Study on the Effect of Bifidobacterium Quadruple Viable Tablets in the Treatment of Ulcerative Colitis

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Abstract: *Objective:* To study the therapeutic efficacy of patients with ulcerative colitis receiving Bifidobacterium quadruple viable tablets. *Methods:* 49 cases were selected from ulcerative colitis patients who attended the clinic from February 2021 to November 2022, and were randomly grouped into group A for addition of Bifidobacterium quadruple viable tablets treatment, and group B for conventional medication. The efficacy, inflammatory factors, nutritional indexes, and adverse reactions were compared between the groups. *Results:* The efficacy of UC patients in group A was higher than that in group B ($P < 0.05$); the inflammatory factors in group A were lower than that in group B ($P < 0.05$); nutritional indicators in group A were higher than that in group B ($P < 0.05$); and the adverse reactions of medication in UC patients in group A were lower than that in group B ($P < 0.05$). *Conclusion:* The treatment of UC patients with the addition of Bifidobacterium quadruple viable tablets can improve the nutritional status of the organism, inhibit the progression of inflammation, and is safe and efficient in treating ulcerative colitis.

Keywords: Ulcerative colitis; Bifidobacterium quadruple viable tablets; Therapeutic effect

1. Introduction

At present, the pathogenesis of ulcerative colitis (UC) is not clear, it refers to the inflammatory lesions of the rectum and colon, which are not specific, and the location of the disease is mostly in the submucosal layer of the large intestine and the mucosal region, i.e., the rectum and the sigmoid region, and it can involve the entire colon, which can aggravate the condition and jeopardize its health if it is not properly diagnosed and treated. UC is a common chronic inflammatory bowel disease, the course of UC is long, the progression is slow, the risk of relapse is high, the onset can be at any age, and the typical symptoms include vomiting, abdominal pain, blood in stools, etc. During routine clinical use, mesalamine has a high application rate in UC, which has the effect of regulating immune function and inhibiting inflammation progression, but it is easy to cause adverse reactions during use, and the prognosis of some patients is undesirable. With the continuous deepening of

clinical research on UC, some scholars have found that UC is closely related to local bacterial imbalance, so it is recommended that probiotic preparations be given in combination with conventional anti-inflammatory drugs to stimulate the activity of intestinal beneficial bacteria and restore the balance of intestinal flora [1]. This paper discusses the efficacy of Bifidobacterium quadruple viable tablets with 49 UC patients admitted from February 2021 to November 2022.

2. General information and methods

2.1. General information

Forty-nine cases were selected from UC patients attending the clinic from February 2021 to November 2022 and randomly grouped. The data of UC patients in group A did not differ from that of group B ($P > 0.05$), as shown in **Table 1**.

Table 1. Analysis of UC information

Group	Gender		Age (years)		Duration of disease (months)		Degree of UC	
	Male	Female	Range	Average	Range	Average	Mild	Moderate
Group A ($n = 25$)	14 (56.00)	11 (44.00)	25–89	45.17 ± 2.11	1–11	6.11 ± 1.35	12 (48.00)	13 (52.00)
Group B ($n = 24$)	12 (50.00)	12 (50.00)	25–90	45.21 ± 2.13	1–12	6.13 ± 1.37	14 (58.33)	10 (41.67)
x^2 / t	0.1770		0.0725		0.0565		0.3357	
P	0.6740		0.9425		0.9552		0.5623	

2.2. Inclusion and exclusion criteria

Inclusion criteria included: (1) Pathology, endoscopy, and other confirmed diagnoses of UC; (2) Patients were not taking any immunosuppressive drugs; (3) Informed consent; and (4) Normal communication and thinking.

Exclusion criteria included: (1) Patients with colitis, dysentery, and other gastrointestinal lesions; (2) Patients with severe UC; (3) Patients with immune ischemia; and (4) Patients with immune dysfunction.

