



ORIGINAL ARTICLE

OPEN ACCESS

Effect of Qingchang Yuyang decoction on treatment efficacy and intestinal flora in patients with ulcerative colitis

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Received 10 February 2025; Accepted 3 April 2025

Available online 1 May 2025

KEYWORDS

intestinal flora;
Qingchang Yuyang
decoction;
traditional Chinese
medicine syndrome
score;
ulcerative colitis

Abstract

This study investigates the therapeutic effects of Qingchang Yuyang Decoction on ulcerative colitis (UC) and its impact on intestinal flora. Using existing case records, a retrospective analysis was conducted utilizing clinical data from 96 UC patients (damp-heat syndrome of the large intestine) treated at our hospital between June 2022 and June 2024. Based on the different treatment methods recorded, 50 patients were included in the observation group and 46 in the control group. The control group received conventional treatment (oral sustained-release mesalazine tablets), while the observation group received oral Qingchang Yuyang Decoction in addition to conventional treatment. The efficacy and effects on intestinal flora were compared between the two groups. The change in the modified Mayo score before and after treatment in the observation group was significantly greater than that in the control group ($p < 0.001$). After treatment, scores for abdominal pain and diarrhea, mucus-pus-bloody stools, tenesmus, anal burning, and short and red urine were significantly lower in the observation group compared to the control group ($p < 0.05$). Post-treatment, the observation group showed significantly higher levels of IL-10 than the control group, while IL-8 and TNF- α levels were lower in the observation group ($p < 0.05$). After treatment, Enterococcus and Enterobacter counts in the observation group were lower, while the observation group had higher levels of Bifidobacterium, Butyric Clostridium, and Lactobacillus compared to the control group ($p < 0.05$). The complication rate was lower in the observation group ($p < 0.05$). The combination of Qingchang Yuyang Decoction with sustained-release mesalazine tablets can improve the clinical efficacy in UC, significantly alleviate clinical symptoms, reduce the inflammatory response, adjust intestinal flora distribution, and promote recovery, making it worthy of clinical application.

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<https://doi.org/10.15586/aei.v53i3.1332>

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Introduction

Ulcerative colitis (UC) is a chronic, nonspecific inflammatory disease that affects the rectum and colon. Symptoms often include diarrhea, mucopurulent bloody stool, abdominal pain, tenesmus, and varying degrees of systemic symptoms. The pathological features include inflammation and ulceration in the rectal and colonic mucosa and submucosa.^{1,2} Ulcerative colitis (UC) has a prolonged course, an extensive lesion area, and frequent relapses. If not treated promptly, it may lead to dysplasia and even develop into colorectal cancer.³ In recent years, the incidence of UC has been rising globally. Current clinical treatments lack specific drugs and protocols, with common methods including 5-aminosalicylic acid, corticosteroids, immunosuppressants, and biologics, as well as emerging therapies such as fecal microbiota transplantation.⁴ However, these medications, though effective in symptom improvement, have significant side effects and a high relapse rate after discontinuation, and fecal microbiota transplantation has limited applicability.⁵ Traditional Chinese Medicine (TCM) offers certain advantages in treating ulcerative colitis through multi-pathway, multi-target intervention with fewer adverse effects and confirmed efficacy from both complex and single formulas in clinical practice, also helping to reduce relapse.⁶ TCM classifies UC under “diarrhea” or “chronic dysentery”, with damp-heat being an important pathogenic factor during the active phase of UC.⁷ Consequently, treatment principles in TCM mainly focus on clearing heat and transforming dampness, supplemented by regulating qi and blood. Qingchang Yuyang Decoction possesses properties that clear heat, detoxify, strengthen the spleen, transform dampness, nourish and invigorate the blood, promote qi, and alleviate pain. This study hypothesizes that Qingchang Yuyang Decoction can significantly improve the clinical symptoms of patients with UC by clearing heat and detoxifying, strengthening the spleen and eliminating dampness, nourishing and activating blood, and promoting qi to relieve pain. It is also expected to reduce inflammatory responses and regulate the distribution of intestinal flora, thereby enhancing the therapeutic effect. Therefore, this study aims to observe the clinical efficacy of Qingchang Yuyang Decoction on ulcerative colitis (UC) and analyze its effect on TCM syndrome scores, intestinal flora, and safety, providing a clinical basis for the optimization of UC treatment.

Materials and Methods

General data

Using existing case records, this study retrospectively included clinical data from 96 patients diagnosed with ulcerative colitis (damp-heat syndrome of the large intestine) who were treated at our hospital from June 2022 to June 2024. The patients were divided into two groups: 50 cases in the observation group and 46 in the control group. The patient enrollment flowchart is shown in Figure 1. This study was approved by the hospital's ethics committee (Approval no. 2024-P-05).

Diagnostic criteria for Western medicine.⁸ The diagnosis is made through a comprehensive analysis that primarily combines clinical symptoms, laboratory tests, imaging examinations, endoscopic evaluations, and histopathological findings, while excluding infectious and other non-infectious types of colitis.

Diagnostic criteria for traditional Chinese medicine syndromes: Meets the diagnostic criteria for damp-heat syndrome in the large intestine.⁹ Primary symptoms: Abdominal pain, diarrhea, mucus-pus-bloody stools, tenesmus, and anal burning. Secondary symptoms: Fever, short voidings of reddish urine, dry mouth, bitter taste, and bad breath. Tongue and pulse: Red tongue with yellow and greasy coating, and slippery pulse.

Inclusion Criteria: (1) Meets the diagnostic criteria of Western medicine and traditional Chinese medicine syndromes mentioned above. (2) Initial and chronic relapses. (3) Mild to moderate active UC patients. (4) Complete, accessible medical records. (5) Signed informed consent.

