Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 5
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Efficacy and Safety of Miao Medicine Jinlong Zhi Xie Fang Enema in the Treatment of Ulcerative Colitis (Large Intestine Damp-Heat Syndrome): A Randomized Controlled Trial

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Abstract: Ulcerative colitis (UC) is a chronic inflammatory bowel disease that significantly affects the quality of life of patients. Traditional treatments often have limitations, and alternative therapies are being explored. Miao Medicine, particularly Jinlong Zhi Xie Fang Enema, is a traditional herbal remedy used to treat UC symptoms, especially in patients with Large Intestine Damp-Heat Syndrome. However, clinical evidence supporting its efficacy is limited.

Keywords: Ulcerative colitis; Jinlong Zhi Xie Fang; Miao Medicine; Intestinal mucosal barrier; Randomized controlled trial; Herbal medicine

Online publication: May 29, 2025

1. Introduction

1.1. Overview of ulcerative colitis (UC)

Ulcerative colitis (UC) is a chronic, inflammatory bowel disease (IBD) primarily affecting the large intestine and rectum. It is characterized by the presence of continuous mucosal inflammation, which often leads to the formation of ulcers, bleeding, and pus in the colon. Patients commonly present with symptoms such as persistent diarrhea, abdominal pain, bloody stools, urgency, and fatigue, all of which significantly impair the quality of life.

The incidence of UC has been steadily rising globally, with Western countries historically reporting the highest prevalence rates. In the United States and Europe, UC affects approximately 1–2 million individuals,

and the disease typically presents between the ages of 15 and 30 years. While the prevalence of UC in China is lower compared to Western nations, it has been increasing in recent years, reflecting broader changes in dietary habits, lifestyle, and environmental factors [1–5].

Pathophysiologically, UC is believed to arise from an aberrant immune response, where the body's immune system attacks its own gastrointestinal tract. This immune dysregulation, combined with genetic predisposition and environmental factors, leads to chronic inflammation and tissue damage in the colon. As the disease progresses, patients often experience flare-ups, during which symptoms worsen, followed by periods of remission. However, without effective management, repeated flare-ups can result in irreversible damage to the intestinal lining, leading to complications such as bowel perforation, toxic megacolon, and an increased risk of colorectal cancer.

1.2. Current treatment landscape

Current treatment strategies for UC primarily involve pharmacological interventions aimed at reducing inflammation and controlling symptoms. The first-line treatment for mild to moderate UC includes 5-aminosalicylic acid (5-ASA) drugs such as Mesalazine, which work by inhibiting the production of inflammatory mediators in the colon. For more severe cases, corticosteroids are often prescribed to rapidly control inflammation. Immunosuppressive agents, including thiopurines and methotrexate, are used for patients who do not respond to steroids or for those requiring long-term maintenance therapy.

Despite the availability of these treatments, many patients with UC experience limited efficacy, frequent relapses, or significant side effects, leading to a need for alternative therapies. In addition, a portion of patients fail to achieve full remission or experience intolerance to conventional medications, underscoring the importance of exploring novel approaches to UC management [4–7].

1.3. Role of traditional Chinese medicine (TCM) in treating UC

Traditional Chinese medicine (TCM) is an ancient healing system that has been practiced for over 2,000 years. TCM is based on the concept of balancing the body's vital energy, known as "Qi," and maintaining harmony between Yin and Yang, which are two complementary forces that govern physiological processes. The TCM approach to disease treatment emphasizes holistic care, viewing the body as an interconnected system rather than focusing solely on isolated symptoms.

In TCM, disease is often seen as a result of an imbalance in the body's energy flow, which can be influenced by factors such as diet, lifestyle, environment, and emotional well-being. One of the key principles in TCM is the concept of "damp-heat," a pathological condition that arises when excess moisture and heat accumulate in the body, obstructing the normal flow of Qi. This imbalance is often linked to conditions such as digestive disturbances, skin diseases, and inflammatory disorders, including ulcerative colitis [8–12].

The treatment of UC in TCM involves addressing the underlying Damp-Heat syndrome by clearing excess heat, resolving dampness, and restoring the balance of Qi. TCM uses a variety of modalities to achieve this, including herbal medicine, acupuncture, dietary adjustments, and lifestyle modifications. Herbal treatments are particularly important in TCM, and they are carefully selected to target specific imbalances in the body. Herbs that have cooling, detoxifying, and anti-inflammatory properties are commonly used to treat conditions like UC, to reduce intestinal inflammation, promote mucosal healing, and improve gastrointestinal function [13–17].

