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Exploring the Effects of Synbiotic Preparations on Constipation Efficacy, Inflammatory Factors, and 5-HT

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Abstract: *Post-stroke constipation is associated with prolonged hospitalization, poor neurological outcomes, and complications. Intestinal microecological agents are believed to modulate gut microbiota. This study aims to investigate the effects of synbiotics on post-stroke constipation. Patients with acute cerebral infarction and constipation admitted to the Department of Neurology of The 989th Hospital of the Joint Logistics Support Force of the Chinese People's Liberation Army from January to July 2024 were selected and randomly divided into a control group (treated with lactulose) and an observation group (treated with chicory probiotic powder). Each group received treatment for two weeks. Assessment indicators included defecation frequency, Bristol Stool Form Scale, Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire, inflammatory markers, changes in 5-HT levels, and safety analysis. A total of 87 patients were enrolled, with 45 in the control group and 42 in the observation group. In the control group, post-intervention results showed increased defecation frequency (t=13.834, P=0.002), decreased PAC-SYM scores (W=484, P<0.001), improved stool consistency, and an adverse reaction incidence of 26.67%. In the observation group, post-intervention results showed increased defecation frequency (t=-1.023, P=0.008), decreased PAC-SYM scores (W=367, P=0.001), improved stool consistency, decreased systemic inflammation response index (SIRI) (W=3.691, P=0.006), decreased CRP levels (W=778, P<0.001), decreased IL-6 levels (W=-5.559, P<0.001), decreased IL-8 levels (W=199, P=0.001), increased IL-10 levels (W=729, P=0.003), increased 5-HT levels (W=206, P=0.001), and an adverse reaction incidence of 7.14%. Chicory probiotic powder can improve defecation frequency, stool consistency, and constipation symptoms in patients with post-stroke constipation, elevate 5-HT levels, effectively regulate inflammatory factors, improve the immune-inflammatory status, and has the advantage of fewer adverse reactions.*

Keywords: *Synbiotics; Post-Stroke Constipation; Inflammatory Factors; 5-Hydroxytryptamine*

1. Introduction

Functional constipation (FC) refers to constipation without an organic cause[1,2]. The symptoms in FC patients primarily include difficult, infrequent, or incomplete defecation, which may be accompanied by abdominal pain and bloating. FC significantly impacts patients' quality of life[2]. Clinically, a high incidence of constipation following acute stroke can be observed. One study indicated the incidence rates of constipation across different stages of stroke: the incidence during the acute stage ranges from 33% to 55%, and during the rehabilitation stage, it ranges from 27% to 79%[1-3]. This demonstrates that post-stroke constipation is very common; however, this complication receives relatively little attention among post-stroke patients.

Traditional treatment methods include the use of osmotic laxatives, enemas, etc., to achieve normal bowel movements. Although traditional treatments are established and safe, they do not provide satisfactory improvement for many patients, which has spurred interest in other therapeutic strategies. Some clinical trials have shown that supplementation with certain probiotics can improve stool frequency in constipated patients and have also reported alterations in the gastrointestinal microbiota[4,5]. Microecological agents are increasingly being used for the treatment of constipation, with the most extensively studied being organisms of the genus Bifidobacterium and Lactobacillus[4,5,8]. Chicory probiotic powder serves as a synbiotic. This study utilized enzyme-linked immunosorbent

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assay (ELISA) to analyze the trends in symptom improvement, inflammatory factors, and 5-hydroxytryptamine (5-HT) levels in patients with post-stroke constipation after the addition of chicory probiotic powder, and to evaluate its safety, thereby assessing its impact on post-stroke constipation.

2. Materials and Methods

2.1 General Information

The study collected patients clinically diagnosed with acute cerebral infarction and functional constipation who were admitted to the Department of Neurology of The 989th Hospital of the Joint Logistics Support Force of the Chinese People's Liberation Army from January to July 2024. These patients served as the study subjects and were divided into a control group and an observation group. They were continuously administered lactulose and chicory probiotic powder, respectively. Based on the treatment phase, they were categorized into pre-treatment and 2-week post-treatment groups. The improvement of constipation symptoms in both groups before and after the intervention was assessed using defecation frequency, the Bristol Stool Form Scale, and the Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire. The incidence of adverse reactions, including abdominal pain, bloating, and diarrhea, was recorded. Serum samples were collected from all patients before and after the intervention. Results for complete blood count and C-reactive protein (CRP) were collected, and levels of PCT, IL-6, IL-8, α-TNF, IL-10, and 5-HT in the serum were measured using the enzyme-linked immunosorbent assay (ELISA) method. The development of this study protocol complied with the relevant requirements of the World Declaration of Helsinki and was reviewed and approved by the Ethics Committee, with the ethics approval number KY2023008-K02.