Exclusion Criteria: (1) Acute explosive type, severe UC, complicated by bowel perforation, intestinal strictures, toxic megacolon, massive lower gastrointestinal bleeding, carcinogenesis, and other complications, as well as the presence of other malignant tumors. (2) Serious internal medicine system diseases, coagulation dysfunction, hepatic or renal dysfunction. (3) Simultaneously suffering from other gastrointestinal diseases such as irritable bowel syndrome. (4) Mental disorders, communication issues, or impaired consciousness. (5) Patients who underwent other treatment measures during the study period.

Treatment methods

This study, being retrospective, relied on previously recorded treatment methods. Both groups received supportive treatment, including electrolyte correction, acid-base balance adjustment, and nutritional support. The control group received conventional treatment, with 1g oral mesalazine sustained-release tablets (Ferring International Center S.A H20181183), administered four times daily.

The observation group received an additional oral administration of Qingchang Yuyang Decoction based on the control group treatment. The decoction composition included: Baitouweng (*Pulsatilla chinensis* (Bunge) Regel), Huanglian (*Coptis*), Huangbai (*Phellodendron*), Cangzhu (*Atractylodes*), Muxiang (*Aucklandia*), Yanhusuo (*Corydalis*), Cheqianzi (*Plantago seed*), Machixian (*Portulaca*), Fuling (*Poria*), Shanyao (*Dioscorea*), Danggui (*Angelica sinensis*), Baishao (*White peony root*), Chao Baizhu (*Fried Atractylodes rhizome*), Bai Biandou (*White Hyacinth Bean*), and Zhi Gancao (*Roasted Licorice*). The decoction was boiled to 200 mL and administered once daily, split into morning and evening doses over an 8-week treatment period.

Observation indicators

As a retrospective study, outcomes were based on existing records and included the following: (1) Disease severity was assessed using the modified Mayo scoring system to evaluate the severity of ulcerative colitis lesions.

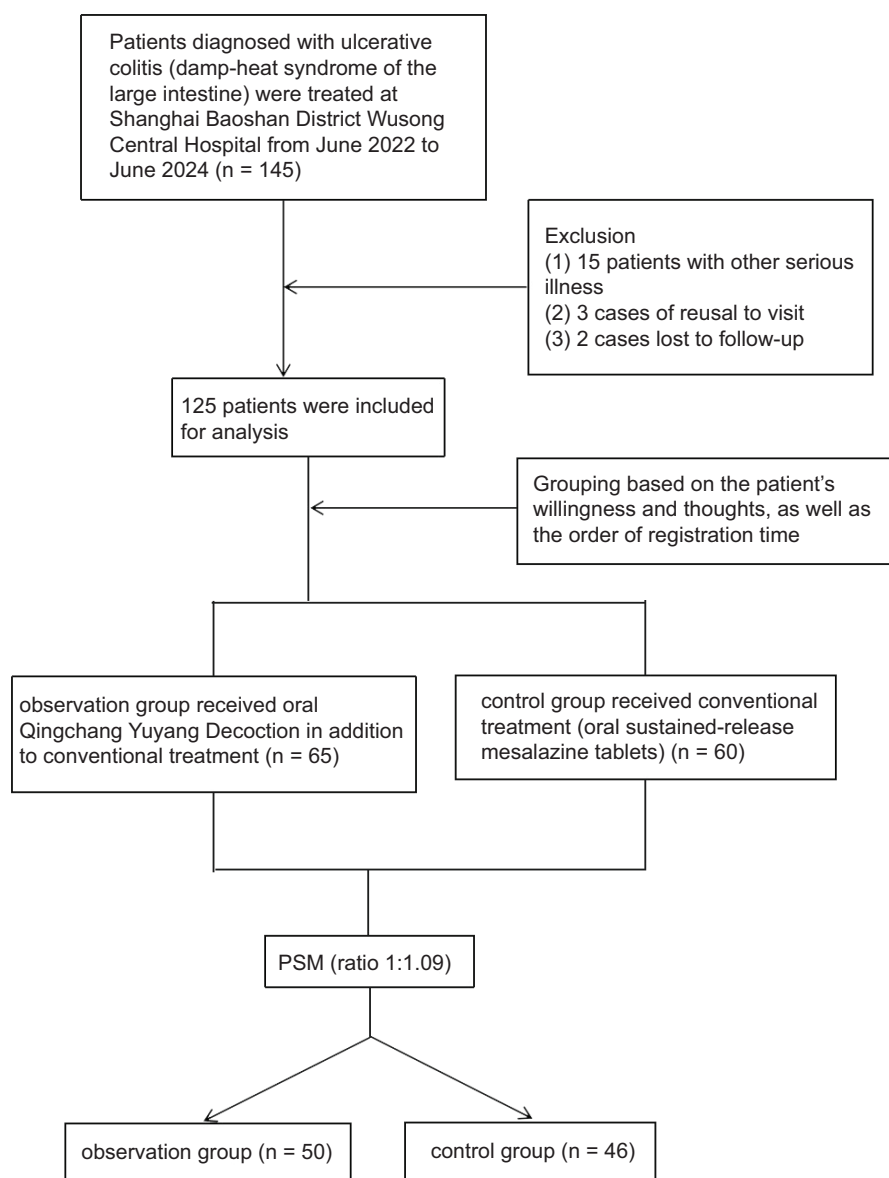


Figure 1 Flow chart of the study design and grouping.

