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Therapeutic effect of *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema on patients with hormone-dependent ulcerative colitis

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Abstract: Objective To explore the efficacy of *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema in patients with hormone-dependent ulcerative colitis (UC) and its effect on serum D-lactic acid levels. **Methods** Eighty patients with hormone-dependent UC admitted to Shijiazhuang Traditional Chinese Medicine Hospital from January 2020 to January 2022 were included in the study, and were randomly divided into enema group (40 cases) and combination group (40 cases) using a random number table method. The enema group was given routine treatment (prednisone, omeprazole, mesalazine) and Chinese medicine enema, and the combination group was supplemented with the hospital's self-developed *Shaoyao Sijun Jianpi* Recipe on the basis of enema group. After 6 weeks of continuous treatment, the clinical efficacy, serum D-lactic acid level, inflammatory factor levels [interleukin (IL)-17, tumor necrosis factor- α (TNF- α), IL-10] and Chinese medicine syndrome scores were compared between the two groups. **Results** The total effective rate of the combination group was higher than that of the enema group (85.00% vs 65.00%, $\chi^2=4.267$, $P=0.039$). After treatment, serum IL-10 levels in both groups were higher than those before treatment, and the combination group was higher than the enema group ($P<0.05$); serum TNF- α and IL-17 levels and Chinese medicine syndrome scores (fatigue, mucopurulent bloody stool, loose stool) in both groups were lower than those before treatment, and the combination group was lower than the enema group ($P<0.05$). Serum D-lactic acid levels in both groups decreased sequentially before treatment, at 3 and 6 weeks of treatment ($P<0.05$), and the combination group was significantly lower than the enema group at 3 and 6 weeks ($P<0.05$). **Conclusion** On the basis of conventional Western medicine treatment, *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema can effectively reduce inflammatory response, improve clinical symptoms, and decrease D-lactic acid level in patients with hormone-dependent UC, with favorable efficacy.

Keywords: Hormone-dependent ulcerative colitis; *Shaoyao Sijun Jianpi* Recipe; Chinese medicine enema; D-lactic acid; Chinese medicine syndrome score; Interleukin-17; Tumor necrosis factor- α ; Interleukin-10

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Severe ulcerative colitis (UC) can involve the terminal ileum and the entire colon, commonly presenting with diarrhea, bloody stools, and abdominal pain [1-2]. The condition tends to recur frequently, severely affecting patients' quality of life. Currently, clinical treatment primarily involves medications such as 5-aminosalicylic acid [3] and corticosteroids; however, some patients develop dependence on these treatments after therapy [4]. In recent years, Chinese medicine has achieved favorable outcomes in treating UC through multi-directional and multi-targeted approaches. Among these, enema with Chinese herbal medicines has been widely used in the treatment of UC, as it can reach the lesion site directly, exert therapeutic effects, and overcome adverse drug reactions [5-6]. *Shaoyao Sijun Jianpi* Recipe, a self-developed recipe by Shijiazhuang City Hospital of Traditional Chinese Medicine, is designed to reinforcing the healthy Qi to eliminate pathogenic factors, invigorating the spleen and draining dampness. Previous studies have demonstrated that it plays a significant role in the treatment of UC [7]. This combined therapy can be simultaneous treatment of the symptoms and root cause. In this study, patients with steroid-dependent UC were given two treatment regimens on the basis of conventional therapy: combination therapy with *Shaoyao Sijun Jianpi* Recipe

and enema with Chinese herbal medicines, or enema with Chinese herbal medicines alone. The efficacy, levels of inflammatory factors, blood D-lactate levels, and Chinese medicine syndrome scores were compared between the two groups, aiming to provide a reference for clinical diagnosis and treatment.

1 Data and Methods

1.1 General Data

Patients with hormone-dependent UC admitted to Shijiazhuang City Hospital of Traditional Chinese Medicine from January 2020 to January 2022 were enrolled in this study.

Inclusion criteria:

(1) Meeting the diagnostic criteria of the *Consensus on Traditional Chinese Medicine Diagnosis and Treatment of Ulcerative Colitis* [8] and classified as the spleen deficiency and dampness-heat syndrome. Primary symptoms: fatigue and lassitude, loose stools, and mucopurulent and bloody stool; secondary symptoms: poor appetite, dry mouth, bitter taste, abdominal pain, burning sensation in the anus, tenesmus, teeth-printed tongue or swollen tongue with a greasy tongue coating, and a thready, rapid pulse.

(2) Meeting the diagnostic criteria of the *Chinese Consensus on Diagnosis and Treatment in Inflammatory Bowel Disease (2018, Beijing)* [9], characterized by persistent or recurrent diarrhea, mucopurulent bloody stools with abdominal pain, tenesmus, and varying degrees of systemic symptoms, with a disease course lasting more than 4–6 weeks. Extraintestinal manifestations such as articular, cutaneous, ocular, oral, and hepatobiliary involvement may be present. Diagnosis was confirmed by colonoscopy and mucosal histology. In addition, patients must meet the diagnostic criteria for hormone-dependent UC, defined as: achieving remission but still unable to reduce prednisone to ≤ 10 mg/day after three months of steroid therapy; or relapse within three months after discontinuing steroids. Patients should have mild to moderate hormone-dependent UC.

(3) Patient aged 18–60 years.

(4) Patient was informed of the study and voluntarily signed the informed consent form.

Exclusion criteria:

(1) Presence of severe complications such as obstruction, perforation, malignancy, or bleeding;

(2) Concurrent cardio- or cerebro-vascular diseases;

(3) Presence of psychiatric disorders;

(4) Allergy to medications used in this study;

(5) Concurrent toxic megacolon;

(6) Inability to complete endoscopic examination or difficulty in receiving enema.