2.2 Diagnostic Criteria

The diagnostic criteria for adult functional constipation were the Rome IV criteria. The diagnosis must include two or more of the following:

a) At least 25% of defecations involve straining;

b) At least 25% of defecations are lumpy or hard stools;

c) At least 25% of defecations are associated with a sensation of incomplete evacuation;

d) At least 25% of defecations are associated with a sensation of anorectal obstruction/blockage;

e) At least 25% of defecations require manual maneuvers to facilitate, and spontaneous defecation occurs less than three times per week.

Loose stools are rarely present without the use of laxatives.

The diagnostic criteria for irritable bowel syndrome are not met.

2.3 Inclusion and Exclusion Criteria

Inclusion Criteria

Patients meeting the following criteria were included:

a) Patients in the acute or subacute phase of stroke;

b) Patients who meet the diagnostic criteria for functional constipation;

c) No history of antibiotic or probiotic use within the past two weeks;

d) No history of organic intestinal diseases or intestinal surgery;

e) No history of long-term abuse of anthraquinone laxatives (such as rhubarb and senna leaves);

f) No history of chronic abdominal pain, bloating, or diarrhea.

Exclusion Criteria

Patients were excluded based on the following criteria:

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a) Long-term use of biological agents or hormones;

b) Comorbid Parkinson's disease, Alzheimer's disease, epilepsy, or intracranial infection;

c) Death during the study period, withdrawal from treatment, or transfer to another hospital;

d) Allergy to the components of the study medications or occurrence of severe adverse reactions;

e) NIHSS score ≧6 or mRS score ≧4;

f) Comorbid diabetes mellitus.

2.4 Treatment Methods

Eligible enrolled patients were randomly assigned using a random number method into a control group and an observation group. The control group received lactulose oral solution (National Drug Approval Number: Guoyao Zhunzi H20065730; Manufacturer: Beijing Hanmi Pharmaceutical Co., Ltd.; Specification: 100ml/bottle) for treatment, administered at 10 mL (equivalent to 6.67g of lactulose) per dose, three times daily. The observation group received chicory probiotic powder (Manufacturer: Shanxi Dayangtang Food Co., Ltd.; Product Standard Code: GB/T 29602; Specification: 300g/(10g30 sachets); Ingredient List: Fructooligosaccharides, Galactooligosaccharides, Inulin (source: chicory root, recommended daily intake ≦ 15 grams), Lactic Acid Bacteria (Lactobacillus acidophilus, Bifidobacterium longum, Lactobacillus paracasei, Lactobacillus rhamnosus, Lactobacillus fermentum, Lactobacillus helveticus, Streptococcus thermophilus), Lactic Acid Bacteria Compound Powder (Lactobacillus rhamnosus* HN001, Bifidobacterium animalis subsp. lactis HN019)) for treatment. The powder was to be taken with warm water, at a temperature not exceeding 37°C, at one sachet per dose, twice daily.

2.5 Research Methods

a) Researchers recorded the defecation frequency, Bristol Stool Form Scale scores, Patient Assessment of Constipation Symptoms (PAC-SYM) questionnaire scores, and adverse reactions for both patient groups before and after the intervention.

b) Complete blood count and CRP results were collected and recorded both before and after the intervention.

c) For the detection of inflammatory factors and 5-HT, blood samples were collected from patients in both groups before and after the treatment period (at 0 and 2 weeks). After collection, the samples were centrifuged at 5000r for 5 minutes. The resulting serum was extracted into sterile cryogenic vials and stored frozen at -80°C. The levels of PCT, IL-6, IL-8, α-TNF, IL-10, and 5-HT in the serum were measured using respective ELISA kits.