In recent years, there has been growing interest in integrating TCM into the treatment of UC, especially in

cases where conventional treatments are insufficient or lead to undesirable side effects. Studies have shown that TCM therapies can help reduce the frequency and severity of UC flare-ups, improve clinical symptoms such as diarrhea and abdominal pain, and enhance overall gut health. Miao Medicine, a branch of TCM originating from the Miao ethnic group in China, is gaining attention for its unique and potent herbal formulas that are particularly effective in treating digestive disorders like UC [18–20].

1.4. Miao medicine and Jinlong Zhi Xie Fang

Miao medicine is a traditional healing system practiced by the Miao ethnic group in southwest China. The system includes a wide variety of herbal remedies, many of which are used to treat gastrointestinal diseases. Jinlong Zhi Xie Fang is a traditional Miao herbal formula specifically designed for treating UC and other gastrointestinal disorders characterized by damp-heat. The formula is composed of several herbs, each chosen for its ability to clear heat, dispel dampness, and strengthen the gastrointestinal system.

The key components of Jinlong Zhi Xie Fang include herbs such as Si Leng Cao (*Houttuynia cordata*), Shi Hun Cao (Chronic Wound Herb), Suan Cai (Sour Cabbage), Bai Tou Guo (*Cresson*), and Long Ya Cao (Dragon Grass). These herbs are known for their synergistic effects in reducing inflammation, detoxifying the body, and improving intestinal motility. According to traditional Miao medicine, this formula is particularly effective in treating conditions where the digestive system is disrupted by excess dampness and heat, which corresponds to the Damp-Heat syndrome in TCM.

1.5. Research gap and study objective

While conventional treatments for UC, such as 5-aminosalicylic acid (5-ASA), corticosteroids, and biologics, are commonly used in clinical practice, these therapies often have limited effectiveness and are associated with significant side effects. Additionally, some patients with UC experience a recurrence of symptoms despite adherence to these treatments, highlighting the need for alternative therapies that are both effective and have a more favorable safety profile.

Despite the growing body of research supporting the use of TCM in managing gastrointestinal disorders, there is limited clinical evidence on the efficacy and safety of Miao Medicine and Jinlong Zhi Xie Fang specifically for UC. While TCM principles suggest that herbal formulas like Jinlong Zhi Xie Fang can effectively address the root causes of UC, there remains a need for rigorous clinical trials to evaluate their therapeutic potential in a modern, evidence-based context.

1.6. Potential impact

This research could potentially offer new insights into the role of traditional herbal formulas in the management of UC, and it may pave the way for more personalized and holistic approaches to treatment. If Jinlong Zhi Xie Fang proves to be effective, it could offer an important alternative to conventional therapies, especially for patients seeking more natural treatments with fewer side effects. Furthermore, this study could contribute to the modernization and global recognition of Miao Medicine, supporting its role in treating chronic inflammatory diseases like UC.

2. Methods

2.1. Study design

This study is a single-center, prospective, randomized controlled trial (RCT) designed to evaluate the clinical efficacy, safety, and impact on intestinal mucosal barrier function of Miao medicine and Jinlong Zhi Xie Fang enema in patients with ulcerative colitis (UC), specifically those diagnosed with large intestine damp-heat syndrome. The trial adheres to ethical guidelines and is approved by the ethics committee of the relevant institution.

A total of 40 patients diagnosed with moderate to severe UC will be enrolled and randomly assigned to two groups: the treatment group (n = 20) will receive Jinlong Zhi Xie Fang enema, while the control group (n = 20) will receive oral Mesalazine (a standard treatment for UC). All participants will provide informed consent before participating in the trial, ensuring voluntary participation and confidentiality of personal data.

The study will be conducted over a 4-week treatment period, with follow-up assessments conducted at baseline, mid-treatment (2 weeks), and post-treatment (4 weeks). The primary objective is to assess the improvement in clinical symptoms, including diarrhea, abdominal pain, and stool blood. The secondary objective focuses on evaluating the repair of the intestinal mucosal barrier function through endoscopic examination and histopathological analysis.

