a trial of a low-FODMAP diet. The study performed by Bohn et al. used the IBS-SSS to evaluate

symptom severity, which is a composite score of abdominal pain/frequency, intensity, and dissatisfaction with bowel habits. Participants with an IBS-SSS reduction  $\geq 50$  points, on a scale from 0-500, were termed as “responders”.<sup>8</sup> The studies conducted by Patcharatrakul et al. and Halmos et al. used the VAS to evaluate symptom severity and changes from baseline, measured in millimeters (mm). The VAS is a composite score of overall GI symptoms, abdominal pain, flatulence, bloating, and dissatisfaction with the consistency of stool. A responder was identified by a decrease in daily symptoms of 30% or more after 4 weeks of the intervention by Patcharatrakul et. al and a change of 10 mm or greater, according to Halmos et al. A higher score is indicative of more severe symptoms, according to both scales.

**Table 1. Demographics and Characteristics of Included Studies**

Study	Type	# Patients	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Bohn <sup>9</sup> (2015)	Parallel, multi-center single-blind RCT	67 patients included in final data	18-70 y.o.	Dx with Rome III criteria for IBS, ages 18-70 y.o. Probiotics, routinely used IBS meds including antidepressants were allowed if taken regularly throughout study, with an established use for at least a month prior to initiation of study.	Severe liver, neurologic, cardiac, or psychiatric diseases, other GI disorders, strict dietary restrictions ( <i>exception: lactose-reduced diets were allowed</i> ).	8	Low FODMAP diet <u>vs.</u> alternative IBS diet
Patcharatrakul <sup>10</sup> (2019)	Single-blind RCT	62 patients included in final data	18-70 y.o.	Dx according to Rome III criteria for IBS, ages 18-70 y.o. with moderate-severe symptoms. No use of probiotics, prebiotics, antibiotics, or symbiotics for 4 weeks prior/during the study. Required to be on stable treatment.	Previous surgery of GI tract ( <i>exception: appendectomy/hemorrhoidectomy</i> ). Presence of IBD/GI malignancy, celiac disease, heart, liver, neurological, psychological, or lung diseases.	4	Extensive dietary advice + low-fodmap diet <u>vs.</u> brief advice + alternative diet
Halmos <sup>11</sup> (2014)	Single-blinded RCT, with cross-over trial	38 patients included in final data	23-60 y.o.	Dx according to Rome III criteria for IBS. Cannot be using any pharmacologic therapy for IBS (laxatives/anti-diarrheals). Patients must not have had prior IBS dietary counseling.	Celiac disease, previous abdominal surgery, comorbidities (i.e. diabetes), or presence of organic disease	7	Low FODMAP diet <u>vs.</u> Australian diet.

## RESULTS

Bohn et al. conducted a parallel, multi-center single-blinded RCT in Sweden, which included 67 female patients ranging from 18-70 years old in the final data.<sup>9</sup> All patients were diagnosed with moderate to severe IBS according to the Rome III Criteria with an IBS-SSS  $\geq$  175.<sup>9</sup> The inclusion and exclusion criteria can be reviewed in Table 1.<sup>9</sup> Eight participants withdrew from the study and were not included in the final data, amounting to less than 20% loss to follow-up.<sup>9</sup> The intervention was four weeks long, with patients following a low-FODMAP diet (n = 33) or another frequently recommended diet in the treatment of IBS (n = 34).<sup>9</sup> Patients in the low-FODMAP diet were provided with a detailed dietary guide of prohibited foods (onion, wheat, lactose, fructose) and replacement options, with a greater emphasis on avoiding particular food.<sup>9</sup> The recommended diet encompassed avoiding large meals, caffeine, gas-producing food and insoluble fiber, with a greater emphasis on the timing and amount of meals.<sup>9</sup>