The modified Mayo scoring system categorizes four observational parameters—number of bowel movements, presence of rectal bleeding, endoscopic findings, and physician's global assessment—into four levels, each rated 0, 1, 2, or 3 points. The specific scoring criteria are detailed in Table 2 below.¹⁰ (2) Comparison of TCM Syndrome Scores: Syndrome scores, including abdominal pain and diarrhea, mucus-pus-bloody stools, tenesmus, anal burning, and short and red urine, were recorded before treatment and after 8 weeks. Individual symptom scores ranged from 0 (no symptoms) to 6 (severe symptoms). (3) Inflammatory Markers: Blood samples (5 mL) were collected for analysis of interleukin-10 (IL-10), interleukin-8 (IL-8), and tumor necrosis factor-alpha (TNF- α) levels before and after treatment. (4) Intestinal Flora Distribution: Samples were collected from patients via colonoscopy one day before treatment and one day after treatment ended. The

intestinal flora composition, including Enterobacteriaceae, Clostridium butyricum, Lactobacillus, Enterococcus, and Bifidobacterium, was evaluated. (5) Adverse Reactions: Common adverse reactions such as headache, nausea and vomiting, rash, and abdominal pain were recorded.

Statistical analysis

Data analysis was performed using SPSS 21.0 (IBM, Armonk, NY, USA). Normally distributed continuous variables were presented as mean $\pm$ standard deviation, with between-group comparisons conducted using independent-sample t-tests. Categorical data were presented as counts and percentages, with group comparisons performed using chi-square tests or Fisher's exact test where applicable. Statistical significance was set at $p < 0.05$.

Table 1 Modified mayo scoring system for assessing activity of ulcerative colitis (UC).

Item	0 Points	1 Points	2 Points	3 Points
Bowel movements	Normal	Increased by 1-2 times per day compared to normal bowel movements	Increased by 3-4 times per day compared to normal bowel movements	Increased by 5 or more times per day compared to normal bowel movements
Hematochezia	No bleeding observed	Blood in stool less than half the time	Blood in stool most of the time	Continuous bleeding
Endoscopic findings	Normal or no active lesions	Mild lesions (reduced erythema vascular pattern, mild fragility)	Moderate lesions (prominent erythema, lack of vascular pattern, fragility, erosion)	Severe lesions (spontaneous bleeding, ulcer formation)
Overall evaluation by the physician	Normal	Mild condition	Moderate condition	Severe condition

Results

Baseline characteristics

In order to reduce confounding bias and more accurately assess the effect of an intervention or treatment, this study utilized Propensity Score Matching (PSM) to control for covariates that might influence the treatment outcomes of the two patient groups. By calculating the propensity score for each individual, it was possible to match treated individuals with untreated individuals, creating a similar control group after matching.

The baseline characteristics of the two groups are shown in Table 2, with no significant differences between the groups ($p > 0.05$).

Comparison of changes in improved mayo rating (UC Activity)

The changes in the modified Mayo score in the observation group were significantly different from those in the control group ($p < 0.001$, Cohen's $d = 2.23$, Cohen's $d = 1.64$) (Table 3).

TCM syndrome scores

Post-treatment, the scores for abdominal pain and diarrhea, mucus-pus-bloody stools, tenesmus, anal burning, and short and red urine in the observation group were significantly lower than those in the control group ($p < 0.05$, Cohen's

Table 2 Comparison of baseline characteristics between two groups.

Items	Pre-PSM				Post-PSM			
	Observation group(n=65)	Control group(n=60)	χ^2/t	p	Observation group(n=50)	Control group(n=46)	χ^2/t	p
Age (year)	45.30±13.21	46.19±12.54	0.390	0.697	43.18±11.23	43.45±12.51	0.115	0.908
Gender (male / female)	35/30	29/31	0.380	0.538	28/22	23/23	0.346	0.556
Lesion site (colon / rectum)	50/15	47/13	0.036	0.850	45/5	41/5	0.019	0.889
Severity (mild/moderate)	25/40	20/40	0.356	0.551	17/33	15/31	0.021	0.885
Clinical type(initial/recurrent)	35/30	30/30	0.185	0.667	28/22	26/20	0.003	0.959
Disease course (month)	33.15±4.25	32.60±4.50	0.715	0.476	30.21±3.24	29.89±3.15	0.491	0.625

Pre-PSM, before propensity score matching; Post-PSM, after propensity score matching.

Table 3 Comparison of modified Mayo scores between the two groups of patients ($\bar{x} \pm s$, score).

Group	n	Before treatment	After treatment	t	p
Observation group	50	7.14±1.65	3.98±1.13	10.576	< 0.001
Control group	46	7.20±1.53	4.96±1.19*	8.724	< 0.001

*After treatment, compared to the observation group, the control group, $p < 0.001$.

$d_{\text{after}} = -0.457$, Cohen's $d_{\text{after}} = -0.472$, Cohen's $d_{\text{after}} = -0.446$, Cohen's $d_{\text{after}} = -1.154$, Cohen's $d_{\text{after}} = -1.061$, Table 4). After Bonferroni correction, although there were no significant differences in mucus-pus-bloody stools, anal burning, and short and red urine in the pre-treatment group, the post-treatment group showed significant improvements in these symptoms. After applying the Bonferroni correction, neither abdominal pain and diarrhea nor tenesmus showed statistical significance at the adjusted significance level of 0.025.

Bonferroni correction (anal burning):

1. Number of comparisons (m): 2 (pre-treatment and post-treatment)
2. Significance level (α): Usually set to 0.05.

We can use Bonferroni correction to calculate the adjusted significance level (α'):

$$\alpha' = \alpha/m = 0.05/2 = 0.025.$$

Compare the original p-values with the adjusted significance level:

Pre-treatment comparison:

Original p-value: 0.657

Adjusted α : 0.025

Since $0.657 > 0.025$, we cannot reject the null hypothesis for this comparison. This means the pre-treatment results are not statistically significant.