2.3. Treatment method

Group A was additionally treated with Bifidobacterium quadruple viable tablets (Hangzhou Yuanda Biological Pharmaceutical Co., Ltd.): taken orally with warm water, a single dose of 1.5 g, 3 times a day. The treatment was administered for 2 months.

Group B was treated with mesalamine enteric-coated tablets (Sunflower Pharmaceutical Group Jiamusi Luling Pharmaceutical Co., Ltd.): taken orally with warm water, a single dose of 0.5 g, 3 times a day; in the case of an acute attack of UC, a single dose of 1 g, 4 times a day. The treatment was administered for 2 months.

2.4. Observation index

The observation indexes in this study included:

(1) UC treatment efficacy: Disappearance of blood in stool and abdominal discomfort, the frequency of stool reduced to 2 times/d or 1 time/d, and colonoscopy suggesting local edema and celiac foci healed were recorded as markedly effective; Reduction of blood in stool and abdominal discomfort, the frequency of stool reduced to 2–4 times/d, and colonoscopy suggesting celiac foci shrinkage were recorded as effective; Colonoscopy suggesting no change in the celiac foci was recorded as ineffective. The efficient rate included those markedly effective and effective.

(2) Inflammatory factors: Detect changes in interleukin-8 (IL-8), IL-17, C-reactive protein (CRP), tumor necrosis factor-alpha (TNF-α), and other indicators.

(3) Nutritional indicators: Detect changes in albumin (Alb), transferrin (TRF), pre-albumin (PA), and other indicators.

(4) UC treatment adverse reactions: Record watery stools, nausea and vomiting, and abdominal discomfort.

2.5. Statistical analysis

The data of UC patients were processed by SPSS 21.0, count data were recorded as % with x^2 validation, and measurement data were recorded as mean ± standard deviation (SD) with t-test validation. There was a difference in comparison when $P < 0.05$.

3. Results

3.1. Comparison of UC treatment efficacy

Table 2 shows that the UC treatment efficacy was 96.00% in group A, which was higher than in group B, 70.83% ($P < 0.05$).

Table 2. Comparison of UC treatment efficacy [n (%)]

Group	Markedly effective	Effective	Ineffective	Efficient rate (%)
Group A (n = 25)	14 (56.00)	10 (40.00)	1 (4.00)	96.00
Group B (n = 24)	13 (54.17)	4 (16.67)	7 (29.17)	70.83
x^2	-	-	-	5.6771
P	-	-	-	0.0172

3.2. Comparison of inflammatory factors

Before treatment, there was no difference between the level of inflammatory factors of UC patients in group A and that of group B ($P > 0.05$); After treatment, the level of inflammatory factors of UC patients in group A was lower than that of group B ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of inflammatory factor levels before and after treatment (mean ± SD)

Group	IL-8 (µg/L)		IL-17 (pg/mL)		CRP (mg/L)		TNF-α (ng/L)	
	Before	After	Before	After	Before	After	Before	After
Group A (n = 25)	57.61 ± 2.84	17.48 ± 1.32	14.11 ± 1.87	10.09 ± 0.87	21.48 ± 2.78	8.01 ± 1.35	49.15 ± 2.84	18.33 ± 1.84
Group B (n = 24)	57.63 ± 2.82	26.11 ± 1.49	14.15 ± 1.96	12.12 ± 0.94	21.47 ± 2.81	14.11 ± 1.96	49.17 ± 2.82	30.37 ± 1.96
t	0.0247	21.4821	0.0731	7.8498	0.0125	12.7324	0.0247	22.1782
P	0.9804	0.0000	0.9420	0.0000	0.9901	0.0000	0.9804	0.0000

3.3. Comparison of nutritional indicators

Before treatment, the level of nutritional indicators of UC patients in group A was not different from that of group B ($P > 0.05$); After treatment, the level of nutritional indicators of UC patients in group A was higher than that of group B ($P < 0.05$), as shown in **Table 4**.