2.6 Observation Indicators

a) The study observed and assessed the dynamic changes in defecation frequency, Bristol Stool Form Scale scores, and Patient Assessment of Constipation Symptoms (PAC-SYM) scores in both the control and observation groups before and after the intervention. The incidence of abdominal pain, bloating, and diarrhea was recorded for both groups.

b) The study measured the dynamic changes in inflammatory markers in both patient groups before and after the intervention.

c) The study detected the dynamic changes in serum 5-HT levels in both patient groups before and after the intervention.

2.7 Statistical Methods

The statistical analysis was performed using SPSS software, version 21.0. Normally distributed continuous variables were expressed as the mean ± standard deviation ($\overline{x} \pm s$), and comparisons between the two groups were made using the t-test; Non-normally distributed continuous variables were expressed as the median (interquartile range), and comparisons between the two groups were made using non-parametric tests. Categorical data were expressed as a percentage (%), and comparisons between the two groups were made using the $\chi 2$ test. The significance level was set at

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α=0.05.

3. Results

3.1 General Information

A total of 87 eligible patients with constipation were enrolled. The control group consisted of 45 patients, with 19 males and 26 females, aged 67.62 ± 9.64 years. The observation group consisted of 42 patients, with 24 males and 18 females, aged 67.6 ± 8.97 years. There were no statistically significant differences between the two groups in terms of age, gender, BMI, NHISS score, baseline defecation frequency, or baseline Patient Assessment of Constipation Symptoms (PAC-SYM) score. However, there was a difference in the Bristol Stool Form Scale (details are provided in Table 1).

Table 1 Comparison of Basic Characteristics between the Two Groups

	Control Group(N=45)	Observation Group(N=42)	t//W /χ2	***P***
Age (years)	67.62±9.64	67.6±8.97	-0.167	0.868
Gender	Male19(42.2%)	Male24(57.1%)	1.383	0.240
	Female26(57.8%)	Female18(42.9%)		
BMI	24.63±4.45	24.02±3.86	-1.743	0.087
NIHSS Score	3(2, 3)	3(2,3.75)	939	0.961
Baseline Defecation Frequency	1.2 ± 0.7	1.3 ± 0.7	1030	0.478
Baseline PAC-SYM	6(4, 6)	5(4, 6)	934.5	0.931
Bristol Stool Form Scale	1Type7(15.6%) 2Type32(71.1%) 3Type6(13.3%)	1Type2(4.8%) 2Type25(59.5%) 3Type15(35.7%)	38.537	<0.001

3.2 Analysis of Differences in Defecation Frequency, Bristol Stool Form Scale, and Constipation Symptom Self-Assessment Scale between the Two Groups before and after Intervention

The experimental results indicated that in the control group, after two weeks of intervention, the defecation frequency increased (1.2 ± 0.7 vs. 2.9 ± 1.2), and the difference was statistically significant (t=13.834, P=0.002). In the observation group, after the intervention, the defecation frequency increased compared to the baseline (1.3 ± 0.7 vs. 3.0 ± 1.3), and the difference was statistically significant (t=-1.023, P=0.008). Details are shown in Figure 1.

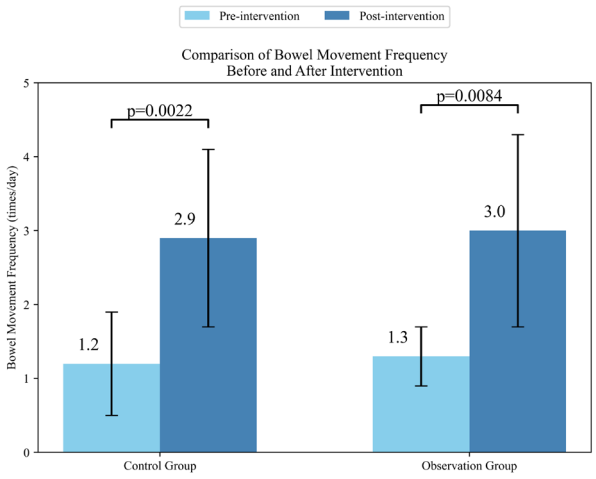

Figure 1 Comparison of Defecation Frequency between the Control Group and the Observation Group Before and After Intervention

After two weeks of intervention, compared with baseline, the PAC-SYM scores in the control group decreased from 6 points to 4 points, showing a statistically significant difference (W=484, P<0.001).