Post-treatment comparison:

Original p-value: < 0.001

Adjusted α : 0.025

Since $< 0.001 < 0.025$, we can reject the null hypothesis. This means the post-treatment results are statistically significant.

Pre-treatment comparison:

Since the p-value of 0.657 is greater than the adjusted significance level of 0.025, no statistical significance was found.

Post-treatment comparison:

Since the p-value of < 0.001 is less than the adjusted significance level of 0.025, statistical significance was found.

Therefore, after Bonferroni correction, the post-treatment group showed significant improvement in anal burning, while the pre-treatment group showed no significant differences. The same reasoning applies to other comparisons.

Inflammatory markers

After treatment, the observation group showed significantly higher IL-10 levels compared to the control group. IL-8 and TNF- α levels in the observation group were significantly lower than those in the control group ($p < 0.05$, Cohen's $d = 0.566$, Cohen's $d = -0.488$, Cohen's $d = -0.617$) (Table 5). After Bonferroni correction, although there were

Table 4 Comparison of traditional Chinese medicine syndrome points ($\bar{x} \pm s$, score).

Group	n	Abdominal pain and diarrhea		Mucus-pus-bloody stools		Tenesmus		Anal burning		Short and red urine	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	50	4.50 $\pm$ 0.65	1.48 $\pm$ 0.58	4.34 $\pm$ 0.63	1.42 $\pm$ 0.54	4.48 $\pm$ 0.74	1.36 $\pm$ 0.49	4.12 $\pm$ 0.63	0.98 $\pm$ 0.59	3.84 $\pm$ 0.58	0.64 $\pm$ 0.83
Control group	46	4.54 $\pm$ 0.72	1.72 $\pm$ 0.46	4.50 $\pm$ 0.69	1.67 $\pm$ 0.52	4.50 $\pm$ 0.78	1.59 $\pm$ 0.54	4.07 $\pm$ 0.57	1.61 $\pm$ 0.49	3.91 $\pm$ 0.63	1.37 $\pm$ 0.49
T	-	0.311	2.240	1.190	2.350	0.129	2.168	0.445	5.645	0.591	5.205
P	-	0.756	0.028	0.237	0.021	0.897	0.033	0.657	< 0.001	0.556	< 0.001

Table 5 Comparison of inflammatory factors in the two groups ($\bar{x} \pm s$).

Group	n	IL-10 (pg/mL)		IL-8 (μg/L)		TNF-α (pg/mL)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	50	13.47±2.63	20.06±5.38	27.74±4.21	10.25±3.34	20.17±1.19	5.74±0.14
Control group	46	13.26±2.52	17.32±4.17	27.46±4.27	12.27±4.85	19.96±1.21	5.86±0.24
<i>t</i>	-	0.386	2.774	0.315	2.402	0.828	3.107
<i>p</i>	-	0.701	0.007	0.753	0.018	0.410	0.002

no significant differences in the levels of IL-10, IL-8, and TNF-α in the pre-treatment group, the post-treatment group showed significant improvements in these levels.

Distribution of intestinal flora

The post-treatment counts of *Enterococcus* and *Enterobacter* in the observation group exhibited lower levels than those in the control group. Conversely, counts of *Bifidobacterium*, *Clostridium butyricum*, and *Lactobacillus* in the observation group were observed to be higher compared to the control group ($p < 0.05$, Cohen's $d_{\text{after}} = -0.411$, Cohen's $d_{\text{after}} = 0.444$, Cohen's $d_{\text{after}} = 0.677$, Cohen's $d_{\text{after}} = -0.486$, Cohen's $d_{\text{after}} = 0.560$) (Table 6). After Bonferroni correction, the post-treatment group showed significant improvements in *Clostridium butyricum* and *Lactobacillus*.

After applying the Bonferroni correction, neither *Enterococcus*, *Bifidobacterium*, nor *Enterobacter* showed statistical significance at the adjusted significance level of 0.025 in the pre- and post-treatment comparisons.

Incidence of complications

The incidence of complications in the observation group was lower than the control group ($p < 0.05$, Cohen's $h = -0.460$) (Table 7).

Discussion

UC is a chronic, non-specific inflammatory bowel disease that primarily affects the colon and rectum.¹¹ Clinically, it presents as persistent or recurrent diarrhea, mucous-purulent bloody stools accompanied by abdominal pain, tenesmus, and varying degrees of systemic symptoms. Extraintestinal manifestations may include involvement of the skin, mucous membranes, joints, eyes, liver, and gallbladder. Initially, the lesions usually begin in the distal rectum and, over time, progress proximally into the colon, eventually affecting the entire colon. Due to its prolonged course, difficulty in achieving a cure, and tendency for frequent relapses, UC significantly impacts patients' quality of life, warranting close clinical attention.^{12,13} Its development involves multiple factors, including genetics, dysbiosis, and immune imbalances, with immune dysfunction playing a critical role. This immune imbalance leads

to abnormal inflammatory mediator release, disruption in anti-inflammatory and pro-inflammatory cytokine secretion, ultimately resulting in oxidative stress and damage to the intestinal mucosal barrier.^{14,15} Current clinical treatment for mild to moderate UC primarily uses mesalazine, whose main active ingredient is 5-aminosalicylic acid. It mainly reduces the synthesis of inflammatory mediators, inhibits the nuclear factor kappa B signaling pathway, and alleviates intestinal inflammation. However, long-term use is required; discontinuation often leads to relapse, and prolonged use may induce severe complications, with the efficacy of using mesalazine alone being limited. Therefore, combination therapy is needed to effectively control the condition.^{16,17} TCM believes that active UC is mostly an excess syndrome, with damp-heat accumulation as the primary pathological mechanism. The treatment should focus on clearing heat, transforming dampness, smoothing the flow of qi, promoting qi circulation, and alleviating pain. Although the disease manifests in the large intestine, it is closely related to liver, spleen, and kidney functions.

