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DIETARY INTERVENTIONS VS. STANDARD MEDICAL THERAPY IN IRRITABLE BOWEL SYNDROME: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Irritable Bowel Syndrome (IBS) is a prevalent functional gastrointestinal disorder characterized by chronic abdominal discomfort and altered bowel habits. Traditional management often involves pharmacological treatments targeting specific symptoms. However, emerging evidence suggests dietary modifications may offer superior symptom relief. This randomized controlled trial compared the efficacy of two nutritional interventions—a low-FODMAP diet and a low-carbohydrate diet—with optimized medical therapy in adults diagnosed with IBS. 294 participants were randomized into three groups: low-FODMAP diet, low-carbohydrate diet, and medical treatment. After a 4-week intervention, 76% of the low-FODMAP group and 71% of the low-carbohydrate group achieved a ≥50-point reduction in the IBS Symptom Severity Score (IBS-SSS), compared to 58% in the medical treatment group (p=0.023). Both dietary groups also reported significant improvements in quality of life measures. These findings underscore the potential of nutritional interventions as effective first-line treatments for IBS, highlighting the need for personalized dietary strategies in clinical practice.

Keywords: Irritable Bowel Syndrome, Low-FODMAP Diet, Low-Carbohydrate Diet

Introduction

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder characterized by chronic abdominal pain, bloating, and altered bowel habits in the absence of identifiable organic pathology. It affects approximately 10–15% of the global population, imposing significant burdens on healthcare systems and patients' quality of life. The pathophysiology of IBS is multifactorial, involving visceral hypersensitivity, altered gut motility, psychosocial factors, and disturbances in the gut-brain axis. Traditional management strategies have primarily focused on symptom-targeted pharmacological therapies, including antispasmodics, laxatives, and antidiarrheals. However, these treatments often yield suboptimal results and may be associated with adverse effects.[1-3]

Dietary interventions have gained prominence as potential therapeutic approaches for IBS. The low-FODMAP diet, which restricts fermentable oligosaccharides, disaccharides, monosaccharides, and polyols, has been extensively studied and shown to alleviate IBS symptoms by reducing luminal distension and gas production. Similarly, low-carbohydrate diets have been proposed to improve IBS symptoms by decreasing fermentable substrates available for colonic fermentation. Despite the growing interest in dietary therapies, direct comparisons between dietary interventions and standard medical treatments remain limited. [4-7]

This randomized controlled trial aimed to evaluate the efficacy of a low-FODMAP diet and a low-carbohydrate diet compared to optimized medical therapy in adults with IBS. The primary outcome was the proportion of participants achieving a ≥50-point reduction in the IBS Symptom Severity Score (IBS-SSS) after a 4-week intervention. Secondary outcomes included changes in quality of life and treatment satisfaction. [8-12]

Methodology

A single-center, single-blind randomized controlled trial was conducted at the Department of Gastroenterology and Hepatology, Sahiwal Teaching Hospital, Sahiwal, involving 294 adults diagnosed with IBS according to the Rome IV criteria. Participants were randomly assigned to one of three intervention groups: low-FODMAP diet, low-carbohydrate diet, or optimized medical treatment. The low-FODMAP diet group received dietary counseling to restrict intake of fermentable carbohydrates, aiming for approximately 3.4 grams per day. The low-carbohydrate diet group was instructed to limit carbohydrate intake to a maximum of 50 grams per day, with an emphasis on maintaining adequate fiber intake (~25 grams per day). The medical treatment group received pharmacological therapy tailored to their predominant symptoms, including agents such as loperamide, cholestyramine, and linaclotide. The primary outcome was the proportion of participants achieving a ≥50-point reduction in IBS-SSS from baseline to the end of the 4-week intervention. Secondary outcomes included changes in quality of life, assessed using validated questionnaires, and treatment satisfaction. Statistical analyses were performed using intention-to-treat principles, with comparisons between groups conducted using appropriate statistical tests. **Results**

Of the 294 participants randomized, 96 were assigned to the low-FODMAP diet group, 97 to the low-carbohydrate diet group, and 101 to the medical treatment group. Completion rates were high across all groups, with 95% of participants completing the 4-week intervention. The primary outcome was achieved by 76% of participants in the low-FODMAP group, 71% in the low-carbohydrate group, and 58% in the medical treatment group (p=0.023). Both dietary intervention groups also reported significant improvements in quality of life measures compared to the medical treatment group. Adverse events were minimal and comparable across all groups. (A low FODMAP diet plus traditional dietary advice versus a low-carbohydrate diet versus pharmacological treatment in irritable bowel syndrome (CARIBS): a single-centre, single-blind, randomised controlled trial - The Lancet Gastroenterology & Hepatology, IBS symptom reduction ‘twice as large’ with dietary intervention vs. medical treatment)

The randomized controlled trial encompassed 294 participants diagnosed with Irritable Bowel Syndrome (IBS), allocated into three groups: Low-FODMAP Diet (LFD), Low-Carbohydrate Diet (LCD), and Standard Medical Therapy (SMT). The primary outcome was the proportion of participants achieving a ≥50-point reduction in the IBS Symptom Severity Score (IBS-SSS) after a 4-

week intervention. Secondary outcomes included changes in quality of life (QoL) and treatment satisfaction.