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The scores in the observation group decreased from 5 points to 4.5 points, also demonstrating improvement (W=367, P=0.001). After two weeks of intervention, the Bristol Stool Form Scale scores in the control group showed statistically significant improvement compared to baseline. The observation group also exhibited statistically significant improvement after the two-week intervention (details are shown in Table 2).

These results indicate that both lactulose and chicory probiotic powder can effectively improve subjective symptoms and stool consistency in patients with constipation.

Table 2 Analysis of the Bristol Stool Form Scale and PAC-SYM in the Two Groups before and after Intervention

	Variable	Pre-intervention	Post-intervention	t/W/χ2	***P***
Control Group	Stool Consistency	1Type7(15.6%) 2Type32(71.1%) 3Type6(13.3%)	2Type7(15.6%) 3Type27(60.0%) 4Type8(17.8%) 5Type3(6.6%)	47.389	<0.001
	PAC-SYM	6(4, 6)	4 (3, 4)	484	<0.001
Observation Group	Stool Consistency	1Type2(4.8%) 2Type25(59.5%) 3Type15(35.7%)	2Type4(9.5%) 3Type19(45.2%) 4Type17(40.5%) 5Type2(4.8%)	37.412	<0.001
	PAC-SYM	5 (4, 6)	4.5 (4, 5)	367	0.001

3.3 Analysis of Differences in Inflammatory Markers and 5-HT between the Two Groups before and after Intervention

The experimental results indicated that after two weeks of intervention, the observation group demonstrated a decrease in the systemic inflammation response index (SIRI) (1.495 vs. 0.985, W=3.691, P=0.006), a decrease in C-reactive protein (CRP) levels (1.795 vs. 1, W=778, P<0.001), a decrease in interleukin-6 (IL-6) levels (1.735 vs. 1.46, W=-5.559, P<0.001), a decrease in interleukin-8 (IL-8) levels (5.99 vs. 4.45, W=199, P=0.001), an increase in interleukin-10 (IL-10) levels (13.935 vs. 17.145, W=729, P=0.003), and an increase in 5-hydroxytryptamine (5-HT) levels (4.675 vs. 6.38, W=206, P=0.001). All these differences were statistically significant (see Table 3). In the control group, no statistically significant differences in inflammatory markers or 5-HT levels were observed before and after the intervention.

Table 3 Analysis of Inflammatory Factors and 5-HT in the Observation Group before and After Intervention

	Pre-intervention	Post-intervention	W	***P***
SIRI	1.495 (0.8, 2.075)	0.985 (0.608, 1.375)	3.691	0.006
CRP	1.795 (1.34, 2.523)	1 (0.6125, 1.353)	778	<0.001
IL-6	1.735 (1.435, 2.165)	1.46 (1.353, 1.51)	-5.559	<0.001
IL-8	5.99 (4.575, 7.623)	4.45 (3.503, 5.365)	199	0.001
IL-10	13.935 (11.618, 15.77)	17.145 (14.618, 18.565)	729	0.003
5-HT	4.675 (4.113, 5.528)	6.38 (4.913, 8.07)	206	0.001

3.4 Comparison of Adverse Reactions between the Two Intervention Groups: Analysis of Safety and Tolerability Based on Abdominal Pain, Abdominal Distension, and Diarrhea

The results showed that in the control group, 7 cases of abdominal distension and 5 cases of diarrhea occurred during the intervention, resulting in an overall incidence of adverse reactions of 26.67%. In the observation group, 2 cases of abdominal distension and 1 case of diarrhea occurred

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during the intervention, yielding an overall incidence of adverse reactions of 7.14%. These findings indicate that the observation group had a lower incidence of adverse reactions and demonstrated higher tolerability.