Discontinuation or withdrawal Criteria:

(1) Poor treatment adherence;

(2) Voluntary request by the patient or their family to withdraw from the study.

This study was approved by the Ethics Committee of Shijiazhuang City Hospital of Traditional Chinese Medicine (Approval No. 2019-1105209).

1.2 Essension of the Volume of Samples

$\alpha=0.10$, $\beta=0.10$, $f(\alpha, \beta)=8.6$. Expected effective rate for enema group, $\pi^1=60\%$. Expected effective rate for combination group, $\pi^2=90\%$. The sample size calculation formula was:

$$n = \frac{\pi^1(100 - \pi^1) + \pi^2(100 - \pi^2)}{(\pi^1 - \pi^2)^2} \cdot f(\alpha, \beta)$$

Considering a dropout rate of 10%, the minimum sample size for each group was 35, and a total of 80 patients were included in this study. According to the random number table, the patients were divided into an enema group (40 cases) and a combination group (40 cases). There was no significant difference in general data between the two groups ($P>0.05$). See **Table 1**.

Tab.1 Comparison of general data between two groups ($n=40$, $\bar{x} \pm s$)

Group	Gender (male/female, case)	Age (years)	BMI (kg/m ²)	Duration of disease (years)
Enema Group	21/19	40.19±4.15	22.43±2.98	3.62±1.18
Combination Group	23/17	41.43±4.26	22.74±3.01	3.41±1.02
χ^2/t value	0.202	1.319	0.463	0.852
P value	0.653	0.191	0.645	0.397

1.3 Treatment

Patients in both groups received regular treatment:

(1) Prednisone (Zhejiang Xianju Pharma, National Drug Approval Number H33021207, 5 mg), p.o. 40 mg, qd. After the condition stabilizes, gradually reduce the dosage by 5 mg per week. When the dosage is reduced to 20 mg/d, reduce it by 2.5 mg every 1–2 weeks until discontinuation.

(2) Omeprazole, (Luoxin Pharmaceutical, National Drug Approval Number H20084507, 20 mg), p.o. 20 mg, qd.

(3) Mesalazine (Heilongjiang Tianhong Pharmaceutical, National Drug Approval Number H20103359, 0.25 g), p.o. 0.5 g, qd.

The enema group received an enema with Chinese herbal medicines in addition to conventional treatment. The herbal decoction included Huangbo (黄柏, *Phellodendri Chinensis Cortex*) 20 g, Kushen (苦参, *Sophorae Flavescens Radix*) 20 g, Hezi (诃子, *Chebulae Fructus*) 6 g, Sanqi (三七, *Notoginseng Radix Et Rhizoma*) powder 2 g, Wubeizi (五倍子, *Galla Chinensis*) 10 g, Baiji (白及, *Bletillae Rhizoma*) 12 g. The solution was prepared by boiling the herbs in water to a volume of 150 mL. The patient was placed in the left lateral position, and the enema was administered every evening as a retention enema. The solution (37–40°C) was infused, the hips were elevated, and the enema was retained for 30 minutes.

The combination group received, in addition to the enema group, the *Shaoyao Sijun Jianpi* Recipe. The composition of the recipe was Shanyao (山药, *Dioscoreae Rhizoma*), Gegen (葛根, *Puerariae Lobatae Radix*), Fuling (茯苓, *Poria*), Xianhecao (仙鹤草, *Agrimoniae Herba*) and Baishao (白芍, *Paeoniae Radix Alba*) 20 g each, Muxiang (木香 *Aucklandiae Radix*), Zhigancao (炙甘草, *Glycyrrhizae Radix et Rhizoma Praeparata cum Melle*), Huangqin (黄芩, *Scutellariae Radix*) and Huanglian (黄连, *Coptidis Rhizoma*) 6 g each, Xixiancao (豨莶草, *Siegesbeckiae Herba*) and Chaobaizhu (炒白术, *Atractylodis Macrocephalae Rhizoma stir-fried with bran*) 12 g each, Dangshen (党参, *Codonopsis Radix*) 10 g, and Danggui (当归, *Angelicae Sinensis Radix*) 6 g. The herbs were decocted in water to a volume of 200 mL, which was taken orally in two divided doses (morning and evening), one dose per day.

Both groups were treated for six weeks.

1.4 Outcome Measures

The primary endpoint was clinical efficacy. Secondary endpoints included serum inflammatory cytokine levels, Chinese medicine syndrome score, and serum D-lactate levels.

1.4.1 Clinical efficacy

Clinical efficacy was assessed according to the *Diagnosis, Classification and Therapeutic Criteria of Ulcerative Colitis* [10].

Complete response: Complete resolution of abdominal pain, diarrhea and other symptoms; normalization of the intestinal mucosa; reduction in

Chinese medicine syndrome score of $\geq 95\%$.

Significant improvement: Significant improvement in clinical symptoms; marked improvement in intestinal mucosal lesions; reduction in Chinese medicine syndrome score of 70%–94%.

Improvement: Some improvement in clinical symptoms; some improvement in lesions; reduction in Chinese medicine syndrome score of 50%–69%.

No response: No improvement or worsening of the above parameters.

Total efficacy rate = [(Complete response + significant improvement + improvement) / Total number of cases] $\times 100\%$.

