Clinical Study of Modified Yanghetang Combined with Mesalazine in Treating Ulcerative Colitis of Spleen-Kidney Yang Deficiency

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Introduction. To explore the clinical effect of modified Yanghe Decoction combined with mesalazine in treating ulcerative colitis with spleen-kidney yang deficiency.

Methods. 100 patients with ulcerative colitis of spleen-kidney yang deficiency type who were treated in our hospital from September 2022 to September 2023 were selected as the research object,and the patients were randomly divided into 50 cases in the control group and 50 cases in the observation group according to the random number table. The control group was treated with mesalazine, while the observation group was treated with mesalazine combined with Yanghe Decoction. The total effective rate, symptom score, serum inflammatory factor index, immune function index, quality of life score and incidence rate were as follows.The total effective rate, symptom score, serum inflammatory factor index, immune function index, quality of life score and incidence of adverse reactions were compared between the two groups. 3)Results: The total effective rates of the observation group and the control group were 98%.

Results. The total effective rates of the observation group and the control group were 98.00% and 86.00% respectively, and the observation group was higher than the control group (P<0.05). Compared with before treatment, the scores of mucopurulent bloody stool, abdominal pain and diarrhea in the two groups decreased after treatment (P<0.05). After treatment, the scores of mucopurulent bloody stool, abdominal pain and diarrhea in the observation group were lower than those in the control group (P<0.05). Compared with before treatment, the levels of serum CRP, PCT, IL-6 and TNF-α in both groups decreased after treatment (P<0.05). Compared with before treatment, the levels of serum CRP, PCT, IL-6 and TNF-α in both groups decreased after treatment (P<0.05). Compared with before treatment, CD3+, CD4+/CD8+, IgG, IgA, IgM in both groups increased after treatment (P < 0.05). After treatment, CD3+, CD4+/CD8+, IgG, IgA and IgM in the observation group were higher than those in the control group (P<0.05). Compared with before treatment, the scores of all factors of quality of life in both groups increased after treatment (P<0.05). Compared with before treatment, the scores of all factors of quality of life in both groups increased after treatment (P<0.05). After treatment, the scores of all factors of quality of life in the observation group were higher than those in the control group (P<0.05). The incidence of adverse reactions in observation group and control group were 6.00% and

4.00% respectively, and there was no significant difference.The incidence of adverse reactions in observation group and control group were 6.00% and 4.00% respectively, and there was no significant difference between the two groups (P>0.05).4)

Conclusion. Mesalazine combined with Yanghe Decoction has a good curative effect on ulcerative colitis of spleen-kidney yang deficiency type, which can effectively control the patient's condition, reduce the inflammatory reaction, regulate the immune function,assist in enhancing the standard of living, minimizing negative responses and promoting a positive quality of life, while ensuring safety.

Keywords. ulcerative colitis; Spleen yang deficiency type; Mesalazine; Yanghetang; Integrated traditional Chinese and western medicine therapy.

INTRODUCTION

Ulcerative colitis is one of the common gastrointestinal diseases in clinic, which refers to the ulcerative lesions occurring in the colon.After the occurrence of this kind of disease, patients will have abdominal pain, diarrhoea, blood in the stools and other symptoms, which will have a great adverse effect on their daily life of patients and lead to a significant decline in their quality of life[1-3]. Therefore, ulcerative colitis needs to be treated aggressively. Mesalazine is the first line of treatment for ulcerative colitis and can alleviate symptoms in patients [4-5]. However, methazine alone may not be effective for some patients[6-7]. In the last few years, the efficacy of a combination of Chinese and Western medicine in treating ulcerative colitis has been widely acknowledged, with Western medicine utilizing mesalazine and Chinese medicine selecting the most appropriate formulae according to the patient's Chinese medicine evidence type. In our hospital, from September 2022 to September 2023.The utilization of both Yanghe Tang and Mesalazine yielded favorable outcomes in the management of spleen and kidney yang deficiency type ulcerative colitis, as documented in the following report.

MATERIALS AND METHODS

General information

A total of one hundred individuals suffering from spleen and kidney yang deficiency type ulcerative colitis, who had been treated at our hospital between September 2022 and September 2023, were chosen to be the study subjects. The control group was split into 50 cases, while the observation group was split into 50 cases using a random number table method. The patients in the control group were aged 20-64 years, with an average age (42.31±12.58) of which 27 were

male and 23 were female. The patients in observation group were aged 21-65 years, with an average age (42.56±12.47) of which 29 were male and 21 were female. There was no statistically significant difference in age or sex between the two groups (P>0.05) and the study was comparable. Patients and their families were notified and consented to the study.

