Original Article Evaluation of the combined use of linaclotide and probiotics on clinical treatment efficacy and quality of life in patients with constipation-predominant irritable bowel syndrome

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Abstract: Objective: To evaluate the effects of combining linaclotide with Bifid Triple Viable Capsules on clinical outcomes and quality of life (QoL) in patients with constipation-predominant irritable bowel syndrome (IBS-C). Methods: A retrospective analysis was performed on data from 189 IBS-C patients treated between April 2021 and January 2024. The control group (91 patients) received linaclotide, while the combined group (98 patients) received linaclotide plus Bifid Triple Viable Capsules. Outcomes assessed included bowel movement frequency, stool consistency scores, constipation severity, anxiety (Self-Rating Anxiety Scale, SAS), depression (Self-Rating Depression Scale, SDS), QoL (Irritable Bowel Syndrome Quality of Life, IBS-QoL), and symptom severity (Irritable Bowel Syndrome Severity Scoring System, IBS-SSS). Logistic regression identified independent risk factors for QoL improvement. Results: Both groups showed significant increases in bowel movement frequency after treatment (P < 0.001). The combined group experienced a significantly greater improvement compared to the control group (P < 0.001). Stool consistency scores improved significantly in both groups (P < 0.001), but no significant difference was observed between groups (P > 0.05). Both groups showed significant reductions in constipation severity, with the combined group showing greater improvement (P < 0.001). SAS and SDS scores decreased significantly in both groups (P <0.001). The combined group showed greater reductions in SAS (P < 0.05) and SDS (P < 0.001). IBS-QoL scores improved significantly in both groups, with the combined group achieving greater improvement (P < 0.001). IBS-SSS scores decreased significantly, with the combined group experiencing a greater reduction (P < 0.001). IBS-QoL scores were positively correlated with bowel movement frequency (r = 0.289, P < 0.001) and negatively correlated with stool consistency scores (r = -0.154, P = 0.036), constipation severity (r = -0.386, P < 0.001), SDS scores (r = -0.150, P = 0.040), and IBS-SSS scores (r = -0.347, P < 0.001). Logistic regression identified treatment regimen (OR = 0.163, P = 0.017), age (OR = 4.666, P = 0.002), monthly income (OR = 0.065, P < 0.001), post-treatment bowel movement frequency (OR = 0.055, P < 0.001), and post-treatment constipation severity (OR = 5.545, P = 0.007) as independent factors influencing QoL improvement. Conclusion: The combined use of linaclotide and Bifid Triple Viable Capsules significantly enhances bowel movement frequency, reduces constipation severity, and improves QoL and psychological well-being in IBS-C patients. This approach offers a promising strategy for the comprehensive management of IBS-C.

Keywords: Constipation-predominant irritable bowel syndrome, linaclotide, probiotics, clinical efficacy, quality of life

Introduction

Constipation-predominant irritable bowel syndrome (IBS-C) is a common functional bowel disorder characterized by abdominal pain, bloating, and difficulty with bowel movements, significantly impairing patients' quality of life [1]. Its etiology is multifactorial, involving gut

motility disorders, visceral hypersensitivity, gut microbiota dysbiosis, and psychological influences [2]. While IBS-C does not lead to severe complications, its persistent symptoms reduce quality of life, work efficiency, and increase psychological burden [3]. Globally, the prevalence of IBS is approximately 10-15%, with constipation-predominant cases accounting for 30-40%

[4, 5]. In China, IBS-C prevalence is relatively high, particularly among women and younger populations [6]. The fluctuating and diverse symptoms of IBS-C present challenges in diagnosis and treatment. Current therapeutic strategies primarily aim at symptom relief and quality of life improvement, but their efficacy varies, necessitating exploration of more effective approaches.

Current treatment options for IBS-C include dietary modifications, pharmacotherapy, and psychological interventions [7]. Probiotics have emerged as a safe and effective therapeutic option, contributing to gut microbiota regulation, enhanced intestinal barrier function, and suppression of harmful bacterial growth [8]. Bifid Triple Viable Capsules, a widely used probiotic formulation, has demonstrated efficacy in alleviating symptoms such as abdominal pain, bloating, and constipation in IBS-C patients [9]. Linaclotide, a guanylate cyclase-C (GC-C) agonist, acts by activating GC-C receptors in the intestine, promoting fluid secretion into the intestinal lumen and enhancing motility, thus relieving constipation symptoms [10]. Clinical studies have shown that linaclotide effectively increases bowel movement frequency while significantly reducing abdominal pain and bloating [11, 12].