1.4.2 Inflammatory cytokine levels

Before treatment and after 6 weeks of treatment, 3 mL of fasting venous blood was drawn from each patient, and serum was separated. Levels of interleukin (IL)-17, IL-10, and tumour necrosis factor (TNF)- α were measured using enzyme-linked immunosorbent assay. Kits (catalogue numbers: YS01053B, YS04842B, YS04866B) were purchased from Shanghai Yaji Biotechnology Co., Ltd.

1.4.3 Chinese medicine syndrome score

Based on the *Guiding Principles for Clinical Research of New Traditional Chinese Medicine Drugs* [11], major symptoms including fatigue and lassitude, loose stools, and mucopurulent and bloody stool were graded as absent, mild, moderate, or severe, scoring 0, 3, 6, and 9 points, respectively. The score is positively correlated with the severity of the condition.

1.4.4 Serum D-lactate level

Before treatment, at 3 weeks of treatment, and at 6 weeks of treatment, 3 mL of fasting venous blood was drawn from each patient, serum was separated, and serum D-lactate levels were measured using the o-dianisidine reagent method.

1.5 Statistical methods

Data were analyzed using SPSS 25.0 software. Continuous variables conforming to a normal distribution are expressed as $\bar{x} \pm s$. For comparisons between two

groups, the independent samples *t*-test was used; for within-group comparisons, the paired *t*-test was used. For comparisons across multiple time points, repeated-measures analysis of variance (ANOVA) was performed, followed by the least significant difference (LSD)-*t* test for pairwise comparisons. Categorical variables are expressed as number (%), and the chi-square test was used for between-group comparisons. A *P* value < 0.05 was considered statistically significant.

2 Methods

2.1 Clinical Efficacy

The total effective rate in the combination group was higher than that in the enema group, and the difference was statistically significant ($P < 0.05$). See **Table 2**.

Tab.2 Comparison of clinical efficacy between two groups ($n=40$, case)

Group	Complete response	Significant improvement	Improvement	No response	Total effective rate (%)
Enema Group	6	8	12	14	65.00
Combination Group	10	11	13	6	85.00
χ^2/t value					4.267
<i>P</i> value					0.039

2.2 Serum Inflammatory Cytokine Levels

After treatment, serum IL-10 levels in both groups were higher than those before treatment, and the level in the combination group was higher than that in the enema group ($P < 0.05$). After treatment, serum TNF- α and IL-17 levels in both groups were lower than those before treatment, and the levels in the combination group were lower than those in the enema group ($P < 0.05$). See **Table 3**.

2.3 Chinese Medicine Syndrome Scores

After treatment, the Chinese medicine syndrome scores for fatigue, bloody mucoid stools, and loose stools in both groups were lower than those before treatment, and the scores in the combination group were lower than those in the enema group ($P < 0.05$). See **Table 4**.

Tab.3 Comparison of serum inflammatory factor levels between two groups ($n=40$, $\bar{x} \pm s$)

Group	TNF- α (ng/L)		IL-17(pg/mL)		IL-10(pg/mL)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Enema Group	55.21 \pm 6.08	27.45 \pm 2.89 ^a	53.36 \pm 5.42	37.21 \pm 3.78 ^a	21.45 \pm 2.34	26.73 \pm 2.71 ^a
Combination Group	54.14 \pm 6.43	23.40 \pm 2.56 ^a	54.12 \pm 5.51	23.35 \pm 2.34 ^a	22.07 \pm 2.42	31.26 \pm 3.15 ^a
<i>t</i> value	0.765	6.635	0.622	19.718	1.165	6.895
<i>P</i> value	0.447	<0.001	0.536	<0.001	0.248	<0.001

Note: Compared with the same group before treatment, ^a $P < 0.05$.

Tab.4 Comparison of Chinese medicine syndrome scores between two groups ($n=40$, $\bar{x} \pm s$)

Group	Fatigue and lassitude		Mucopurulent and bloody stool		Loose stool	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Enema Group	4.03 \pm 0.45	2.16 \pm 0.31 ^a	5.63 \pm 0.58	3.85 \pm 0.42 ^a	5.02 \pm 0.51	3.56 \pm 0.37 ^a
Combination Group	3.89 \pm 0.41	1.97 \pm 0.26 ^a	5.51 \pm 0.52	3.63 \pm 0.37 ^a	5.11 \pm 0.53	2.74 \pm 0.32 ^a
<i>t</i> value	1.454	2.970	0.974	2.486	0.774	10.602
<i>P</i> value	0.150	0.004	0.333	0.015	0.441	<0.001

Note: Compared with the same group before treatment, ^a $P < 0.05$.

2.4 Serum D-Lactate Levels

Both time and group effects on serum D-lactate levels were significant in the two groups ($P < 0.05$). Serum D-lactate levels in both groups decreased sequentially before treatment, at 3 weeks of treatment, and at 6 weeks of treatment ($P < 0.05$). See **Table 5**.

Tab.5 Comparison of serum D-lactic acid levels between two groups ($n=40$, mg/L, $\bar{x} \pm s$)

Group	Before treatment	3 weeks after treatment	6 weeks after treatment
Enema Group	19.87±2.16	15.91±1.56 ^a	13.22±1.35 ^{ab}
Combination Group	19.45±1.98	14.24±1.42 ^a	11.26±1.14 ^{ab}
<i>F/P</i> _{time} value		40.605/ <0.001	
<i>F/P</i> _{between-group} value		416.464/ <0.001	
<i>F/P</i> _{interaction} value		4.973/0.501	

Note: Compared with the same group before treatment, ^a $P < 0.05$; Note: Compared with the same group 3 weeks after treatment, ^b $P < 0.05$.