Inclusion criteria: 1) confirmed diagnosis of ulcerative colitis by symptom observation, imaging examination and colonoscopy, and the Chinese medicine evidence type of spleen and kidney yang deficiency; 2) age ≥18 years; 3) mental alertness and cooperation with treatment.

Exclusion criteria: 1) previous history of allergy to the drugs used in this study; 2) with impaired consciousness and mental disorders; 3) combined with severe hepatic and renal insufficiency; 4) combined with malignant tumours; and 5) combined with other digestive system pathologies.

Methods

The control group was treated with metharazine and oral mesalazine enteric-coated tablets, 0.8g three times a day before meals for 2 weeks.

The observation group was treated with mesalazine enteric-coated tablets combined with Modified Yanghe Tang, mesalazine enteric-coated tablets were administered in the same way as in the control group, and the basic prescription of Yanghe Tang was Rehmanniae Radix Praeparata(30g), Cassia Cinnamon(3g), Antler Glue(9g), Mustard Seed(6g),Ephedra(5g), Baked Ginger(5g), Baked Licoric(5g), and in case of severe diarrhoea, add Ash Bark(10g), Pulsatillae Radix(10g), Pomegranate Bark(5g), and in case of serve serious hematochezia, add Paeoniae Radix Alba(10g), Puerariae Lobatae Radix(5g), Sichuan Chinaberry(10g), Corydalis Tuber(5g), for severe bloating, add Curcumae Rhizoma(10g), Rhizome of Swordlike Atractylodes(10g), Atractylodis Macrocephalae Rhizoma (10g), Aurantii Fructus(5g), supplied by Herbal Pharmacy of Dongzhimen Hospital East Area of Beijing University of Chinese Medicine, decocted in the decoction room, 1 dose/day, 1 dose of two sachets, 250 ml for each sachet, divided in the morning and evening.

Observation indicators

The two groups were compared in terms of their overall effective rate, symptom score, serum inflammatory factor index, immune function index (including CD3+,CD4+ /CD8+,IgG, IgA,IgM), quality of life score, and the occurrence of adverse reactions.

Overall effective rate = cure rate + improvement rate, as assessed by: 1) complete symptom elimination, with no abnormalities detected during endoscopy; 2) remission of symptoms and abnormal reduction of mucosa observed during endoscopy. 3) The symptoms remain unresolved, and the endoscopy reveals that the mucosal abnormalities persist without any alleviation or exacerbation.

Symptom scoring: the intensity of symptoms like mucopurulent blood stools, abdominal pain, and diarrhoea was evaluated through visual analogue scoring (VAS), where a score ranging from 0 to 10 indicated that the more severe the symptoms, the higher the score.

Serum inflammatory factor indexes: including C-reactive protein (CRP), procalcitonin (PCT), interleukin-6 (IL-6),tumour necrosis factor-α (TNF-α), immunoturbidimetric assay was used to measure C-reactive protein (CRP), procalcitonin (PCT), interleukin-6 (IL-6), tumour necrosisfactor-α (TNF-α), CRP, while immunochromatographic assay was employed to measure PCT, and enzyme-linked immunosorbent assay was utilized to measure IL-6 and TNF-α.

Quality of Life Score:The WHOQOL-BREF, a Quality of Life Rating Brief Form developed by the WHO, was selected to assess the patients' quality of life. The scale is broken down into four dimensions - physical, psychological, environmental and social relationships - with a score of 0-100, and the higher the score, the better the quality of life [8].

Statistical methods

The application of SPSS 22.0 software involved testing the count data (n/%) using the $\chi 2$ test, followed by testing the measured data()using the t-test, resulting in a statistically significant difference at a significance level of $P<0.05$.

RESULTS

Comparison of overall efficacy rate between the two groups

The observation group exhibited a 98.00% overall efficacy rate, while the control group showed an 86.00% overall efficacy ($P < 0.05$). See Table 1 for details:

Table 1 Comparison of overall efficacy rate between the two groups [n(%)].

groups	number of examples	clinically cured	improving	ineffective	overall efficacy rate
Control group	50	23 (46.00%)	20(40.00%)	7(14.00%)	43 (86.00%)
Observation group	50	28 (56.00%)	21(42.00%)	1 (2.00%)	49 (98.00%)*

*P<0.05 compared to control group.