The results of this study demonstrate that the improved Mayo score in the observation group showed significant changes compared to the control group. This highlights the efficacy of the formula in treating UC. The medicinal ingredients in the Qingchang Yuyang Decoction have complementary therapeutic effects: *Pulsatilla chinensis* (Bunge) Regel and *Portulaca* clear heat, detoxify, and cool the blood to stop dysentery; *Coptis* is effective in clearing heat and dampness from the intestines; *Phellodendron* is good at clearing damp-heat from the large intestine and bladder; *Poria* and *Plantago* seed promote water metabolism, resolve dampness, and stop diarrhea; Fried *Atractylodes* and *Chinese yam* strengthen the spleen and resolve dampness; *Angelica sinensis* and *White peony root* nourish the blood, activate blood circulation, soothe excessive liver qi, and protect the spleen; *Aucklandia* and *Corydalis* tuber strengthen the spleen, soothe the liver, smooth the flow of qi, promote qi circulation, and relieve pain. Fried licorice harmonizes the spleen and stomach. When these herbs are used in combination, they effectively clear heat, detoxify, strengthen the spleen, resolve dampness, nourish and activate the blood, promote the movement of qi, relieve pain, and promote the rapid repair and regeneration of the intestinal mucosa, leading to the healing of ulcers.¹⁸⁻²⁰ The combination of Qingchang Yuyang Decoction with mesalazine can treat UC from multiple aspects, rapidly resolving inflammation, enhancing colonic immunity, and alleviating disease progression through a variety of mechanisms.

Table 6 Comparison of intestinal flora distribution of two groups ($\bar{X} \pm s$, log 10 CFU/g).

Group	n	Enterococcus		Bifidobacterium		Clostridium butyricum		Enterobacter		Lactobacillus	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	50	9.35±1.20	7.10±0.54	8.15±0.78	9.78±1.25	5.15±0.46	6.89±0.67	10.25±1.62	8.24±0.13	7.18±0.59	9.96±0.84
Control group	46	9.45±1.15	7.36±0.722	8.21±0.83	9.30±0.85	5.18±0.52	6.47±0.56	10.32±1.56	8.41±0.49	7.13±0.65	9.50±0.80
t	-	0.414	2.038	0.359	2.171	0.308	3.250	0.189	2.287	0.393	2.752
P	-	0.679	0.045	0.720	0.033	0.759	0.002	0.851	0.026	0.695	0.007

This integrated TCM and Western approach addresses both symptoms and underlying causes, resulting in a more comprehensive therapeutic effect. Hence, the combined treatment demonstrates superior efficacy compared to mesalazine sustained-release tablets alone.²¹ The modified Mayo scoring system is a crucial tool for evaluating the severity of UC. An improvement in the score indicates a significant alleviation of symptoms such as abdominal pain, diarrhea, and hematochezia. Clinically, symptom relief typically leads to an enhanced quality of life, and thus, improvements in the modified Mayo score can be interpreted as beneficial outcomes for patients.

According to Xue JiaChen,²² nearly 40% of UC patients currently use herbal natural products in combination with conventional medications to reduce adverse effects. Flavonoids, among the most widespread polyphenolic compounds found in plants and fruits, possess notable antioxidant and anti-inflammatory activities. Flavonoid-based TCM has shown significant efficacy in the treatment of UC. Their pharmacological mechanisms are associated with anti-inflammatory effects, promotion of mucosal healing, maintenance of intestinal immune homeostasis, and regulation of gut microbiota.

Post-treatment, the observation group showed significantly lower scores for TCM syndrome compared to the control group. This indicates that the combined therapy effectively improves clinical symptoms. Mesalazine sustained-release tablets are pH-dependent drugs that allow the drug to be continuously released in the terminal ileum and colon. This sustained-release mechanism ensures an effective drug concentration in the intestine, enhances its local anti-inflammatory effect, and minimizes systemic impact.²³ Mesalazine suppresses the synthesis and release of inflammatory mediators such as intestinal prostaglandins and leukotrienes, exerting a notable anti-inflammatory effect on the intestinal wall and controlling localized inflammatory factor accumulation. However, while mesalazine is effective in reducing intestinal inflammation, its therapeutic effect focuses primarily on inflammation suppression and lacks the ability to promote the repair of damaged tissue and healing of ulcerated areas, making it challenging to cure the disease and reduce recurrence. In contrast, the herbs in Qingchang Yuyang Decoction offer broader therapeutic benefits: *Pulsatilla chinensis* (Bunge) Regel and *Coptis*, *Phellodendron* clear heat, detoxify, eliminate dampness, and drain fire, with significant antibacterial and anti-inflammatory effects. *Plantago seed* helps to expel dampness and stop diarrhea, promotes urination, and helps transform liquid feces during diarrhea into normal solid feces. *Portulaca* clears heat, detoxifies, cools the blood, and stops bleeding, relieving dysentery.²⁴ *Poria* strengthens the spleen, promotes water metabolism, and calms the mind. *Chinese yam* tonifies the spleen and kidneys and has good tonifying effects. *Angelica sinensis* tonifies the blood, activates blood circulation, and relieves pain. It plays a role in promoting blood circulation. *White peony root* nourishes the blood, softens the liver, relieves spasms, and alleviates pain. It regulates the liver and spleen, helping to soothe overactive liver Qi and stop pain. Fried *Atractylodes* rhizome strengthens the spleen, tonifies Qi, dries dampness, and promotes water metabolism.²⁵ *White Hyacinth Bean* strengthens the spleen, eliminates

Table 7 Comparison of the complications (n(%)).