Table 4. Comparison of nutritional indicators before and after treatment (mean ± SD)

Group	Alb (g/L)		TRF (g/L)		PA (mg/L)	
	Before	After	Before	After	Before	After
Group A (n = 25)	30.64 ± 3.25	40.82 ± 4.18	1.73 ± 0.11	2.59 ± 0.35	214.52 ± 35.36	374.25 ± 41.36
Group B (n = 24)	30.66 ± 3.21	35.74 ± 3.82	1.75 ± 0.14	2.01 ± 0.27	214.49 ± 35.41	279.66 ± 39.74
t	0.0217	4.4353	0.5573	6.4757	0.0030	8.1576
P	0.9828	0.0001	0.5800	0.0000	0.9976	0.0000

3.4. Comparison of UC treatment adverse reactions

Table 5 shows that the rate of UC treatment adverse reactions in group A was 4.00%, which was lower than in group B, 25.00% ($P < 0.05$).

Table 5. Comparison of UC treatment adverse reaction rates [n (%)]

Group	Watery stools	Nausea and vomiting	Abdominal discomfort	Incidence
Group A (n = 25)	1 (4.00)	0 (0.00)	0 (0.00)	4.00
Group B (n = 24)	1 (4.17)	2 (8.33)	3 (12.50)	25.00
x^2	-	-	-	4.4100
P	-	-	-	0.0357

4. Discussion

UC belongs to inflammatory lesions with the pathogenesis yet to be elucidated, and it is related to the influence of various triggers. The common triggers of UC are as follows:

(1) Related to immune factors: After the body's immune function is lowered, the inflammatory cell infiltration at the intestinal mucosa is evoked, leading to long-term chronic inflammation and resulting in damage to the intestinal mucosal barrier, which can induce UC.

(2) Related to genetic factors: There are family hereditary characteristics of UC.

(3) Intestinal microecological disorders, such as changes in intestinal flora number, species, and functionality.

After the occurrence of UC, the typical symptoms of patients included diarrhea and bloody stools, which can be assessed whether the UC patients enter the active stage, and the amount of blood in the stool and the stool nature can assess the degree of lesions in UC patients. Symptoms of abdominal pain such as common paroxysmal pain in the lower abdominal region or total abdominal pain are reported in some patients, and defecation may relieve the pain symptoms [2]. At present, most clinical repair of intestinal mucosa uses anti-inflammatory drugs for the treatment of UC, of which mesalamine is the most commonly used drug, and can be used to treat segmental ileitis. Relevant literature reports that UC patients have abnormally elevated levels of leukotrienes and prostaglandins under long-term inflammatory stimulation, and leukotrienes and prostaglandins can further aggravate the progression of inflammation, hence lowering the levels of leukotrienes and prostaglandins is extremely important for controlling the condition of UC [3]. Mesalamine treatment not only plays a role in the colonic mucosa area of UC patients but also blocks the body's production of leukotrienes and prostaglandins, acts on neutrophils, inactivates lipoxygenase, blocks the body's production of oxygen free radicals, and reduce the amount of platelet-activating factor generated by the body, thereby reducing the level

of various inflammation indicators [4]. However, when mesalamine is used to treat patients with UC, it is unable to reduce abdominal pain and stool frequency as well as stimulate healing of the ulcer surface, thus the overall efficacy is limited.

The occurrence and progress of UC are related to the imbalance of intestinal flora, so some scholars suggest giving Bifidobacterium quadruple viable tablets in addition to anti-inflammatory drugs to restore the balance of flora. Bifidobacterium quadruple viable tablet contains four kinds of beneficial bacteria, it is compound-prepared and suitable for the treatment of dyspepsia, constipation, and other dysbiosis-type gastrointestinal diseases. The tablet contains *Lactobacillus acidophilus*, *Bifidobacterium bifidum*, and *Enterococcus faecalis* which belong to the normal intestinal flora and can be detected in healthy people, therefore, taking the tablet can rebuild the intestinal bio-barrier and enhance the intestinal antidisease ability. The aforementioned exogenous beneficial bacteria can be planted in the intestinal tract, which can have an inhibitory effect on the propagation of pathogenic bacteria. They can also rebuild the balance of the bacteria group after 10 days of planting, which can stimulate normal peristalsis of the gastrointestinal tract [5]. In addition to the aforementioned three bacteria, *Bacillus cereus* is not part of the normal intestinal flora, and it can be excreted together with feces after 48 hours of colonization [6]. However, it should be noted that *Bacillus cereus* is an oxygen-consuming bacterium that can increase the consumption of intestinal oxygen and create an excellent environment for anaerobic bacteria such as Bifidobacteria, hence it is conducive to the colonization of the aforementioned three beneficial bacteria.