IBS-C not only affects physical health but also has profound psychological impacts, including anxiety and depression, driven by recurrent abdominal pain, bloating, and difficulty with bowel movements [13]. This interplay of symptoms creates a vicious cycle, exacerbating the condition [14]. Despite the availability of various treatments, limitations remain. Monotherapies often provide limited efficacy and fail to comprehensively address patients' symptoms. Long-term use of certain medications may lead to resistance or side effects, diminishing compliance. Moreover, most treatments focus predominantly on alleviating intestinal symptoms, often overlooking psychological well-being and overall quality of life [15, 16].

This study aims to comprehensively evaluate the effects of combination therapy on IBS-C through multidimensional assessments, including bowel movement frequency, abdominal symptoms, quality of life, and psychological state. Using a retrospective real-world design ensures the results are representative and

reflective of clinical practice. We hypothesize that combining linaclotide with Bifid Triple Viable Capsules will demonstrate significant advantages in improving clinical symptoms and quality of life in IBS-C patients, providing valuable insights for optimizing treatment strategies and improving patient outcomes.

Materials and methods

General information

A retrospective analysis was conducted on 189 IBS-C patients treated at Baoji High Tech Hospital between April 2021 and January 2024. The control group consisted of 91 patients who received linaclotide treatment, while the combined group included 98 patients treated with linaclotide and probiotics. The study was approved by the Medical Ethics Committee of Baoji High Tech Hospital.

Inclusion and exclusion criteria

Inclusion criteria: 1. Age \geq 18 years, diagnosed with IBS-C according to the 2020 Chinese Expert Consensus on Irritable Bowel Syndrome [17]. 2. Symptoms not effectively relieved by other treatment methods. 3. Normal findings on hepatobiliary, pancreatic, and splenic ultrasound, with complete clinical data available.

Exclusion criteria: 1. Constipation due to central nervous system diseases such as Parkinson's disease, spinal cord injury, or multiple sclerosis. 2. Mechanical bowel obstruction caused by tumors, hernias, megacolon/megarectum, pseudo-obstruction, weight loss surgery, gastrointestinal resection, or diabetic neuropathy. 3. Known or suspected organic bowel diseases, including inflammatory bowel disease, ulcerative colitis, Crohn's disease, or active peptic ulcer. 4. Symptoms suggesting serious conditions such as unexplained lower gastrointestinal bleeding, anemia, significant weight loss, or infection/colitis. 5. Severe cardiovascular, hepatic, renal, respiratory, neurological, or psychiatric conditions.

Treatment protocol

The control group received oral linaclotide capsules (National Drug Code: HJ20190002, Almac Pharma Services Limited) at a dosage of one capsule daily, taken 30 minutes before breakfast. This protocol was designed to evalu-

ate the effectiveness of single-drug intervention for IBS-C symptoms.

Patients in the combined group were treated with linaclotide and Bifid Triple Viable Capsules (National Drug Code: S10950032, Shanghai Sine Pharmaceutical Laboratories Co., Ltd.). Dosage was 2-4 capsules twice daily, taken 30 minutes after meals, with adjustments made based on individual patient conditions. This combination therapy aimed to explore the synergistic effects of linaclotide and probiotics.

Both groups received standard supportive treatment, including dietary modifications, regular routines, and moderate exercise to enhance intestinal health. The treatment period lasted 14 days, during which various indicators were recorded to evaluate therapeutic efficacy.

Efficacy evaluation

Efficacy was categorized into three levels based on symptom relief:

Significant: Major symptoms completely or largely resolved; bowel movements occurred 1-2 times daily, with soft, formed stools and no mucus.

Effective: Partial improvement in major symptoms, with some increase in bowel movements and better stool consistency.

Ineffective: Little or no improvement in symptoms, with minimal changes in bowel movements or stool consistency.

The total clinical effective rate was calculated as: (number of significant + effective cases)/ total cases * 100%.