Comparison of symptom scores between the two groups

The scores of mucopurulent blood stool, abdominal pain and diarrhoea in both groups decreased after treatment when compared to the pre-treatment period (P<0.05),and the observation group exhibited a reduction in the prevalence of mucopurulent blood stool, abdominal pain, and diarrhoea when compared to the control group (P < 0.05). See Table 2 for details:

Table 2 Comparison of symptom scores between the two groups($\bar{x} \pm s$,points)

groups	times	mucopurulent blood stool	abdominal pain	diarrhoea
Control group (n=50)	pre-treatment	6.35±1.39	6.18±1.42	6.42±1.27
	post-treatment	4.98±1.13#	4.87±1.16#	4.36±0.85#
Observation group (n=50)	pre-treatment	6.26±1.41	6.04±1.53	6.31±1.32
	post-treatment	3.87±0.94 *#	3.72±0.98 *#	3.41±0.74 *#

# P<0.05 compared to this group before treatment; *P<0.05 compared to the control group.

Comparison of serum inflammatory factorindices between the two groups

The levels of serum CRP, PCT, IL-6, and TNF-α in both groups exhibited a significant decrease following treatment in comparison to the pre-treatment period (P<0.05). Subsequent to the treatment, the observation group displayed a substantial decrease in serum CRP, PCT, IL-6, and TNF-α levels in comparison to the control group (P < 0.05)..See Table 3 for details

Table 3 Comparison of serum inflammatory factor indices between the two groups ($\bar{x} \pm s$)

groups	periods	CRP (mg/L)	PCT (ng/ml)	IL-6 (pg/ml)	TNF-α (mg/L)
Control group (n=50)	pre-treatment	9.83±1.61	1.35±0.40	176.61±32.49	16.81±3.10
	post-treatment	7.02±1.27#	0.69±0.23#	114.50±25.87#	13.49±2.46#
Observation group (n=50)	pre-treatment	9.72±1.64	1.34±0.43	175.28±33.52	16.62±3.12
	post-treatment	5.89±1.06 *#	0.46±0.15 *#	87.64 ± 19.32*#	10.83±2.07 *#

# P<0.05 compared to this group before treatment; *P<0.05 compared to the control group.

Comparison of immune function indicators between the two groups of patients

Compared with the pre-treatment, here was a significant increase in $CD3^+$, $CD4^+$ /$CD8^+$,IgG, IgA, IgM levels in both groups (P<0.05); after the treatment, the observation group exhibited higher levels of $CD3^+$, $CD4^+$ /$CD8^+$,IgG, IgA and IgM compared to the control group (P<0.05). See Table 4 for details:

Table 4 Comparison of immune function indicators between the two groups ($\bar{x} \pm s$)

groups	periods	$CD3^+$ (%)	$CD4^+$ /$CD8^+$	IgG (g/L)	IgA (g/L)	IgM (g/L)
Control group (n=50)	pre-treatment	39.12±2.07	1.07±0.38	4.10±1.25	0.47±0.15	0.32±0.10
	post-treatment	41.59±2.25#	1.50±0.42#	8.69±2.34#	1.21±0.39#	1.48±0.49#
Observati-on group (n=50)	pre-treatment	39.25±2.03	1.09±0.37	4.15±1.19	0.48±0.16	0.31±0.09
	post-treatment	45.28±2.91*#	2.14±0.55 *#	11.73±2.90*#	1.79±0.50 *#	2.20±0.63*#

# P<0.05 compared to this group before treatment; *P<0.05 compared to the control group.

Comparison of quality of life scores between the two groups

Compared with the pre-treatment period, the scores of all factors of quality of life in both groups increased after treatment (P<0.05). The observation group showed a improvement in their quality of life scores compared to the control group after the treatment (P < 0.05). See Table 5 for details:

Table 5 Comparison of quality of life scores between the two groups ($\bar{x} \pm s$, points)

groups	periods	physical	psychosocial	environmental	social relationships
Control group	pre-treatment	76.35±5.14	75.24±5.06	76.61±5.02	77.59±5.17
(n=50)	post-treatment	83.34±5.92#	82.63±5.30#	83.16±5.23#	84.45±5.31#
Observation	pre-treatment	76.56±5.17	75.47±5.01	76.83±5.09	77.80±5.24
group (n=50)	post-treatment	90.07±6.29*#	89.95±5.97 *#	89.05±5.48 *#	90.36±5.63 *#

# P<0.05 compared to this group before treatment; *P<0.05 compared to the control group.

Comparison of the incidence of adverse reactions between the two groups

The observation group encountered one case of dry mouth, one case of nausea, and one case of abdominal distention, whereas the control group experienced two cases of nausea., and the incidence rates of adverse reactions in the observation group and the control group were 6.00% and 4.00%, respectively, and the differences were not statistically significant when comparing between the groups (P>0.05).