3 Discussion

UC primarily involves the colonic and rectal mucosa and submucosa, characterized by recurrent episodes of ulceration and erosion. It is currently believed to be associated with genetic susceptibility, inflammatory factors, and autoimmunity [12]. Corticosteroid therapy is an effective approach for alleviating the severity of UC, but approximately 20% of patients do not achieve the expected therapeutic effect. Moreover, long-term use of corticosteroids may prolong the disease course and lead to hormone-dependence [13]. For patients with hormone-dependence, other treatment modalities such as immunosuppressants or biologics may be administered. However, evidence on how to optimally use these treatments is limited, highlighting the need to investigate the optimal treatment regimen for steroid-dependent UC and to improve future clinical practice [14]. In recent years, Chinese medicine has made certain progress in the treatment of UC. Therefore, based on the Chinese medicine pathogenesis and syndrome differentiation of steroid-dependent UC, this study explored new and more effective treatment approaches.

The pathological focus of hormone-dependence UC lies in the intestine and is closely related to the liver, spleen, and kidney. In Chinese medicine, it falls under the categories of "Changpi" (intestinal dysentery), "Futong" (abdominal pain), and "Xiexie" (diarrhea). The most common syndrome is spleen deficiency with dampness-heat. Modern dietary habits, particularly the preference for pungent and spicy foods, tend to impair the spleen and stomach, leading to dampness-heat accumulation in the middle-energizer. This disrupts the spleen's function of ascending clear *Qi* and descending turbid *Qi*, resulting in systemic dysfunction and triggering the disease. As recorded in *The Jingyue Quanshu* regarding diarrhea (《景岳全书·泄泻》): "The root of diarrhea is invariably attributed to the spleen and stomach... eventually leading to the downward passage of turbid substances, resulting in diarrhea and dysentery." Therefore, dampness-heat accumulation constitutes the fundamental pathogenesis of

this disease, with the main treatment principles being clearing heat, resolving dampness, strengthening the spleen, and supplementing *qi*. *Shaoyao Sijun Jianpi* Recipe can strengthen the body's resistance, eliminate pathogens, supplement *Qi*, invigorate the spleen, and resolve dampness, demonstrating good efficacy in treating UC [15]. Meanwhile, Chinese herbal enema can complement the oral decoction; local administration allows the medication to reach the lesion directly, rapidly absorb inflammation, and promote ulcer healing. Therefore, this study treated hormone-dependent UC with Chinese herbal enema combined with *Shaoyao Sijun Jianpi* Recipe. The results showed that the clinical efficacy in the combination group was significantly higher than that in the enema group, indicating that the combination therapy has good clinical efficacy in treating hormone-dependent UC, with superior outcomes compared to Chinese herbal enema alone.

The occurrence of UC is associated with colorectal immune dysfunction, triggered by an imbalance between the anti-inflammatory cytokine IL-10 and the pro-inflammatory cytokines TNF- α and IL-17, with pro-inflammatory factors predominating. IL-17 is a common inflammatory mediator in clinical practice. It is highly expressed in UC patients, enhances cell permeability, recruits neutrophils, induces intestinal mucosal inflammation, and subsequently causes pathological damage, leading to symptoms such as mucopurulent bloody stools, diarrhea, and abdominal pain [16]. IL-10, as an anti-inflammatory cytokine, inhibits the secretion of effector T cells and neutrophils, exerting anti-inflammatory effects, and is expressed at low levels in UC patients [17]. TNF- α participates in thrombosis, cell apoptosis, and metabolism; it can chemoattract inflammatory factors, induce inflammatory reactions in the intestinal mucosa, and consequently damage the intestinal mucosa [18]. This study found that compared with before treatment, serum IL-10 levels increased significantly in both groups after treatment, with the combination group showing higher levels than the enema group. After treatment, serum TNF- α and IL-17 levels, as well as Chinese medicine syndrome scores for fatigue, mucopurulent bloody stools, and loose stools, decreased significantly in both groups, with the combination group showing lower levels than the enema group. These findings suggest that Chinese herbal enema combined with *Shaoyao Sijun Jianpi* Recipe can effectively reduce inflammatory responses and improve patients' clinical symptoms, with favorable outcomes. The possible reasons are as follows: In the Chinese herbal enema formula, Baiji (白及, *Bletillae Rhizoma*) reduces swelling, promotes tissue regeneration, astringes bleeding, and stops bleeding; Kushen (苦参, *Sophorae Flavescentis Radix*) clears heat, resolves dampness, cools blood, and detoxifies; Huangbo (黄柏, *Phellodendri Chinensis Cortex*) reduces fire, detoxifies, exerts antibacterial and anti-inflammatory effects, and clears heat with dampness; Sanqi (三七, *Notoginseng Radix Et Rhizoma*) relieves pain, reduces swelling, and invigorates blood; Hezi (诃子, *Chebulae Fructus*) astringes the intestines and directs *Qi* downward;