Functional scores

Stool consistency score: Assessed using the Bristol Stool Form Scale (BSFS) [18], ranging from 1 to 7. Higher scores indicate looser stools; lower scores indicate harder stools.

Constipation severity: Evaluated using the Wexner Constipation Score [19], with scores ranging from 0 to 30. Higher scores reflect more severe constipation.

Self-rating anxiety scale (SAS): Anxiety levels were assessed using the SAS [20], with scores

ranging from 20 to 80. Higher scores indicate more severe anxiety.

Self-rating depression scale (SDS): Depression levels were assessed using the SDS [21], with scores ranging from 20 to 80. Higher scores indicate more severe depression.

Irritable bowel syndrome quality of life (IBS-QoL): Quality of life was evaluated using the IBS-QoL scale [22], with scores ranging from 0 to 100. Higher scores reflect better quality of life.

Irritable bowel syndrome severity scoring system (IBS-SSS): Severity of IBS symptoms was assessed using the IBS-SSS [23], with scores ranging from 0 to 500. Higher scores indicate greater severity.

Outcome measures

1. Comparison of weekly bowel movements, stool consistency scores, and constipation severity before and after treatment. 2. Comparison of SAS and SDS scores before and after treatment. 3. Comparison of IBS-QoL and IBS-SSS scores before and after treatment, 4. Evaluation of differences in clinical efficacy post-treatment. 5. Correlation analysis between IBS-QoL scores and functional scores, weekly bowel movements, stool consistency scores, and constipation severity after treatment. 6. Classification of patients into improved and unimproved groups based on whether IBS-QoL scores increased by more than 15% post-treatment, followed by an analysis of risk factors affecting quality of life improvement.

Statistical analysis

Statistical analysis was conducted using GraphPad Prism 9.5.1 (GraphPad Software Inc., San Diego, CA, USA). The K-S test was used to assess the distribution of measurement data. Normally distributed data were analyzed using t-tests, while non-normally distributed data were analyzed using the rank-sum test. Independent sample t-tests were used for group comparisons, and paired t-tests were used for within-group comparisons. Categorical data were analyzed using chi-square tests. Pearson's correlation analysis evaluated the relationship between IBS-QoL scores and other indicators. Receiver operating characteristic (ROC) curves determined optimal cutoff values

Table 1. Comparison of clinical data

Variables	Control group (n = 89)	Combination group (n = 98)	χ²/t Value	P Value
Age (years)	49.85±5.19	49.34±4.24	-0.742	0.459
Gender (M/F)	31/58	26/72	1.517	0.218
Disease duration (years)	4.00 [3.00, 5.00]	4.00 [3.00, 6.00]	0.624	0.529
BMI (kg/m²)	23.88±4.00	24.54±4.07	1.116	0.266
Diabetes history (Y/N)	11/78	15/83	0.338	0.561
Hypertension history (Y/N)	7/82	10/88	0.309	0.578
Residence (urban/rural)	48/41	44/54	1.523	0.217
Marital status (married/others)	69/20	79/19	0.269	0.604
Monthly family income (RMB)	4333.71±1422.62	4611.22±1461.38	1.315	0.19

Note: BMI, Body mass index.

for measurement data. Logistic regression analysis identified independent risk factors affecting quality of life improvement. Forest plots were generated using R (version 4.3.2) with the forestplot package. A *P*-value < 0.05 was considered statistically significant.

Results

Comparison of general data

Baseline data comparisons revealed no significant differences between the two groups, confirming their comparability (all P > 0.05; **Table 1**).

Comparison of bowel movement frequency, stool consistency scores, and constipation severity

Before treatment, no significant differences were observed between the control and combined groups in bowel movement frequency, stool consistency scores, or constipation severity (all P > 0.05). After treatment both groups showed significant increases compared to baseline (P < 0.001), with the combined group demonstrating significantly greater bowel movement frequency than the control group (P < 0.001). Regarding stool consistency score significant improvements were observed in both groups compared to baseline (P < 0.001), but there was no significant difference between the groups after treatment (P > 0.05).

As for constipation severity, both groups exhibited significant reductions compared to baseline (P < 0.001), and the combined group showed significantly lower constipation severity than the control group (P < 0.001; **Figure 1**).