Group	n	Headache	Nausea and vomiting	Rash	Abdominal pain	Total
Observation group	50	2(4.00)	4(8.00)	0	1(2.00)	7(14.00)
Control group	46	5(10.87)	5(10.87)	3(6.52)	2(4.35)	15(32.61)
χ^2	-					4.697
P	-					0.030

dampness, and harmonizes the spleen and stomach. *Fried Licorice* tonifies the spleen, boosts Qi, harmonizes the spleen and stomach, relieves spasms, and alleviates pain. It also moderates the overactive properties of other medicinal herbs, promoting coordination among them. When these herbs are used in combination, the primary focus is on clearing heat and transforming dampness, while supporting the vital Qi and expelling pathogenic Qi. This approach ensures that dampness is expelled without harming the vital Qi and that pathogenic Qi is not retained when tonifying the spleen. The combination of Qingchang Yuyang Decoction with mesalazine optimizes synergy, regulating the patient's constitution, boosting immunity, enhancing cellular activity throughout the body, which helps reduce inflammatory responses. On the other hand, it promotes blood circulation in the intestinal mucosa, enhances absorption, and accelerates the repair of damaged mucosa and ulcerative tissues. This alleviates pain and quickly relieves symptoms of ulcer bleeding within a short time frame. Overall, integrating Traditional Chinese Medicine (TCM) and Western medicine offers a comprehensive treatment approach, rapidly alleviating clinical symptoms and promoting the healing and repair of ulcerated colonic tissues. In a study by Jingrui Dou,²⁶ the clinical efficacy and impact on myocardial enzymes of combining Jiawei Gegen Qinlian Decoction (JGQD) with Western medicine in treating pediatric rotavirus enteritis with damp-heat syndrome were explored. Children diagnosed with this condition were randomly assigned to a control group and an observation group. The control group received symptomatic treatment with Western medicine, while the observation group was additionally treated with JGQD. After 5 days of treatment, the total effective rate in the observation group was significantly higher than that in the control group. Post-treatment scores for bowel movement frequency, abdominal distension, thirst, irritability, fatigue, and anorexia were all lower than before treatment in both groups, with the observation group showing significantly lower scores in all five TCM symptom indicators. This suggests that combining JGQD with Western medicine can rapidly alleviate signs and symptoms, shorten the disease course, and reduce myocardial damage—findings consistent with the present study, which supports the notion that integrated TCM and Western medicine therapy for colitis yields better outcomes and quicker recovery in pediatric patients.

When investigating the clinical relevance of differences in TCM syndrome scores to patient outcomes, the following aspects should be considered:

1. Components of TCM Syndrome Scores: These typically encompass multiple symptoms and signs, such as

abdominal pain and diarrhea, mucus-pus-bloody stools, tenesmus, anal burning, and short, red urine. These symptoms directly impact patients' quality of life and daily functioning. If the observation group shows significantly lower scores in these domains compared to the control group, it indicates symptom improvement, which may directly enhance the patients' quality of life.

2. Changes in Clinical Symptoms: The significantly lower TCM syndrome scores in the observation group suggest effective control of clinical symptoms. Frequent diarrhea and severe abdominal pain can restrict social activities or interfere with work and daily life. Alleviating these symptoms can lead to improvements in the patients' overall functional status.
3. Relationship with Inflammatory Response: The study noted elevated IL-10 levels and reduced IL-8 and TNF- α levels in the observation group, indicating a mitigated inflammatory response. This biological improvement complements the reduction in TCM syndrome scores, suggesting that controlling inflammation may directly translate into symptom relief and an improved quality of life.
4. Long term effects and follow up: While short-term improvements in TCM syndrome scores are significant, further longitudinal studies are needed to assess whether these improvements persist and lead to better long-term outcomes, such as reduced recurrence and improved psychological health.

After treatment, IL-10 levels were significantly higher in the observation group compared to the control group. Meanwhile, IL-8 and TNF- α levels were lower in the observation group than in the control group. This indicates that the combined therapy can significantly reduce the levels of pro-inflammatory factors in patients, promote the restoration of intestinal mucosal immune balance, effectively alleviate inflammatory responses, and promote ulcer healing. IL-10 is an anti-inflammatory factor that can inhibit the inflammatory response, while IL-8 is a multifunctional cytokine that promotes the aggregation and activation of inflammatory cells. TNF- α , as an inflammatory cytokine, releases a large amount of inflammatory mediators that can exacerbate the condition.²⁷ Mesalazine, as a 5-aminosalicylic acid drug, can effectively inhibit certain inflammatory mediators through continuous administration, thereby improving inflammation of the intestinal mucosa.²⁸ However, due to individual differences among patients, the therapeutic effect of mesalazine alone is limited. Modern pharmacological research shows that certain components in Qingchang Yuyang Decoction contribute to its anti-inflammatory effects. *Pulsatilla chinensis* (Bunge) Regel exhibits anti-inflammatory, antibacterial, antioxidant,

and immune-enhancing therapeutic effects.²⁹ Coptis and Phellodendron have significant anti-inflammatory, antibacterial, and antioxidant properties, and they enhance intestinal barrier function, making them commonly used for conditions such as gastroenteritis.³⁰ Portulaca extract possesses multiple bioactivities, including anti-inflammatory, antibacterial, antiviral, antioxidant, and immune-regulatory effects. It helps resist inflammation, infection, and oxidative stress, and is commonly used to treat dysentery and inflammation.³¹ Compared to Western medicine, TCM fundamentally adjusts the body's internal balance, addressing the root cause of the disease in addition to providing symptomatic relief. TCM can intervene in mild to moderate UC during the early stages of the disease. Integrative medicine leads to quicker recovery and healing of the intestinal mucosa to a certain extent, significantly improving symptoms, enhancing the patient's immunity, and effectively preventing the condition from worsening.³² Consequently, after treatment, the patients in the observation group exhibited lower levels of pro-inflammatory factors, higher levels of anti-inflammatory factors, and marked improvement in inflammatory responses.