Wubeizi (五倍子, *Galla Chinensis*) detoxifies, astringes the intestines, and stops bleeding. The combined use of these Chinese herbs in the enema achieves antidiarrheal, dampness-resolving, and hemostatic effects. In the *Shaoyao Sijun Jianpi* Recipe, honey-fried gancào (炙甘草, *Glycyrrhizae Radix et Rhizoma Praeparata cum Melle*), Chaobaizhu (炒白术, *Atractylodis Macrocephalae Rhizoma stir-fried with bran*), Fuling (茯苓, *Poria*), and Dangshen (党参, *Codonopsis Radix*) strengthen the body's resistance, eliminate pathogens, invigorate the spleen, and resolve dampness; Danggui (当归, *Angelicae Sinensis Radix*) invigorates and nourishes blood; Xianhecao (仙鹤草, *Agrimoniae Herba*) cools blood and stops bleeding; Huangqin (黄芩, *Scutellariae Radix*) and Huanglian (黄连, *Coptidis Rhizoma*) transform stasis, stop bleeding, clear heat, and resolve dampness; Baishao (白芍, *Paeoniae Radix Alba*) nourishes blood, astringes yin, and softens the liver; Shanyao (山药, *Dioscoreae Rhizoma*) tonifies and benefits the spleen and stomach; Xixiancao (豨莶草, *Siegesbeckiae Herba*) relieves pain, moves qi, and resolves dampness; Gegen (葛根, *Puerariae Lobatae Radix*) elevates the spleen and stomach's yang qi. The combined use of these herbs detoxifies, reduces carbuncles, clears heat, resolves dampness, strengthens the spleen, and harmonizes the stomach, thereby promoting remission of symptoms in hormone-dependent UC.

D-lactate is produced by intestinal bacteria and cannot be metabolized through other pathways. When the intestinal mucosa is damaged, D-lactate can enter the bloodstream; therefore, it can serve as an indicator of intestinal mucosal injury [19]. This study investigated this marker and showed that serum D-lactate levels in both groups decreased sequentially before treatment, at 3 weeks of treatment, and at 6 weeks of treatment, with the combination group showing significantly lower levels than the enema group at 3 and 6 weeks of treatment. This suggests that the combined use of the two treatments effectively reduces D-lactate levels. The possible reason is that *Shaoyao Sijun Jianpi* Recipe can supplement middle Qi, regulate the spleen and stomach, and treat the root cause. When combined with enema using Chinese herbal medicine, which cools blood, stops bleeding, clears heat, and resolves dampness, the two approaches together address both the root cause and clinical manifestations. They improve local symptoms while internally regulating the *zang-fu* organs and repairing the intestinal mucosa, thereby enhancing the overall therapeutic efficacy.

In conclusion, for hormone-dependent UC, the addition of Chinese herbal enema combined with *Shaoyao Sijun Jianpi* Recipe to conventional Western medical treatment can effectively reduce inflammation, improve patients' clinical symptoms, and lower serum D-lactate levels, demonstrating favorable therapeutic effects.

Conflict of Interest None

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· 炎症性肠病专题·论著·

芍药四君健脾方与中药灌肠联合治疗对激素依赖型溃疡性结肠炎患者的疗效

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摘要: **目的** 探究对激素依赖型溃疡性结肠炎(UC)患者使用芍药四君健脾方联合中药灌肠的疗效及其对血清D-乳酸水平的影响。**方法** 纳入2020年1月至2022年1月石家庄市中医院收治的80例激素依赖型UC患者进行研究,随机数字表法分为灌肠组(40例)和联合组(40例)。灌肠组采用常规治疗(泼尼松、奥美拉唑、美沙拉秦)及中药灌肠,联合组在灌肠组基础上加用本院自拟的芍药四君健脾方。连续治疗6周后,比较两组患者临床疗效、血清D-乳酸、炎症因子水平[白细胞介素(IL)-17、肿瘤坏死因子- α (TNF- α)、IL-10]及中医证候积分。**结果** 联合组治疗总有效率高于灌肠组(85.00% vs 65.00%, $\chi^2=4.267, P=0.039$)。治疗后,两组血清IL-10水平高于治疗前,且联合组高于灌肠组($P<0.05$);治疗后,两组血清TNF- α 、IL-17水平及中医证候积分(神疲乏力、黏液脓血便、大便稀溏)低于治疗前,且联合组低于灌肠组($P<0.05$)。两组随治疗时间延长血清D-乳酸水平逐渐降低($P<0.05$),且治疗3周、6周时联合组显著低于灌肠组($P<0.05$)。**结论** 激素依赖型UC患者在西药常规治疗的基础上使用芍药四君健脾方联合中药灌肠治疗,可有效减轻炎症反应,改善临床症状,降低D-乳酸水平,效果较好。

关键词: 激素依赖型溃疡性结肠炎;芍药四君健脾方;中药灌肠;D-乳酸;中医证候积分;白细胞介素-17;肿瘤坏死因子- α ;白细胞介素-10

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Therapeutic effect of *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema on patients with hormone-dependent ulcerative colitis

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Abstract: Objective To explore the efficacy of *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema in patients with hormone-dependent ulcerative colitis (UC) and its effect on serum D-lactic acid levels. **Methods** Eighty patients with hormone-dependent UC admitted to Shijiazhuang Traditional Chinese Medicine Hospital from January 2020 to January 2022 were included in the study, and were randomly divided into enema group (40 cases) and combination group (40 cases) using a random number table method. The enema group was given routine treatment (prednisone, omeprazole, mesalazine) and Chinese medicine enema, and the combination group was supplemented with the hospital's self-developed *Shaoyao Sijun Jianpi* Recipe on the basis of enema group. After 6 weeks of continuous treatment, the clinical efficacy, serum D-lactic acid level, inflammatory factor levels [interleukin (IL)-17, tumor necrosis factor- α (TNF- α), IL-10] and Chinese medicine syndrome scores were compared between the two groups. **Results** The total effective rate of the combination group was higher than that of the enema group (85.00% vs 65.00%, $\chi^2=4.267, P=0.039$). After treatment, serum IL-10 levels in both groups were higher than those before treatment, and

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the combination group was higher than the enema group ($P<0.05$); serum TNF- α and IL-17 levels and Chinese medicine syndrome scores (fatigue, mucopurulent bloody stool, loose stool) in both groups were lower than those before treatment, and the combination group was lower than the enema group ($P<0.05$). Serum D-lactic acid levels in both groups decreased sequentially before treatment, at 3 and 6 weeks of treatment ($P<0.05$), and the combination group was significantly lower than the enema group at 3 and 6 weeks ($P<0.05$). **Conclusion** On the basis of conventional Western medicine treatment, *Shaoyao Sijun Jianpi* Recipe combined with Chinese medicine enema can effectively reduce inflammatory response, improve clinical symptoms, and decrease D-lactic acid level in patients with hormone-dependent UC, with favorable efficacy.