Comparison of anxiety and depression scores

Before treatment, there were no significant differences between the two groups in SAS or SDS scores (both P > 0.05). After treatment, both groups showed significantly reduced SAS and SDS scores compared to baseline (both P < 0.001), with the combination group achieving significantly lower anxiety and depression scores than the control group (both P < 0.05; Figure 2).

Comparison of IBS-QoL and IBS-SSS scores

Before treatment, there were no significant differences in IBS-QoL and IBS-SSS scores between the two groups (both P > 0.05). After treatment, both groups showed significant improvement in IBS-QoL scores compared to baseline (P < 0.0001), with the combined group achieving significantly higher scores than the control group (P < 0.0001). Regarding IBS-SSS scores, both groups demonstrated significant reductions compared to baseline (P < 0.0001), with the combined group showing significantly lower scores than the control group (P < 0.0001; Figure 3).

Comparison of treatment efficacy

In the control group, 33 cases were classified as significantly effective, 43 as effective, and 13 as ineffective, resulting in a total effective rate of 85.39%. In the combined group, 79 cases were significantly effective, 16 were effective, and 3 were ineffective, with a total effective rate of 96.94%. Statistical analysis confirmed that the total effective rate was significantly higher in the combined group ($\chi^2 = 7.946$, P = 0.005; **Table 2**).

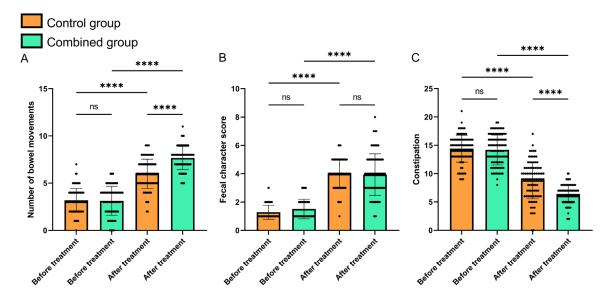


Figure 1. Comparison of bowel movement frequency, stool consistency score, and constipation severity. A: The image shows bowel movement frequency before and after treatment in the control and combination groups. B: The image shows stool consistency scores before and after treatment in the control and combination groups. C: The image shows constipation severity before and after treatment in the control and combination groups. Note: ns P > 0.05, ****P < 0.0001.

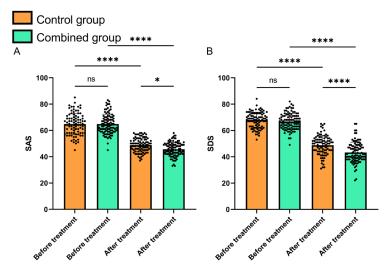


Figure 2. Comparison of SAS and SDS scores. A: This image shows SAS scores before and after treatment in the control and combination groups. B: This image shows SDS scores before and after treatment in the control and combination groups. Note: ns P > 0.05, *P < 0.05, ****P < 0.001; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale.

Correlation analysis of IBS-QoL with other scores after treatment

Post-treatment IBS-QoL scores showed: Positive correlation: Significant positive correlation with the bowel movement frequency (r = 0.289, P < 0.001; Figure 4A).

Negative correlation: Significant negative correlations with stool consistency scores (r = -0.154, P = 0.036; Figure 4B), constipation severity (r = -0.386, P < 0.001; Figure 4C), SDS scores (r = -0.150, P = 0.040; Figure 4E), and IBS-SSS scores (r = -0.347, P < 0.001; Figure 4F).

There were no significant correlations between IBS-QoL scores and other post-treatment scores (P > 0.05; Figure 4D).

Comparison of adverse reactions

No significant differences were observed in the incidence of adverse reactions, including diarrhea, bloating, abdominal pain, dizziness, and rash, be-

tween the two groups ($\chi^2 = 1.729$, P = 0.188; **Table 3**).