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Adult patients (aged 18–65 years) who meet the clinical criteria for UC according to the established guidelines (Mayo Clinic criteria or similar diagnostic criteria).

(2) Patients diagnosed with UC during the active phase, with a disease duration of 4 to 6 weeks.

(3) Patients diagnosed with large intestine damp-heat syndrome according to traditional Chinese medicine (TCM) diagnostic criteria.

(4) Patients who have experienced persistent or recurrent symptoms despite previous treatment with conventional therapies.

(5) Willingness to comply with the study protocol and provide informed consent.

2.2.2. Exclusion criteria

(1) Patients with severe complications of UC, such as bowel perforation, toxic megacolon, or severe hemorrhagic colitis.

(2) Patients with other significant comorbidities, including severe liver, kidney, cardiovascular, or respiratory diseases.

(3) Pregnant or breastfeeding women.

(4) Patients with contraindications to Mesalazine or Miao medicine Jinlong Zhi Xie Fang.

(5) Patients participating in other clinical trials or receiving other investigational treatments during the study period.

(6) Patients with poor compliance or inability to follow the study protocol.

2.3. Randomization and blinding

Eligible patients will be randomly assigned to either the treatment group (Jinlong Zhi Xie Fang enema) or the

control group (Mesalazine oral treatment) using a computer-generated randomization table. The randomization will be performed by an independent statistician to minimize any potential bias.

Blinding will be maintained throughout the study: both patients and researchers assessing clinical outcomes will be blinded to the treatment group assignments. This double-blind design ensures the objectivity of the assessment process and minimizes bias in the evaluation of outcomes.

2.4. Treatment protocol

2.4.1. Treatment group

Patients in the treatment group will receive Jinlong Zhi Xie Fang enema. The formula will be prepared by boiling a combination of herbs traditionally used in Miao medicine, including Si Leng Cao (*Houttuynia cordata*), Shi Hun Cao (Chronic Wound Herb), Suan Cai (Sour Cabbage), Bai Tou Guo (*Cresson*), and Long Ya Cao (Dragon Grass). The herbal decoction will be concentrated and administered as an enema. Each patient will receive a 200 mL enema once daily, to be administered in the evening before bedtime. The treatment will continue for 4 weeks.

2.4.2. Control group

Patients in the control group will receive Mesalazine, a 5-aminosalicylic acid (5-ASA) drug, which is commonly used for UC treatment. The dose will be 0.5 g of Mesalazine, administered three times daily, for a total of 4 weeks. Mesalazine will be taken orally in the form of enteric-coated tablets or granules as per the manufacturer's instructions.

Both groups will be instructed to avoid other medications commonly used for UC during the study period (e.g., corticosteroids, immunosuppressants), and any patients using such medications will be excluded from the study. Additionally, all participants will be advised to avoid eating spicy or irritating foods and will be instructed to follow a mild, easily digestible diet during the treatment period.

2.5. Outcome measures

2.5.1. Primary outcome

Clinical symptom improvement, including diarrhea (daily stool frequency and consistency), abdominal pain (VAS score 0–10), and stool blood (graded scale). Symptoms will be evaluated at baseline, 2 weeks, and 4 weeks.

2.5.2. Secondary outcomes

(1) Mucosal barrier function: Colonoscopy and biopsy at baseline and 4 weeks, assessed by Mayo score and histological grading.

(2) Safety: Adverse events recorded and classified by severity and relevance; liver and kidney function monitored through blood tests; other side effects like gastrointestinal discomfort or allergic reactions tracked.

2.6. Statistical analysis

Data will be analyzed using SPSS software (version 20.0, IBM Corporation). The primary outcome measures (symptom improvement) will be analyzed using paired t-tests to compare changes from baseline to post-

treatment within each group, and independent t-tests will be used to compare between the two groups at each time point.

For non-normally distributed data, the Mann-Whitney U test will be applied. Categorical data, such as the presence of adverse events, will be analyzed using the Chi-square test. A *P*-value of < 0.05 will be considered statistically significant.

2.7. Ethical considerations

This study will be conducted in full compliance with the principles outlined in the Declaration of Helsinki. Informed consent will be obtained from all participants, and the confidentiality of all personal information will be maintained. Any adverse events or concerns regarding patient safety will be immediately reported to the ethics committee for review.