Keywords: Hormone-dependent ulcerative colitis; *Shaoyao Sijun Jianpi* Recipe; Chinese medicine enema; D-lactic acid; Chinese medicine syndrome score; Interleukin-17; Tumor necrosis factor- α ; Interleukin-10

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严重溃疡性结肠炎(ulcerative colitis, UC)可累及末端回肠及全结肠,多表现为腹泻、血便、腹痛^[1-2],病情反复发作,对患者生活质量造成严重影响。目前临床主要采用5-氨基水杨酸^[3]、激素等药物治疗,但部分患者治疗后会产生产生依赖性^[4]。近年来,中医药采用多方位、多靶点的方式治疗UC已取得较好效果。其中中药灌肠能够直达病灶,发挥药物作用,克服药物不良反应,已广泛用于治疗UC^[5-6]。芍药四君健脾方为石家庄市中医院自拟方剂,能够扶正祛邪、补气健脾祛湿,已有研究证明其可在UC患者的治疗中发挥重要作用^[7]。两者联合使用可标本同治。本研究对激素依赖型UC患者在常规治疗基础上给予两种方案:芍药四君健脾方和中药灌肠联合治疗、单行中药灌肠治疗,进一步对比二者疗效、炎症因子水平、血D-乳酸水平和中医证候积分的差异,以期为临床诊治提供参考。

1 资料与方法

1.1 一般资料 选取2020年1月至2022年1月石家庄市中医院收治的激素依赖型UC患者纳入研究。纳入标准:(1)符合《溃疡性结肠炎中医诊疗共识意见》^[8]诊断标准,为脾虚湿热证型。主症:神疲乏力、大便稀溏、黏液脓血便;次症:纳差、口干口苦、腹痛、肛门灼热、里急后重,舌有齿痕或淡胖、舌苔腻、脉细数。(2)符合《炎症性肠病诊断与治疗的共识意见(2018年·北京)》^[9]诊断标准,临床表现为持续或反复发作的腹泻,黏液脓血便伴腹痛、里急后重和不同程度的全身症状,病程在4~6周以上,可有相关节、皮肤、眼、口腔及肝胆等肠道外表现,结肠镜和黏膜组织学检查确诊。而且符合激素依赖型UC诊断标准,虽保持缓解,但激素治疗3个月后,泼尼松仍不能减量至10 mg/d;或停用激素3个月内复发;为轻中度激素依赖型UC

患者。(3)患者年龄18~60岁。(4)患者自愿签署知情同意书。排除标准:(1)合并梗阻、穿孔、癌变、出血等严重并发症;(2)合并心、脑血管系统疾病;(3)存在精神疾病;(4)对本研究所用药物过敏;(5)合并中毒性巨结肠症;(6)不能完成镜检或灌肠困难者。脱落、退出标准:(1)治疗依从性差;(2)患者或家属自行要求退出治疗。本研究获得石家庄市中医院伦理委员会批准(批准号:2019-1105209)。

1.2 样本量估算 α 为0.10, β 为0.10,查表得 $f(\alpha,\beta)=8.6$ 。 π^1 为灌肠组预期有效率(%),即60%; π^2 为联合组预期有效率(%),即90%。代入样本量计算公式, $n=\frac{\pi^1(100-\pi^1)+\pi^2(100-\pi^2)}{(\pi^1-\pi^2)^2} \cdot f(\alpha,\beta)$,考虑到10%

脱落率,每组最低纳入样本量为35例,最终本研究共纳入80例患者。按随机数字表法分为灌肠组(40例)和联合组(40例),两组基线资料比较差异无统计学意义($P>0.05$)。见表1。

1.3 治疗方法 两组患者入院后均给予常规治疗:泼尼松(国药准字H33021207,浙江仙琚制药,5 mg)口服,每次40 mg,每天1次,病情稳定后逐渐减量,每周减5 mg,减至20 mg/d时每1~2周减2.5 mg直至停用;奥美拉唑肠溶胶囊(国药准字H20084507,山东罗欣药业,20 mg)口服,每天20 mg/次;美沙拉秦肠溶片(国药准字H20103359,黑龙江天宏药业,0.25 g)口服,0.5 g/次,1次/d。灌肠组在常规治疗基础上给予中药灌肠(黄柏、苦参各20 g,诃子6 g,三七粉2 g,五倍子10 g,白及12 g)加水煎制150 mL,患者取左侧卧位,每晚保留灌肠,注入药液(37~40℃药液),臀部抬高,保留30 min。联合组在灌肠组基础上给予芍药四君健脾方(山药、葛根、茯苓、仙鹤草、白芍各20 g,木香、炙甘草、黄芩、黄连各6 g,豨莶草、炒白术各12 g,党参10 g,当归9 g)加水煎至200 mL,分早晚两次服