Comparison of data between improved and unimproved patients

Patients were classified as improved (n = 130) or unimproved (n = 57) based on whether IBS-

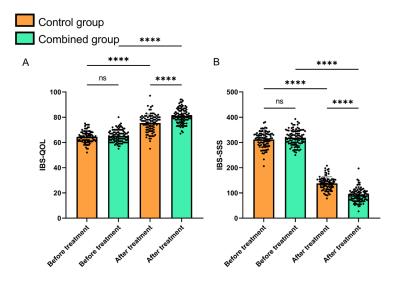


Figure 3. Comparison of IBS-QoL and IBS-SSS scores. A: The image shows IBS-QoL scores before and after treatment in the control and combination groups. B: The image shows IBS-SSS scores before and after treatment in the control and combination groups. Note: ns P > 0.05, ****P < 0.0001; IBS-QoL, Irritable Bowel Syndrome Quality of Life; IBS-SSS, Irritable Bowel Syndrome Severity Scoring System.

Table 2. Comparison of treatment efficacy

	Significantly	Effoctivo	Ineffective	Total effective	
	effective	LHECTIVE	menective	rate	
Control group	33	43	13	76	
Combination group	79	16	3	95	
χ² value	36.798	22.099	7.946	7.946	
P value	< 0.001	< 0.001	0.005	0.005	

QoL scores increased by more than 15% after treatment. The results showed that the proportion of patients receiving combination therapy was significantly higher in the improved group (P = 0.005). The improved group included significantly more women (P = 0.022), had a younger average age (P < 0.001), and reported higher monthly family incomes (P < 0.001).

The improved group showed significantly better outcomes in post-treatment bowel movement frequency, constipation severity, and IBS-SSS scores (all P < 0.001) compared to the unimproved group.

Other variables, including diabetes history, hypertension history, place of residence, marital status, disease duration, BMI, and post-treatment SAS and SDS scores, showed no significant differences (P > 0.05; **Table 4**).

Analysis of risk factors affecting improvement in patients' quality of life

For logistic regression, ROC curve-derived cutoff values were used to categorize data (**Figure 5**).

Univariate analysis revealed that the significant factors included treatment plan (OR = 2.491, P = 0.005), age (OR = 5.077, P < 0.001), monthly income (OR = 0.075, P < 0.001), gender (OR = 2.138, P = 0.024), post-treatment bowel movement frequency (OR = 0.096, P < 0.001), post-treatment constipation severity (OR = 5.913, P < 0.001), and post-treatment IBS-SSS score (OR = 4.607, P < 0.001; Figure 6).

Multivariate analysis showed that independent factors affecting quality of life improvement were the treatment plan (OR = 0.163, P = 0.017), age (OR = 4.666, P = 0.002), monthly income (OR = 0.065, P < 0.001), post-treatment bowel movement frequency (OR = 0.055, P < 0.001), and post-treatment con-

stipation severity (OR = 5.545, P = 0.007; **Figure 7**).

Discussion

The combination of linaclotide and Bifid Triple Viable Capsules was highly effective in treating IBS-C. Patients in the combined group showed greater improvements in bowel movement frequency, stool consistency, and constipation severity compared to the control group. Psychological health, assessed via SAS and SDS scores, also improved significantly in the combined group, alongside notable enhancements in IBS-QoL and IBS-SSS scores, underscoring the clinical advantages of combination therapy.

Linaclotide improves constipation by activating guanylate cyclase-C (GC-C) receptors, increasing intestinal fluid secretion and enhancing

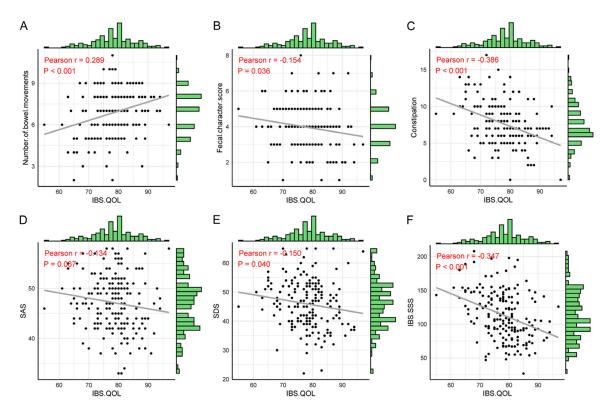


Figure 4. Correlation analysis of IBS-QoL scores with other indicators after treatment. A: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment number of bowel movements. B: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment stool consistency scores. C: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment constipation severity. D: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment anxiety scores. E: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment depression scores. F: This image shows the correlation between post-treatment IBS-QoL scores and post-treatment IBS-SSS scores. Note: SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; IBS-QoL, Irritable Bowel Syndrome Quality of Life; IBS-SSS, Irritable Bowel Syndrome Severity Scoring System.