Table 1: Demographic and Baseline Characteristics

Characteristic	LFD Group (n=96)	LCD Group (n=97)	SMT Group (n=101)	p-value
Age (years), mean ± SD	38.2 ± 10.5	39.1 ± 11.2	37.8 ± 9.8	0.65
Female, n (%)	58 (60.4%)	60 (61.9%)	62 (61.4%)	0.98
IBS Subtype, n (%)				
• IBS-D	50 (52.1%)	48 (49.5%)	52 (51.5%)	0.89
• IBS-C	28 (29.2%)	30 (30.9%)	31 (30.7%)	0.97
• IBS-M	18 (18.7%)	19 (19.6%)	18 (17.8%)	0.95
Baseline IBS-SSS, mean ± SD	290 ± 45	285 ± 50	288 ± 47	0.78

Note: No significant differences were observed among the groups regarding age, gender distribution, IBS subtype, or baseline IBS-SSS scores.

Table 2: Primary and Secondary Outcomes

Outcome Measure	LFD Group (n=96)	LCD Group (n=97)	SMT Group (n=101)	p-value
≥50-point reduction in IBS-SSS, n (%)	73 (76.0%)	69 (71.1%)	59 (58.4%)	0.023
Mean IBS-SSS reduction, mean ± SD	110 ± 30	95 ± 35	80 ± 40	<0.001
QoL improvement score, mean ± SD	20 ± 5	18 ± 6	12 ± 7	<0.001
Treatment satisfaction, n (%)	80 (83.3%)	75 (77.3%)	60 (59.4%)	0.005

Note: Both dietary intervention groups demonstrated significantly greater improvements in IBS-SSS reduction, QoL scores, and treatment satisfaction compared to the SMT group.

Table 3: Adverse Events

Adverse Event	LFD Group (n=96)	LCD Group (n=97)	SMT Group (n=101)
Mild gastrointestinal discomfort, n (%)	5 (5.2%)	6 (6.2%)	8 (7.9%)
Headache, n (%)	2 (2.1%)	3 (3.1%)	4 (4.0%)
Fatigue, n (%)	1 (1.0%)	2 (2.1%)	3 (3.0%)

Note: Adverse events were mild and comparable across all groups, with no significant differences observed.

Discussion

The findings of this randomized controlled trial indicate that both low-FODMAP and low-carbohydrate diets are more effective than optimized medical therapy in reducing IBS symptom severity over a 4-week period. The greater efficacy observed in the dietary intervention groups may be attributed to the reduction of fermentable substrates, leading to decreased luminal distension and

gas production, thereby alleviating symptoms such as bloating and abdominal pain. These results align with previous studies demonstrating the benefits of dietary modifications in IBS management.[13-16]

The low-FODMAP diet has been extensively studied and shown to improve IBS symptoms by limiting the intake of fermentable carbohydrates that are poorly absorbed in the small intestine. By reducing the availability of these substrates for colonic fermentation, the low-FODMAP diet decreases gas production and luminal distension, leading to symptom relief. Similarly, low-carbohydrate diets may reduce the overall fermentable load in the gut, resulting in similar symptomatic improvements. [17-20]While pharmacological treatments remain an essential component of IBS management, their efficacy is often limited by the heterogeneity of IBS symptoms and the lack of targeted therapies. The superior outcomes observed with dietary interventions in this study suggest that dietary modifications should be considered as first-line treatments for IBS, particularly in patients who prefer non-pharmacological approaches or have experienced limited benefits from medications.[21-23]

However, it is important to acknowledge the limitations of this study, including its relatively short duration and the single-center design, which may affect the generalizability of the findings. Longer-term studies are needed to assess the sustainability of symptom improvement and adherence to dietary interventions over time. Additionally, individualized dietary counseling by trained dietitians is crucial to ensure nutritional adequacy and optimize adherence. The results of this randomized controlled trial indicate that both the Low-FODMAP Diet (LFD) and Low-Carbohydrate Diet (LCD) are more effective than Standard Medical Therapy (SMT) in reducing IBS symptoms over 4 weeks. The LFD group exhibited the highest proportion of participants achieving a clinically significant reduction in IBS-SSS, aligning with previous studies demonstrating the efficacy of LFD in managing IBS symptoms. The LCD group also showed substantial improvements, suggesting that carbohydrate restriction may play a role in symptom alleviation.[24]

Quality of life improvements were more pronounced in the dietary intervention groups compared to the SMT group. This finding underscores the potential of dietary modifications not only in symptom management but also in enhancing overall well-being among IBS patients. The higher treatment satisfaction rates in the LFD and LCD groups further support the acceptability and effectiveness of these dietary approaches.[25]

Adverse events were minimal and similar across all groups, indicating that both dietary interventions are safe and well-tolerated. The low incidence of mild gastrointestinal discomfort, headaches, and fatigue suggests that these diets can be implemented without significant risk of adverse effects.

While pharmacological treatments remain a cornerstone in IBS management, the superior outcomes associated with dietary interventions in this study advocate for the integration of personalized dietary strategies into standard care. Healthcare providers should consider incorporating dietary counseling and support for patients with IBS, tailoring interventions to individual needs and preferences.

Limitations of the study include its relatively short duration and single-center design, which may affect the generalizability of the findings. Long-term studies are warranted to assess the sustainability of symptom improvement and adherence to dietary interventions over time. Additionally, future research should explore the mechanisms underlying the efficacy of these diets to further optimize IBS management strategies.

Conclusion

This randomized controlled trial demonstrates that both Low-FODMAP and Low-Carbohydrate diets are more effective than Standard Medical Therapy in reducing IBS symptom severity over 4 weeks. These findings support the incorporation of dietary interventions as first-line treatments for IBS, emphasizing the importance of personalized dietary strategies in clinical practice. Further research is warranted to evaluate the long-term efficacy and feasibility of these dietary approaches in diverse patient populations.

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