用,每天1剂。两组均治疗6周。

1.4 观察指标 本研究主要终点指标为临床疗效,次要终点指标为血清炎症因子水平、中医证候积分、血清D-乳酸水平。

1.4.1 临床疗效 临床疗效评估依据《溃疡性结肠炎的诊断、分型及疗效标准》^[10]。痊愈:腹痛、腹泻等症状完全消失,肠黏膜恢复正常,中医证候积分减少 $\geq 95\%$ 。显效:临床症状明显好转,肠黏膜病灶显著改善,中医证候积分减少70%~94%。有效:临床症状有所改善,病灶有所好转,中医证候积分减少50%~69%。无效:上述情况均无改善或加重者。总有效率=[(痊愈+显效+有效)/例数] $\times 100\%$ 。

1.4.2 炎症因子水平 在治疗前、治疗6周后,分别抽取患者空腹静脉血3 mL,分离血清,采用酶联免疫吸附法检测白细胞介素(IL)-17、IL-10、肿瘤坏死因子(TNF)- α 水平,试剂盒(货号:YS01053B、YS04842B、YS04866B)购自上海雅吉生物科技有限公司。

1.4.3 中医证候积分 中医证候积分依据《中药新药临床研究指导原则》^[11],将患者神疲乏力、黏液脓血便、大便稀溏等主证情况按照证候无、轻、中、重分级,分别记0、3、6、9分,分数与病情严重程度正相关。

1.4.4 血清D-乳酸水平 在治疗前、治疗3周、治疗6周,分别抽取患者空腹静脉血3 mL,分离血清,检测患者血清D-乳酸水平(以邻联苊香胺试剂法)。

1.5 统计学方法 使用SPSS 25.0软件分析数据。符合正态分布的计量资料以 $\bar{x}\pm s$ 表示,组间比较为独立样本 t 检验,组内比较为配对 t 检验;多个时间点比较行重复测量方差分析,两两比较用LSD- t 检验;计数资料以例(%)表示,组间比较用 χ^2 检验。 $P<0.05$ 表示差异有统计学意义。

2 结果

2.1 临床疗效 联合组治疗总有效率高于灌肠组,差异有统计学意义($P<0.05$)。见表2。

2.2 血清炎症因子水平 治疗后,两组血清IL-10水平高于治疗前,且联合组高于灌肠组($P<0.05$);治疗后,两组血清TNF- α 、IL-17水平低于治疗前,且联合组低于灌肠组($P<0.05$)。见表3。

2.3 中医证候积分 治疗后,两组神疲乏力、黏液脓血便及大便稀溏中医证候积分低于治疗前,且联合组低于灌肠组($P<0.05$)。见表4。

2.4 血清D-乳酸水平 两组血清D-乳酸水平存在显著的时间、组间效应($P<0.05$)。两组治疗前和治疗3周、6周血清D-乳酸水平依次降低($P<0.05$)。见表5。

表1 两组一般资料比较 ($n=40, \bar{x}\pm s$)

Tab.1 Comparison of general data between two groups ($n=40, \bar{x}\pm s$)

组别	男/女(例)	年龄(岁)	BMI(kg/m ²)	病程(年)
灌肠组	21/19	40.19 \pm 4.15	22.43 \pm 2.98	3.62 \pm 1.18
联合组	23/17	41.43 \pm 4.26	22.74 \pm 3.01	3.41 \pm 1.02
χ^2 值	0.202	1.319	0.463	0.852
P 值	0.653	0.191	0.645	0.397

表2 两组临床疗效比较 ($n=40, \text{例}$)

Tab.2 Comparison of clinical efficacy between two groups ($n=40, \text{case}$)

组别	痊愈	显效	有效	无效	总有效率(%)
灌肠组	6	8	12	14	65.00
联合组	10	11	13	6	85.00
χ^2 值					4.267
P 值					0.039

表3 两组血清炎症因子水平比较 ($n=40, \bar{x}\pm s$)

Tab.3 Comparison of serum inflammatory factor levels between two groups ($n=40, \bar{x}\pm s$)

组别	TNF- α (ng/L)		IL-17(pg/mL)		IL-10(pg/mL)	
	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
灌肠组	55.21 \pm 6.08	27.45 \pm 2.89*	53.36 \pm 5.42	37.21 \pm 3.78*	21.45 \pm 2.34	26.73 \pm 2.71*
联合组	54.14 \pm 6.43	23.40 \pm 2.56*	54.12 \pm 5.51	23.35 \pm 2.34*	22.07 \pm 2.42	31.26 \pm 3.15*
t 值	0.765	6.635	0.622	19.718	1.165	6.895
P 值	0.447	<0.001	0.536	<0.001	0.248	<0.001

注:与同组治疗前比较,* $P<0.05$ 。

表4 两组中医证候积分比较 ($n=40, \text{分}, \bar{x}\pm s$)

Tab.4 Comparison of Chinese medicine symptom scores between two groups ($n=40, \text{point}, \bar{x}\pm s$)

组别	神疲乏力		黏液脓血便		大便稀溏	
	治疗前	治疗后	治疗前	治疗后	治疗前	治疗后
灌肠组	4.03 \pm 0.45	2.16 \pm 0.31*	5.63 \pm 0.58	3.85 \pm 0.42*	5.02 \pm 0.51	3.56 \pm 0.37*
联合组	3.89 \pm 0.41	1.97 \pm 0.26*	5.51 \pm 0.52	3.63 \pm 0.37*	5.11 \pm 0.53	2.74 \pm 0.32*
t 值	1.454	2.970	0.974	2.486	0.774	10.602
P 值	0.150	0.004	0.333	0.015	0.441	<0.001