Table 3. Comparison of adverse reactions

Adverse reactions	Diarrhea	Bloating	Abdominal pain	Dizziness	Rash	Total
Control group	16	22	2	3	0	43
Combination group	13	20	3	1	1	38
χ² value	0.790	0.498	0.119	1.231	0.913	1.729
P value	0.374	0.481	0.73	0.267	0.339	0.189

motility [24]. Zhao et al. [25] confirmed linaclotide's efficacy and safety in treating IBS-C and chronic constipation, despite its higher incidence of adverse reactions. Fukudo et al. [26] found linaclotide increased complete spontaneous bowel movements in IBS-C patients, though it was associated with diarrhea risk. Bifid Triple Viable Capsules mitigate symptoms such as abdominal pain and bloating by restoring gut microbiota balance, enhancing intestinal barrier function, and inhibiting harmful bacterial growth. Shekhar et al. [27] demonstrated that probiotics effectively alleviate IBS-C symptoms, reduce costs, and improve quality of life. Chen et al. [28] suggested probiotics provide significant but short-term IBS symptom relief. Nelson [29] highlighted linaclotide's superior efficacy compared to placebos for relieving bloating among FDA-approved IBS-C drugs.

Our study demonstrates that combining linaclotide with Bifid Triple Viable Capsules offers significant clinical benefits in treating IBS-C.

Table 4. Comparison of data between improved and unimproved patients

Variable	Improved group (n = 130)	Unimproved group (n = 57)	χ²/t	Р
Treatment plan (Control/Combination)	53/77	36/21	7.963	0.005
Gender (Male/Female)	33/97	24/33	5.228	0.022
Diabetes history (Yes/No)	18/112	8/49	0.001	0.973
Hypertension history (Yes/No)	10/120	7/50	1.009	0.315
Place of residence (Urban/Rural)	64/66	28/29	< 0.001	0.989
Marital status (Married/Other)	53/77	36/21	0.189	0.664
Age (years)	48.29±4.38	52.53±4.11	6.355	< 0.001
Disease course (years)	4.00 [3.00, 6.00]	4.00 [3.00, 5.00]	-0.506	0.609
Body mass index (kg/m²)	24.39±4.05	23.85±4.01	-0.837	0.405
Monthly family income (Yuan)	4853.85±1424.71	3624.56±1094.84	-6.422	< 0.001
Post-treatment bowel movements (per week)	7.00 [6.00, 8.00]	6.00 [5.00, 7.00]	-5.179	< 0.001
Post-treatment stool consistency score	4.00 [3.00, 5.00]	4.00 [3.00, 5.00]	0.904	0.352
Post-treatment constipation severity	7.00 [6.00, 8.00]	9.18±2.78	5.163	< 0.001
Post-treatment SAS	46.83±5.51	47.95±5.36	1.299	0.197
Post-treatment SDS	45.48±8.27	46.86±7.63	1.112	0.269
Post-treatment IBS-SSS	105.84±32.08	129.46±37.33	4.151	< 0.001

Note: SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; IBS-QoL, Irritable Bowel Syndrome Quality of Life; IBS-SSS, Irritable Bowel Syndrome Severity Scoring System.

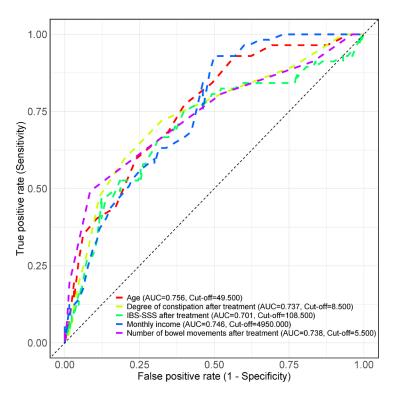


Figure 5. ROC curve for characteristic factors of improved and unimproved patients.

Linaclotide enhances bowel motility by increasing fluid secretion through GC-C receptor activation, while Bifid Triple Viable Capsules allevi-

ate abdominal pain and bloating by regulating gut microbiota and strengthening the intestinal barrier [30, 31]. This combination not only addresses IBS-C symptoms comprehensively but also significantly improves patients' quality of life. Additionally, the incidence of adverse reactions was comparable between the groups, confirming the combination therapy's efficacy and safety.