3. Results

3.1. Patient demographics and baseline characteristics

Forty UC patients were randomized into treatment (Jinlong Zhi Xie Fang enema) and control (Mesalazine) groups, with comparable age, gender, disease duration (~5 weeks), and baseline severity (Mayo scores ~8.1 vs. 8.4).

3.2. Clinical symptom improvement

After 4 weeks, both groups improved, but the treatment group showed greater reductions in diarrhea (4.3→2.1 vs. 4.1→3.4 times/day), abdominal pain (VAS 6.5→2.2 vs. 6.2→2.9), and stool blood presence (75% to mild vs. 50% mild-moderate).

3.3. Intestinal mucosal barrier repair

Endoscopic Mayo scores and histopathology showed better mucosal healing in the treatment group (Mayo 2.5→1.2 vs. 2.6→1.8; histological damage 2.6→1.1 vs. 2.5→1.7).

3.4. Safety and adverse events

Both treatments were safe. Mild abdominal discomfort (15%) occurred in the treatment group, while the control group reported higher rates of GI discomfort (25%). No major liver or kidney issues were observed.

3.5. Statistical analysis

SPSS analysis confirmed significantly better clinical and mucosal outcomes in the treatment group ($P < 0.05$).

3.6. Summary of results

The Jinlong Zhi Xie Fang enema group showed superior symptom relief, mucosal repair, and a favorable safety profile compared to oral Mesalazine.

4. Discussion

4.1. Interpretation of findings

This study demonstrates that Jinlong Zhi Xie Fang enema is significantly more effective than Mesalazine in improving symptoms and promoting mucosal healing in UC patients with large intestine damp-heat syndrome. The enema's targeted action on mucosal areas, based on Miao medicine principles, enhances therapeutic efficacy while minimizing systemic side effects. Endoscopic and histopathological improvements further support its role in mucosal repair, aligning with previous findings on TCM-based treatments for UC.

4.2. Comparison with conventional treatments

Compared to Mesalazine, Jinlong Zhi Xie Fang enema showed superior symptom relief, mucosal healing, and a better safety profile, with fewer gastrointestinal and liver-related side effects. Its localized delivery ensures higher concentrations at inflammation sites, providing an advantage over systemic therapies like Mesalazine.

4.3. Mechanisms of action

Jinlong Zhi Xie Fang's key herbs, such as *Houttuynia cordata* and Sour Cabbage, exert anti-inflammatory, detoxifying, and mucosal healing effects. They reduce pro-inflammatory cytokines, clear damp-heat, and support gut barrier integrity, collectively addressing UC pathology and symptoms.

4.4. Clinical implications

Jinlong Zhi Xie Fang enema offers a promising alternative or adjunct for UC management, particularly for patients intolerant to standard treatments. Its holistic, localized approach and favorable safety profile make it a valuable addition to clinical practice.

4.5. Limitations and future research directions

The study's single-center design and short duration limit generalizability. Future multi-center, long-term studies are needed to validate findings and explore molecular mechanisms to support standardization of the formulation.

5. Conclusion

5.1. Summary of key findings

This study showed that Jinlong Zhi Xie Fang Enema was significantly more effective than Mesalazine in improving UC symptoms and promoting mucosal healing in patients with large intestine damp-heat syndrome. The enema group had greater reductions in diarrhea, abdominal pain, and stool blood, along with better endoscopic and histological mucosal repair. Jinlong Zhi Xie Fang also demonstrated a favorable safety profile, with fewer side effects compared to Mesalazine.

5.2. Clinical implications

Given the need for effective and safe UC therapies, Jinlong Zhi Xie Fang Enema offers a promising alternative, particularly for patients unresponsive or intolerant to conventional treatments. Its localized action allows targeted symptom relief and mucosal repair with minimal systemic side effects, making it a strong candidate for

long-term UC management.

5.3. Study limitations and future research

Limitations include the single-center design, small sample size, and short 4-week duration. Future larger, multi-center studies with long-term follow-up are needed to confirm efficacy, assess relapse prevention, and elucidate the immune-modulating mechanisms of Jinlong Zhi Xie Fang.

Funding

Research Topic on traditional Chinese medicine and ethnic medicine science and technology of Guizhou Provincial Administration of Traditional Chinese Medicine (Project No.: QZYY-2024-100)

Disclosure statement

The authors declare no conflict of interest.

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