Combined with the data analyzed in this paper, the UC treatment efficacy of 96.00% in group A was higher than that of 70.83% in group B ($P < 0.05$). It indicated that the combination of Bifidobacterium quadruple viable tablets treatment could enhance the UC treatment efficacy. The reason is that mesalamine is commonly used in UC treatment, which can reduce leukotriene and prostaglandin production as well as protect the intestinal mucosa, and the combination of Bifidobacterium quadruple viable tablets can stimulate gastrointestinal peristalsis, strengthen the efficacy of antimicrobial therapy, and help to maintain the balance of intestinal flora. Another set of data showed that the level of inflammatory factors in group A UC patients was lower than that in group B ($P < 0.05$). This indicated that the anti-inflammatory effect was better after giving Bifidobacterium quadruple viable tablets. Analyzing the reasons, UC patients mostly have the problem of *Helicobacter pylori* (Hp) infection and Hp long-term colonization in the epithelial region of the digestive tract, resulting in local long-term inflammatory infiltration environment, which leads to lymphocytes and granulocytes entering the gastric mucosa, aggravating the condition of UC [7]. Pro-inflammatory factors such as IL-8, IL-17, CRP, and TNF-α can aggravate the infection of Hp and increase the area of the ulcer, and the addition of Bifidobacterium quadruple viable tablets can enhance the anti-inflammatory effect [8]. After entering the human body, Bifidobacterium quadruple viable tablets can generate a protective film in the digestive tract to block the invasion of bacteria, and at the same time, it can inhibit the Hp infection, reduce Hp activity, and further control the progression of inflammation. In addition, *Lactobacillus acidophilus*, *Bifidobacterium bifidum*, and other components within the quadruple viable tablets can decompose sugars, generate lactic acid, acetic acid, and other acidic components, and then downregulate the local pH value, which then inhibits the role of gastric acid to promote the propagation of beneficial bacteria; *Enterococcus faecalis* can enhance the ability of gastrointestinal resistance to pathogens; and *Bacillus cereus* can construct a local anaerobic environment, destroying the environment for Hp growth and reproduction [9].

Another set of data shows that the level of nutritional indicators of UC patients in group A was higher than that in group B ($P < 0.05$). This indicated that the addition of Bifidobacterium quadruple viable tablets can regulate the individual's nutritional status. Oral administration of Bifidobacterium quadruple viable tablets can enhance the number of beneficial bacteria in the gastrointestinal tract, restore the biological barrier function of

the gastrointestinal tract, destroy the growth environment of pathogens, block the release of endotoxin from the bacteria, enhance the immune function of the individual, and reduce the acute attack of UC, thereby restoring the function of the gastrointestinal tract in the absorption of nutrients [10]. The last set of data showed that the rate of UC treatment adverse reactions in group A was 4.00%, which was lower than that in group B, 25.00% ($P < 0.05$). It indicated that the addition of Bifidobacterium quadruple viable tablets was safe and efficient. The additional administration can not only strengthen the anti-inflammatory efficacy but also reduce the degree of oxidative stress, hence the rate of medication discomfort reaction is lower.

In conclusion, the addition of Bifidobacterium quadruple viable tablets to the treatment of UC patients can enhance the anti-inflammatory effect of conventional medication, reduce the discomfort symptoms of UC, and enhance the nutritional level of UC patients, which has the value of promotion.

Disclosure statement

The author declares no conflict of interest.

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