Correlation analysis revealed significant associations between IBS-QoL scores and clinical indicators. Specifically, IBS-QoL scores positively correlated with the bowel movement frequency, indicating that increased bowel movements enhance quality of life. IBS-QoL scores negatively correlated with stool consistency, constipation severity, SDS, and IBS-SSS scores, suggesting that improved stool consistency,

reduced constipation symptoms, and better psychological health contribute to a better quality of life.

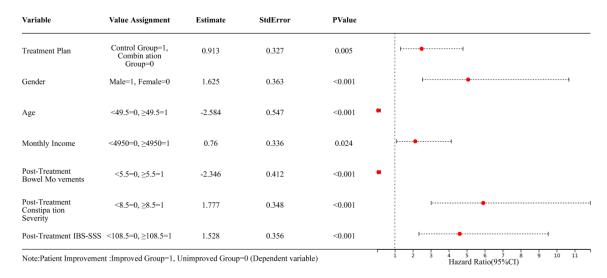


Figure 6. Univariate logistic regression analysis. Note: IBS-SSS, Irritable Bowel Syndrome Severity Scoring System.

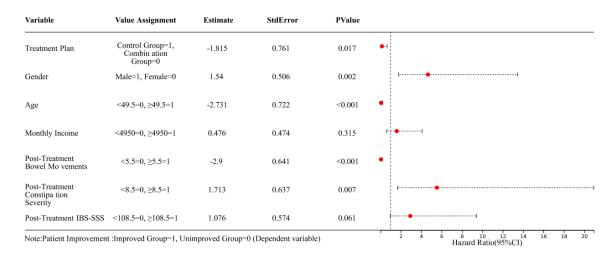


Figure 7. Multivariate logistic regression analysis. Note: IBS-SSS, Irritable Bowel Syndrome Severity Scoring System.

These findings emphasize the importance of a multidimensional treatment approach targeting both physical symptoms and psychological well-being in IBS-C management. IBS-C significantly impairs quality of life due to symptoms like abdominal pain, bloating, and difficulty with bowel movements, which affect physical health, psychological state, and social functioning [32]. Symptom relief has been shown to reduce psychological distress and improve overall quality of life [33].

Logistic regression identified the treatment plan, age, monthly income, post-treatment bowel movement frequency, and constipation severity as independent predictors of quality of

life improvement. Older patients often experience more severe symptoms and face treatment challenges due to declining physical function and comorbidities, limiting quality of life improvements [34, 35]. Higher-income patients can afford effective treatments such as linaclotide and are more likely to benefit from improved outcomes. Economic studies have shown linaclotide improves quality-adjusted life years (QALYs: 0.821 vs. 0.795 and 0.781) while reducing total costs (7,721 RMB vs. 8,797 RMB and 9,481 RMB) compared to other drugs [36]. Higher-income patients also have better access to comprehensive treatment, including dietary adjustments and psychological support, enhancing quality of life [37, 38]. Frequent bowel

movements and reduced constipation severity alleviate physical discomfort, reduce psychological stress, and improve intestinal function, enhancing overall well-being.

The combination of linaclotide and Bifid Triple Viable Capsules leverages the strengths of both treatments, offering a comprehensive approach to improving IBS-C symptoms and quality of life. This study has several limitations. Firstly, the focus on short-term effects limits the understanding of the long-term efficacy and safety of combination therapy. Secondly, conducting the study in a single medical center may introduce regional biases, limiting generalizability. Lastly, while linaclotide has demonstrated good cost-effectiveness, this study did not analyze the economic feasibility of combination therapy for low-income patients. Future studies should include long-term follow-up to assess the sustainability of treatment effects and safety. Additionally, economic analyses in diverse healthcare environments are needed to evaluate the feasibility of combination therapy for different socioeconomic groups. In conclusion, the combination of linaclotide and Bifid Triple Viable Capsules demonstrates significant efficacy in IBS-C treatment, improving bowel movement frequency, stool consistency, and constipation while enhancing quality of life and psychological health. This therapy offers a promising option for the comprehensive management of IBS-C.

Disclosure of conflict of interest

None.

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