The primary outcome focused on symptom reduction, which was accomplished in both groups, with P-values  $< 0.001$  proving valuable information.<sup>9</sup> Of the 33 patients with IBS, about 58% (n=19) of patients on the low-FODMAP and 50% (n=17) of patients on the alternative IBS diet, were considered responders.<sup>9</sup> All subjects, whether responders or non-responders, were consuming equivalent levels of FODMAPs by day 29 of the study.<sup>9</sup> Changes from baseline scores of 78 (24%) and 66 (22%) were seen within the IBS-SSS, in the low-FODMAP diet and alternative IBS diet, respectively. Individually, the diets show significant results ( $p < 0.001$ ), while the p-value in between intervention groups was insignificant ( $p = 0.62$ ).<sup>8</sup> The results are summarized in Table 2 below.



**Table 2. Change in Symptom Severity according to IBS-SSS<sup>9</sup>**

	<b>Baseline mean <math>\pm</math> SD</b>	<b>Week 4 mean <math>\pm</math> SD</b>	<b>Change from baseline</b>	<b>P-value</b>	<b>P-Value between intervention groups</b>
Low FODMAP diet (n = 33)	324 $\pm$ 69	246 $\pm$ 127	- 78 (24%)	< 0.001	0.62
Traditional IBS diet (n = 34)	302 $\pm$ 61	236 $\pm$ 78	- 66 (22%)	< 0.001	

Patcharatrakul et al. conducted a similar study assessing how dietary counseling in conjunction with specific diets, can decrease symptom severity in patients with IBS.<sup>10</sup> Four patients were lost to follow-up, amounting to less than 20%, and not included in the final data.<sup>10</sup> This data included 62 female patients ranging from 18-70 years old who were recruited from an outpatient clinic in Bangkok, Thailand diagnosed with moderate to severe IBS according to the Rome III Criteria.<sup>10</sup>

Patients were not permitted to use probiotics, prebiotics, symbiotics, or antibiotics for the month prior, or throughout the study.<sup>10</sup> Those with previous GI surgery, not including an appendectomy or hemorrhoidectomy; IBD; GI malignancy; celiac disease; heart, liver, neurological, psychological, or lung diseases were excluded from the study.<sup>10</sup>

This single-blinded RCT placed patients in either an experimental group, following a low-FODMAP diet (n=30), or in the control group, following a frequently recommended diet (n=32).<sup>10</sup> The control group received less than five minutes of dietary advice recommending avoidance of large meals and GI distress food triggers; the term “FODMAP” was not used.<sup>10</sup> The experimental group received 30 minutes of personalized recommendations on how to identify high-FODMAP foods and alternative replacements for trigger foods in their diary; informative pamphlets reinforced the information.<sup>10</sup> At the conclusion of the study, eighteen (60%) patients in the experimental group and nine (28%) patients in the control group, fit the criteria for being a

responder ( $p = 0.001$ ).<sup>10</sup> At baseline, both groups had similar VAS scores, but at the completion of the study, only the low-FODMAP group ( $38.5 \pm 20.0$ ) had a significantly lower symptom score than the frequently recommended diet ( $53.5 \pm 1.92$ ) ( $p < 0.01$ ).<sup>10</sup> The symptom change from baseline in the low-FODMAP group was approximately 37% ( $p < 0.001$ ), with a statistically insignificant change in symptoms of only approximately 5% ( $p = 0.30$ ) in the frequently recommended diet.<sup>10</sup> The results are summarized in Table 3 below.

**Table 3. Change in Symptom Severity according to VAS (0-100)**<sup>10</sup>

	<b>Baseline mean <math>\pm</math> SD</b>	<b>Week 4 mean <math>\pm</math> SD</b>	<b>Change from baseline</b>	<b>P-value</b>	<b>P-Value post intervention, between groups</b>
<b>Low-FODMAP diet (n = 30)</b>	61.2 $\pm$ 21.0	38.5 $\pm$ 20.0	- 22.7 (37.1%)	< 0.001	0.006
<b>Frequently Recommended diet (n = 32)</b>	56.3 $\pm$ 17.8	53.5 $\pm$ 19.2	- 2.8 (4.97%)	0.30	

Halmos et al. conducted a single-blinded RCT, with a cross-over trial that included 30 patients with IBS and 8 healthy control patients, ranging from 23 to 60 years old.<sup>11</sup> Patients were diagnosed according to the Rome III criteria for IBS.<sup>11</sup> The inclusion and exclusion criteria can be reviewed in Table 1.