In this study, post-treatment changes in inflammatory markers (IL10, IL8, and TNF- α) were significantly associated with symptom improvement. Although these biomarker changes were statistically significant, further investigation is necessary to determine whether they translate into meaningful clinical outcomes. (1) Clinical relevance of inflammatory markers: IL10 Elevation: IL10 is an anti-inflammatory cytokine; increased levels typically indicate suppression of inflammation. In UC, elevated IL10 may reflect enhanced immune control over intestinal inflammation, implying symptom remission and disease improvement. Reduction in IL8 and TNF- α : These are pro-inflammatory cytokines, and their reduction implies attenuation of inflammation, which is likely associated with symptom relief, such as less abdominal pain and diarrhea. Studies suggest that lowering these markers often results in symptom relief and improved quality of life (2) Relationship between symptom improvement and quality of life: The observation group had significantly lower scores for symptoms such as abdominal pain, diarrhea, and mucus-pus-bloody stools compared to the control group, suggesting a correlation between changes in inflammatory markers and symptom improvement. Quality of life is closely linked to these symptoms, and their alleviation directly enhances patients' daily functioning and psychological well-being. (3) Conclusions and future research directions: Despite the statistical association between inflammatory markers and symptom improvement, more prospective studies are needed to verify their clinical relevance across diverse patient populations. In conclusion, while the study provides clinically meaningful insights, further in-depth exploration and validation are essential to ensure that observed changes in biomarkers can be translated into outcomes that truly matter for patients.

In Wen Lin Pang's study,³³ pharmacological research indicates that the traditional Chinese medicine *Saussurea costus* (SC) possesses beneficial antibacterial and anti-inflammatory properties. Firstly, the main active components of SC were identified through analysis. Subsequently, different doses of SC were administered to UC mice to assess its efficacy. The results showed that SC could reduce the levels

of TNF α , IL1B, IL8, and IL18, while promoting the expression of IL10 and IL22. Moreover, 16S rRNA gene sequencing analysis indicated that SC decreased the number of harmful bacteria such as Proteobacteria and increased the levels of beneficial bacteria such as Lactobacillus, thereby helping to improve UC pathology. These findings further demonstrate the potential of the herbal medicine SC in managing UC by attenuating inflammatory responses, restoring intestinal barrier function, and modulating the composition of the gut microbiota, providing insights into potential strategies for advancing UC treatment.

Li Han's³⁴ prospective clinical research involved UC patients who were divided into two groups (control group and experimental group). The expression levels of peripheral blood TLR4 protein, NFkB, IL6, and IL17 were measured in patients from both groups before and one month after medication. The results showed that the expression levels of TLR4 and NFkB in the experimental group were significantly lower than those in the control group; the levels of IL6 and IL17 in the experimental group were also significantly lower than those in the control group. The expression of TLR4 protein in the experimental group was positively correlated with the downstream signal NFkB and the downstream inflammatory cytokines IL6 and IL17. This indicates that the retention enema of Qingchang Yuyang Decoction (Intestinal Clearing Ulcer Healing Decoction) alleviates UC inflammation through the TLR4/NFkB signaling pathway.

Chunxiao Liang et al.³⁵ pointed out that *Valeriana jatamansi* Jones (*V. jatamansi*) is a TCM widely used to treat gastrointestinal diseases, such as UC. Ultrahigh-performance liquid chromatography-mass spectrometry was used to determine the pharmacokinetic characteristics of orally administered *V. jatamansi*. The effects of absorbed compounds on the intestinal barrier were evaluated in NCM460 cells. Fuzzy matter-element analysis was used to explore the main compounds, and the results were validated using FITC-dextran analysis. The results showed that *V. jatamansi* alleviated symptoms, inflammatory responses, and intestinal barrier damage induced by dextran sodium sulfate (DSS) in UC. It effectively mitigated DSS-induced epithelial barrier injury in NCM460 cells. Pharmacokinetic analysis indicated that five components (chlorogenic acid, hesperidin, valerenic acid, isochlorogenic acid B, and cryptochlorogenic acid) were rapidly absorbed into the bloodstream after oral administration of *V. jatamansi*. Fuzzy matter-element analysis and FITC-dextran analysis indicated that valerenic acid and chlorogenic acid played important roles in protecting against intestinal barrier damage. This suggests that *V. jatamansi* improves intestinal barrier damage in UC mice through multiple components. Valerenic acid and chlorogenic acid were identified as anti-colitis compounds, providing new insights into the search for active components in UC treatment and aiding in the clinical application of *V. jatamansi*.

Post-treatment, the observation group showed lower counts of enterococci and enterobacteria. Additionally, the counts of bifidobacteria, *Clostridium butyricum*, and lactobacilli were higher in the observation group compared to the control group. This suggests that Qingchang Yuyang Decoction, combined with mesalazine, can regulate the balance of gut microbiota in the treatment of ulcerative

colitis (UC), improving microbial distribution and preventing gut epithelial barrier damage caused by microbiota imbalance, which may lead to bacterial translocation and gut-derived infections. Studies have shown that *Pulsatilla chinensis* (Bunge) Regel can significantly reduce the levels of enteric pathogens, primarily *Escherichia coli*, in dysbiotic microbiota.³⁶ *Coptis* extract can increase the number of beneficial bacteria and reduce pathogenic bacteria, thereby reducing the infiltration of inflammatory cells and repairing the intestinal mucosal barrier.³⁷ *Portulaca oleracea* alleviates UC by modulating immune function and gut microbiota.³⁸ *Atractylodes macrocephala* extract improves UC by regulating the gut microbiota and tryptophan metabolism.³⁹ Herbal plants and their extracts have a positive regulatory effect on gut microecology, and the unique ability of traditional Chinese medicine (TCM) to modulate the gut microbiota contributes to overall gut health.⁴⁰ Coupled with mesalazine's significant anti-inflammatory effects, the combined therapy exerts a synergistic effect, comprehensively improving gut microbiome distribution in patients. The lower complication rate in the observation group compared to the control group indicates that integrated Chinese-Western therapy has a relatively high safety profile.