DISCUSSION

The incidence of ulcerative colitis, a lesion of the gastrointestinal tract marked by localized ulcerative lesions in the colon, has increased in recent years as a result of changes in dietary patterns and practices[9-10]. Patients with ulcerative colitis often experience abdominal pain, diarrhoea, blood in the stool, and other symptoms, with the progress of the disease, patients with focal ulcerative lesions of the colon continue to expand, causing perforation and necrosis of the bowel, and even some patients may involve other tissues such as skin and joints, causing systemic symptoms such as high fever and fatigue, with a higher risk of cancer, causing serious harm to patients' physical and mental health [11-14].

The incidence of ulcerative colon is clinically associated with inflammatory infections and imbalance of intestinal flora[15], current stage involves the utilization of 5-aminosalicylic acid for the clinical management of ulcerative colitis., and according to a multi-center retrospective study, 5-aminosalicylic acid treatment is a protective factor against colorectal carcinogenesis in ulcerative colitis[16].Mesalazine is an aminosalicylic acid preparation commonly used in the treatment of ulcerative colitis, which is less absorbed in the small intestine and mostly enters into the colon, where it is rapidly decomposed into 5-aminosalicylic acid, which complexes with the connective tissue of the intestinal wall, delaying the release of the active ingredient, allowing the drug to remain in the intestinal wall tissue of the colon, inhibiting the activity of pathogenic bacteria in the colon, reducing the release of inflammatory factors, and correcting the imbalance of intestinal flora, correct the imbalance of intestinal flora and rebuild the balance of intestinal flora to achieve the purpose of controlling the condition.[17-19] , some studies have pointed out that the combination of western medicine and Chinese medicine can achieve better therapeutic effect in the treatment of ulcerative colitis, and this kind of combination of traditional Chinese and western medicine therapy has been widely recognised and affirmed in the clinic. In Chinese medicine, ulcerative colitis belongs to the category of "diarrhoea disease" and "intestinal disease", and the spleen and kidney yang-deficiency type is more common. The pathogenesis of spleen and kidney yang-deficiency type of ulcerative colitis is that the spleen and kidney are weak, and there is a failure of transport and transformation, and dampness is generated within the body, and cold and dampness flourish within the body, which obstructs qi and blood transport, and the qi stagnates, blood stagnates, and the blood stagnation obstructs the channels, and then injects down into the large intestine, which affects the transmission function of the large intestine. To treat this disease, traditional Chinese medicine advocates choosing the medicine[20-22] that warms Yang, disperses cold, and replenishes blood and moves Qi. Yanghe Tang is a formula commonly used in the treatment of intestinal ulcers, the combination of these herbs can warm the middle Jiao, disperse cold, warm the liver and kidney, regulate qi and open the channels. In addition to the basic prescription,Yanghe Tang Plus Minus Therapy also adjusts the prescription according to the specific symptoms of the patients, which can provide more effective treatment for their conditions[23-24]. In this study, the observation group was treated with modified Yanghe Tang + mesalazine enteric-coated tablets, and the control group was treated with mesalazine enteric-coated tablets, and after comparing the results of the two groups of patients, it was found that: 1) the total effective rate of the observation group and the control group was 98.00% and 86.00%, respectively, and the observation group was higher than the control group ($P<0.05$), and the symptoms of the observation group (mucopurulent blood

stool, abdominal pain, diarrhoea) after treatment The scores of symptoms (mucopurulent blood stool, abdominal pain, diarrhoea), serum inflammatory factors (CRP, PCT, IL-6, TNF-α) were lower than those of the control group (P<0.05), and the scores of CD3+ , CD4+ /CD8+ , IgG, IgA, IgM, and the quality of life of the observation group were higher than those of the control group after the treatment (P<0.05), which indicated that the combination of the Chinese and Western medicines of modified Yanghe Tang and mesalazine could enhance the effect on the patients' conditions. This indicates that the combined application of modified Yanghe Tang and Mesalazine can enhance the control effect of the patients' condition, play a better role in helping their inflammatory reaction and immune dysfunction, with remarkable therapeutic effect, and avoid the adverse effects on their quality of life.2) The incidence of adverse reactions in the observation group and the control group was 6.00% and 4.00% respectively, and the difference was not statistically significant when compared between the groups (P>0.05), indicating that the application of Yanghe Tang on the basis of mesalazine will not increase the adverse reactions of the medication, and the safety of the medication has been ensured.

CONCLUSION

Modified Yanghetang combined with mesalazine has significant efficacy in the treatment of spleen and kidney yang deficiency type ulcerative colitis, which can effectively control the patient's condition, reduce the inflammatory response, regulate the immune function, and help to improve the quality of life level, and the combination of medication has been proven to be safe with fewer adverse reactions.

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