注:与同组治疗前比较,* $P<0.05$ 。

表5 两组血清D-乳酸水平比较 (mg/L, $\bar{x}\pm s$)
Tab.5 Comparison of serum D-lactic acid levels between two groups (mg/L, $\bar{x}\pm s$)

组别	例数	治疗前	治疗3周	治疗6周
灌肠组	40	19.87±2.16	15.91±1.56 ^a	13.22±1.35 ^{ab}
联合组	40	19.45±1.98	14.24±1.42 ^a	11.26±1.14 ^{ab}
$F_{\text{时间}}/F_{\text{组间}}/F_{\text{交互}}$ 值		40.605/416.464/4.973		
$P_{\text{时间}}/P_{\text{组间}}/P_{\text{交互}}$ 值		<0.001/<0.001/0.501		

注:与同组治疗前比较,^a $P<0.05$;与同组治疗3周比较,^b $P<0.05$ 。

3 讨论

UC主要累及结肠黏膜及其下层,以溃疡及糜烂反复发作为特征,目前多认为与基因易感性、炎症因子及自身免疫有关^[12]。皮质类固醇激素治疗是缓解UC病情严重程度的高效方法,但约有20%的患者没有达到预期的疗效,且长期使用激素治疗可能会导致病程延长,造成激素依赖^[13]。对于激素依赖患者可给予免疫抑制剂、生物制剂等其他治疗方法治疗,但关于如何较好地使用这些治疗方法的证据有限,因此需要研究激素依赖型UC的最佳治疗方案并改善未来的临床实践^[14]。近年来,中医药在UC治疗方面已取得一定进展,因此本研究基于激素依赖型UC中医病机、辨证等方面,探究新的、更为有效的治疗方法。

激素依赖型UC病灶在肠,与肝脾肾关系密切,中医中属“肠癖”“腹痛”“泄泻”的范畴,最常见的即为脾虚湿热证。现代人喜欢吃辛辣之物,容易导致脾胃损伤,湿热中阻,引发脾胃升降浊进而使机体发生功能失调,引发本病。《景岳全书·泄泻》曰:“泄泻之本,无不由于脾胃……乃致合污下降为泻痢作矣。”因此,湿热蕴结为本病基本病机,主要以清热化湿、健脾益气为治疗原则。而芍药四君健脾方可扶正祛邪、补气健脾祛湿,用于治疗UC效果较好^[15]。而中药灌肠可与汤药相辅相成,局部用药能够直达病灶,快速减轻炎症,促进溃疡愈合。因此,本研究对激素依赖型UC使用中药灌肠联合芍药四君健脾方治疗,结果显示,联合组临床疗效明显高于灌肠组,提示中药灌肠联合芍药四君健脾方治疗激素依赖型UC的临床疗效较好,且其疗效高于单独使用中药灌肠治疗的患者。

UC的发生与结肠免疫功能紊乱有关,因炎症因子IL-10、促炎因子TNF- α 、IL-17失衡所引发,其中促炎因子优势显著。IL-17为临床常见的一种炎症介质,在UC患者中呈高表达,可使细胞的渗透性增强,募集中性粒细胞,引发肠黏膜炎症反应,进而引起病

理性损伤,引发黏液脓血便、腹泻、腹痛等症状^[16]。IL-10作为抑炎因子能够抑制效应T细胞及中性粒细胞分泌起抗炎作用,在UC患者中呈低表达^[17]。TNF- α 可参与血栓形成、细胞的凋亡、代谢等,能够趋化炎症因子,使肠黏膜出现炎症反应,进而损伤肠黏膜^[18]。本研究发现,与治疗前比较,两组治疗后血清IL-10水平明显升高,且联合组高于灌肠组;两组治疗后血清TNF- α 、IL-17水平以及神疲乏力、黏液脓血便、大便稀溏等中医证候积分明显降低,且联合组低于灌肠组。这提示中药灌肠联合芍药四君健脾方可有效减轻炎症反应,改善患者临床症状,效果较好。分析其原因,可能是因为中药灌肠方中白及能够消肿生肌、收敛止血;苦参可清热燥湿、凉血解毒;黄柏可泻火解毒、抗菌消炎、清热燥湿;三七能够止痛消肿活血;诃子能涩肠下气;五倍子可解毒、涩肠止血。诸药联合灌肠可止泻、燥湿、止血。芍药四君健脾方中炙甘草、炒白术、茯苓、党参可扶正祛邪、健脾祛湿;当归可活血补血;仙鹤草可凉血止血;黄芩、黄连可化痰止血、清热燥湿;白芍能养血敛阴柔肝;山药补益脾胃;豨莶草可止痛行气燥湿;葛根升举脾胃阳气。诸药联合可解毒消痈、清热利湿、健脾和胃,从而促进激素依赖型UC症状的缓解。

D-乳酸由肠道细菌产生,不能通过其他途径代谢,D-乳酸在肠道黏膜受损时可进入血液,因此可作为衡量肠道黏膜受损的指标^[19]。本研究对其进行探究显示,两组治疗前、治疗3周、6周血清D-乳酸水平依次降低,且治疗3周、6周时联合组明显低于灌肠组。提示,两种方法联合使用可有效降低D-乳酸水平。可能是因为芍药四君健脾方可补中气,调脾胃,可治本,与凉血止血、清热化湿的中药灌肠联合治疗能够标本兼治,改善局部症状的同时还可内调脏腑,修复肠道黏膜,进而使整体疗效得以提高。

综上所述,激素依赖型UC在常规西药治疗基础上使用中药灌肠联合芍药四君健脾方治疗可有效减轻炎症反应,改善患者临床症状,降低血清D-乳酸水平,效果较好。

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