The counts of *Enterococcus* and *Enterobacter* in the observation group were lower than those in the control group, while the counts of *Bifidobacterium*, *Butyricicoccus*, and *Lactobacillus* were significantly higher than those in the control group. The healthy balance of gut microbiota is closely related to the control of ulcerative colitis. The increase in probiotics (such as *Bifidobacterium* and *Lactobacillus*) and the reduction in harmful bacteria (such as *Enterobacter* and *Enterococcus*) may be directly related to the therapeutic effect. Research suggests that a healthy gut microbiota is closely associated with good symptom control and reduced recurrence rates.⁴¹ Therefore, improving the gut microbiota may have a positive impact on the long-term health and recovery of patients. The incidence of complications in the observation group was lower, indicating that the combined application of Qingchang Yuyang Decoction might effectively reduce the risk of complications in ulcerative colitis. Reducing complications not only improves patients' quality of life but also reduces medical costs and resource consumption, providing significant clinical and economic value.

Since this study is a retrospective study, it may be subject to selection bias and potential confounding factors. These are detailed as follows:

1. Selection bias.

- (a) Case selection: In retrospective studies, patient selection often relies on past case records, which may lead to the inclusion of only those patients who meet specific criteria, thus affecting the representativeness of the sample. For example, if patients with milder or more severe conditions are preferentially selected for the observation and control groups, this could lead to bias in the results.
- (b) Treatment allocation: In this study, patients were divided into an observation group and a control group, but this division may have been influenced by the subjective judgment of the researchers or other factors. If patient selection and grouping

were not random, it could lead to bias in treatment effects. For example, doctors may be more likely to assign more severe or certain types of patients to the observation group, leading to an overestimation of the effectiveness of the Qingchang Yuyutang treatment.

2. Potential confounding factors:

- (a) Baseline conditions and patient characteristics: Factors such as age, sex, disease duration, comorbidities, and other characteristics could affect the treatment outcomes for ulcerative colitis (UC). If these factors are unevenly distributed between the observation and control groups, it could influence the results. For instance, if the patients in the observation group tend to be younger or have less severe conditions, it might make the treatment effects appear better.
- (b) Treatment adherence: Differences in patient adherence to treatment could also affect the study results. If patients in the observation group are more adherent to the Qingchang Yuyang Decoction, and patients in the control group have lower adherence to conventional treatments, this could result in better outcomes for the observation group, thereby creating a confounding effect.
- (c) Environmental and lifestyle factors: Dietary habits, lifestyle, and psychological factors could also affect the disease progression and treatment outcomes of UC. These factors may differ between the two groups but were not controlled in the study, potentially causing bias in the results.

Impact of Patient Classification Based on the 2023 ACG/CAG UC Guidelines:

The updated diagnostic standards may more accurately identify the severity of the disease, leading to changes in the classification of some patients, from mild to severe or vice versa. Some patients may be reclassified into different disease stages, which could influence their treatment plans and prognostic evaluations. The updated classification based on the new standards may prompt doctors to formulate more personalized treatment plans tailored to the patient's disease progression. Changes in classification may also affect monitoring strategies and follow-up frequency to ensure timely adjustments to treatment.

Limitations of this study include a small sample size and limited examination of patients' baseline conditions, with a smaller sample and single-center design potentially restricting generalizability. Moreover, research on factors influencing patient recurrence is still limited. Additional data analysis in this area could provide insights into the effects of these two approaches on recurrence. Lastly, considering that risk factors for complications have not been fully explored, further analysis is needed to improve clinical management. Future research should incorporate larger sample data, include diverse patient backgrounds, and conduct multi-center studies to investigate complication-related risk factors, recurrence, and enhance the accuracy and comprehensiveness of findings.

Conclusion

In conclusion, Qingchang Yuyang Decoction has anti-inflammatory, antibacterial, microbiota-regulating, intestinal mucosal protective, and promoting ulcer-healing properties. When combined with mesalazine sustained-release tablets, they work synergistically, providing effective treatment for UC. This combination significantly reduces inflammation, markedly improves clinical symptoms, regulates gut microbiota imbalance, and offers good safety.

Ethics Approval and Consent to Participate Statement

Ethical approval was obtained from the Clinical Trials Ethics Committee of Shanghai Baoshan District Wusong Central Hospital (Approval no. 2024-P-05). This study adhered to the principles of the Helsinki Declaration. Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article. Before analysis, patient data was fully anonymized to ensure confidentiality. All identifying information was removed, and data were securely stored in compliance with applicable data protection regulations (e.g. HIPAA or local regulations). Access to the data is restricted to authorized personnel only. Informed consent was obtained from the patients' legally authorized representatives.

Data Availability

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

Authors Contributions

JW and LC designed the study and carried them out, JW, LC supervised the data collection, JW, LC, YZ analyzed and interpreted the data, JW and LC prepare the manuscript for publication and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

Conflict of Interest

The authors declare no conflicts of interest.

Funding

No funding was used in this study.

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