4. Discussion

4.1 Research Background and Significance

Stroke ranks as one of the leading causes of mortality and disability worldwide[1,2], not only severely impacting individual patient health but also posing a significant burden on public health systems and creating substantial economic pressure. Functional constipation (FC), a type of constipation without organic causes, is characterized primarily by difficult, infrequent, or incomplete defecation, often accompanied by abdominal pain and bloating[2]. Post-stroke constipation is a common complication among stroke patients, with a reported incidence ranging from 29% to 79%[1,2,3]. It is primarily triggered by factors such as post-stroke immobility, drowsiness, inadequate water or nutritional intake, depression, decreased mobility, cognitive impairment, reduced consciousness, and medication use[3]. Post-stroke constipation not only prolongs hospitalization but is also closely associated with poor neurological outcomes, further complications, and even mortality[1]. It significantly reduces patients' quality of life and imposes both economic and psychological pressures on patients and their families. In recent years, research on intestinal microecological agents has provided new perspectives for constipation treatment. The gut microbiota, composed of hundreds of bacterial species, plays a crucial role in host health[4,5,6]. Dysbiosis not only disrupts the intestinal microenvironment, affecting the secretion and function of intestinal active substances, but also modulates the immune system by producing molecules with immunoregulatory and anti-inflammatory functions[7-9]. Numerous studies have confirmed that gut microbiota dysbiosis is one of the important pathogenesis mechanisms of functional constipation[10,11]. Intestinal microecological agents include probiotics, prebiotics, and synbiotics. Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host[4,5,8]. Chicory probiotic powder, as a synbiotic containing both prebiotic and probiotic components, represents an ideal intestinal microecological agent.

4.2 Analysis of Results

Research indicates that modulating gut microbiota through probiotics can help increase defecation frequency and alleviate constipation symptoms in up to 70% of patients with constipation. Yang et al. found that administering a synbiotic (SBT) containing Lactobacillus acidophilus, Lactobacillus rhamnosus, and Plantarum effectively alleviated loperamide-induced constipation in mice[12,13], improved some constipation-related symptoms, and increased serum 5-hydroxytryptamine (5-HT) levels. 5-HT acts on intestinal 5-HT receptors to promote the contraction of gastrointestinal smooth muscle, thereby alleviating constipation symptoms[2,14,15]. These research findings provide a theoretical basis for the application of probiotics in constipation treatment. The results of this study demonstrate that intervention with chicory probiotic powder can improve symptoms in patients with post-stroke constipation, increase defecation frequency, improve stool consistency, and elevate serum 5-HT levels. 5-HT stimulates colonic motility via its 5-HT3 and 5-HT4 receptors, thereby promoting intestinal peristalsis[5,14,15]. These findings are consistent with previous research results, further validating the efficacy of synbiotics in the treatment of constipation

Regarding immunomodulation, the observation group exhibited significant anti-inflammatory properties. Studies show that probiotics can modulate systemic immune responses by activating mucosal antigen-presenting cells[7,16,17]. Certain strains of Lactobacillus and Bifidobacterium can increase the concentration of the anti-inflammatory cytokine IL-10 and inhibit pro-inflammatory responses[7,8]. Furthermore, probiotics can regulate macrophage signaling pathways, influencing the production of pro-inflammatory factors[7,8,16,17]. This study found that after the intervention with chicory probiotic powder, the systemic inflammation response index (SIRI), serum C-reactive protein (CRP), and levels of the pro-inflammatory factors IL-6 and IL-8 decreased, while the level of the anti-inflammatory factor IL-10 increased. This further verifies the role of synbiotics in regulating the body's immune-inflammatory response.

Regarding the incidence of adverse reactions, the results of this study show that the overall incidence of adverse reactions, including abdominal distension, abdominal pain, and diarrhea, was

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higher in the control group than in the observation group.

In summary, chicory probiotic powder demonstrates effectiveness in improving symptoms, promoting 5-HT secretion, and reducing pro-inflammatory factor levels in patients with post-stroke constipation, while also exhibiting higher tolerability and safety.

4.3 Innovations and Limitations

Although the limited sample size of this study may impose certain constraints on the conclusions drawn, the potential of chicory probiotic powder in treating post-stroke constipation has been preliminarily validated. Research on the application of chicory probiotic powder for functional constipation is rarely reported, and the focus on post-stroke constipation patients in this study differs from previous constipation research subjects, indicating certain innovative aspects. However, this study did not observe significant results regarding PCT and α-TNF. Future multi-center, large-sample studies are required to comprehensively evaluate the long-term efficacy and safety of chicory probiotic powder in patients with post-stroke constipation.

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