The study had three phases each of 21 days: treatment vs control, “wash-out period,” and reversed control vs treatment, respectively. Treatment consisted of following a low-FODMAP diet, and the control group followed an Australian diet; the third phase directed participants to the alternate condition they had not had previously.<sup>11</sup> In this study, all the meals and snacks were provided in unlimited quantities.<sup>11</sup> The primary outcome measured was a change from baseline in GI symptom severity using the VAS.<sup>11</sup>

At baseline, patients with IBS averaged a score of 36.0 mm on the VAS ( $p < 0.001$ ).<sup>11</sup> After day seven, patients in the low-FODMAP group averaged decreased scores at 22.8 mm ( $p <$

0.001) on the VAS, while those on the Australian diet showed increased scores at 44.9 mm on the VAS ( $p < 0.001$ ).<sup>11</sup> Differences between the groups were statistically significant ( $p < 0.001$ ).<sup>11</sup> Scores at day 21 were reported based on a 0-300 mm VAS score and were not included in the analysis as they could not be accurately interpreted.<sup>11</sup> Throughout the crossover study, 21 of the 30 patients with IBS (70%) were identified as responders, with improvement of 10 mm or more in overall GI symptoms according to the VAS.<sup>11</sup> The results are summarized in Table 4 below.

**Table 4. Change in Symptom Severity According to VAS (0-100)<sup>11</sup>**

	<b>Baseline Mean (mm) <math>\pm</math> SD</b>	<b>Last 14 days* (mm) <math>\pm</math> SD</b>	<b>Change from baseline (mm)</b>	<b>P-Value</b>	<b>P-Value post intervention, between groups</b>
<b>Low FODMAP diet</b>	36.0 (29.5-42.5)	22.8 (16.7-28.8)	- 13.2 (36.67%)	$p < 0.001$	$p < 0.001$
<b>Australian diet</b>	36.0 (29.5-42.5)	44.9 (36.6-53.1)	+ 8.9 (24.72%)	$p < 0.001$	

## DISCUSSION:

Proper understanding of the etiology and pathophysiology of IBS is necessary to facilitate beneficial medical treatment to relieve patients' symptoms, but this has yet to be achieved. As such, a non-pharmacologic intervention, such as a low-FODMAP diet, can be advantageous. If enough evidence suggests the low-FODMAP diet is effective then patient costs for pharmacotherapy and the need for insurance company approvals will decrease. Yet, studies reviewed have limitations and possible confounding factors, warranting ongoing research in this area.

With a known trigger of IBS symptoms being related to food consumption, the current review assessed the efficacy of a low-FODMAP diet in reducing symptoms of IBS. Bohn et al. reported statistically significant improvements in scores according to the IBS-SSS using the low-

FODMAP diet, with 50% of patients experiencing greater than a 50% reduction in their symptoms. Results further concluded that patients with IBS-D responded more favorably to the low-FODMAP diet, than those with IBS-C.<sup>9</sup> While the low-FODMAP diet and alternative IBS diet were successful in reducing symptoms, a high P-value between intervention groups ( $p = 0.62$ ), suggests little difference in outcomes for participants following either of the diets.<sup>9</sup> Potential confounds to this study include the population selected (female adults from Sweden) and permitted use of regimented probiotics and pharmacotherapy throughout the study. Given the similar efficacy in reducing symptoms, noting a change from baseline of 24% in the low-FODMAP diet and 22% in the alternative IBS diet, these interventions should be evaluated in conjunction for future studies.

The study conducted by Patcharatrakul et al. revealed that the low-FODMAP diet significantly improved the symptoms by 50-80%, in comparison to a frequently recommended diet, which did not reach clinical significance in reducing symptoms.<sup>10</sup> The sample population focusing on females from chosen clinics in Bangkok, Thailand limits the generalizability of these results to persons of similar culture and care.<sup>10</sup> Another limiting factor is the exclusion from the use of pharmacotherapy prior to or during the study.

In contrast to the study by Halmos et al. which provided participants with meals, the study by Patcharatrakul et al., simulated real-life experiences where patients had to plan and prepare their own meals after appropriate dietary advice was given. While personalized dietary advice likely inflated the change in score from baseline, the idea of teaching these patients long-term, beneficial habits can be very useful. These findings offer valuable direction for future research, with extensive symptom reduction in the low-FODMAP diet.

Additional noteworthy conclusions were reported by Halmos et al., where patients with IBS consuming the low-FODMAP diet experienced more than a 50% reduction in symptoms.<sup>11</sup> The resolution of symptoms experienced by the patients was seen almost instantaneously, with the peak symptom control being achieved by day seven.<sup>11</sup> Halmos et al. reported significant symptom resolution across all subclasses of IBS following a low-FODMAP diet.<sup>11</sup> The study reports a 22% decrease in symptom severity when comparing the effects of a low-FODMAP diet with a typical Australian diet, where symptoms worsened.<sup>11</sup>

While Halmos et al. delineated notable positive findings, this study has several potential confounds, limitations, and lacks generalizability. Prohibiting the use of pharmacotherapy and providing meals throughout this intervention makes the study less like typical non-study conditions.<sup>11</sup> However, by preparing the meals for participants, perhaps, a truer evaluation of the intervention itself is revealed. Additionally, Halmos et al. concludes that significant blinding was achieved by avoiding the use of the word “FODMAP”, yet 83% of patients in the low-FODMAP groups were able to guess their diet, which could have introduced bias. Although data and conclusions reported by Halmos et al. support the efficacy of the low-FODMAP diet, it is unclear why data was reported arbitrarily from the last 14 days of the study, instead of day twenty-one of the study. Furthermore, it is unclear why the overall conclusions from day twenty-one were reported and drawn from a VAS scored on a 0-300 mm scale, versus the rest of the study, which uses a 100 mm scale.

Based on the statistically significant, yet cautioned results, the Halmos et al. findings should be used in conjunction with the other studies to better understand the low-FODMAP diet. Overall, all three studies were dichotomous, randomized, single-blinded trials and could have stronger validity with double-blinded trials. While limitations and lack of generalizability are

present across all studies, these findings offer valuable direction for future research regarding low-FODMAP diets.

## **CONCLUSION**

With few proven efficacious treatments, this systematic review highlights the validity and benefits of the low-FODMAP diet in the treatment of IBS. Results stated by Bohn, Patcharatrakul, and Halmos, et al., mutually report statistically significant decreases in the symptom scores from baseline of patients with IBS, according to the IBS-SSS and VAS in as little as seven days.

With females being affected to a much higher degree than males, the studies by Bohn and Patcharatrakul et al. focused only on adult females. Future studies should also investigate males and pediatric populations. The incorporation of diverse samples of populations, diets, and geographical locations should be used to further understand trends about the disease.

Future directions for research should include a RCT conducted through a mobile application, allowing patients to attend nutritional counseling sessions and record their meals, while also reporting their symptoms according to the IBS-SSS. The use of logging food and symptoms post-consumption could be used to identify what foods may worsen patients' symptoms. The nutritionists' lessons would encompass information regarding IBS and the low-FODMAP diet, what foods to avoid, and alternative options to eat when they have cravings. By hypothetically launching the application through GI clinics internationally, a larger patient sample would be reached. All in all, the studies reviewed described efficacious treatments reflecting symptom severity reduction, and considerations for overcoming these studies' limitations in the future.

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