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Comparison of enema and oral administration of Hongteng decoction: a randomized controlled study based on inflammatory markers and pelvic microenvironment

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Abstract: Objective: To investigate the comparative effects of enema and oral administration of Hongteng decoction on inflammatory markers and the pelvic microenvironment in patients with chronic pelvic inflammatory disease (CPID) to provide empirical support for the development of clinical treatment plans. **Methods:** 120 patients with CPID admitted to our hospital between March 2021 and March 2023 were randomly divided into an enema group and an oral administration group, 60 patients in each group. The enema group received enema treatment with Hongteng decoction, while the oral administration group received oral administration with Hongteng decoction. Both groups were treated for 4 consecutive weeks. The two groups were compared before and after treatment for inflammatory markers (interleukin-6 (IL-6), tumor necrosis factor-α (TNF-α), and C-reactive protein (CRP)), pelvic microenvironmental indicators (pelvic blood flow resistance index and pelvic effusion volume), and clinical efficacy. **Results:** After treatment, IL-6, TNF-α, and CRP levels were lower in both groups than before treatment, with those in the enema group lower than those in the oral administration group ($P < 0.05$). Both groups showed lower pelvic blood flow resistance indexes and less pelvic fluid volume than before treatment, with the enema group showing greater improvement than the oral group ($P < 0.05$). The total effective rate in the enema group was 93.33%, higher than the oral group's 80.00% ($P < 0.05$). **Conclusion:** Hongteng decoction enema treatment for chronic pelvic inflammatory disease surpasses oral administration in reducing inflammatory markers, improving the pelvic microenvironment, and enhancing clinical efficacy, suggesting great potential for clinical application.

Keywords: Hongteng decoction, enema, oral administration, chronic pelvic inflammatory disease, inflammatory markers, pelvic microenvironment

0 Introduction

Chronic pelvic inflammatory disease is a common gynecological disease, which is often caused by incomplete or prolonged treatment of acute pelvic inflammatory disease. Patients with pelvic inflammatory disease often experience symptoms of lower abdominal distension, pain, and discomfort in the lumbar region, which often recur, and their quality of life suffers a major setback [1]. Antibiotics are widely used in the treatment of chronic pelvic inflammatory disease. Long-term use of antibiotics may induce side effects such as drug resistance and intestinal flora imbalance. Hongteng decoction has a pharmacological mechanism of clearing heat and detoxifying, promoting blood circulation and removing blood stasis, and reducing swelling and relieving pain. It is widely used in the treatment of chronic pelvic inflammatory disease. Inconsistency in the route of administration may have a restrictive effect on the efficacy [2].

In recent years, the application of traditional Chinese medicine in chronic pelvic inflammatory disease has been increasingly studied. Ye Zixing et al. used a self-prepared Hongteng decoction combined with acupuncture to treat chronic pelvic inflammatory disease and found that this regimen can significantly reduce the serum IL-4 and TGF-β1 levels of patients and correct immune disorders. Hongteng decoction has an outstanding performance in regulating the balance of inflammatory factors [3]. In the study of pelvic pain symptoms, Chen Xiuling et al. used enema of Euonymus and Red Vine Decoction combined with moxibustion for treatment, and the patients' pain condition was significantly improved. The combination of Chinese medicine enema and physical therapy significantly enhanced the improvement effect of chronic pelvic pain [4]. In the treatment of pelvic inflammation-related diseases, according to the research of Yao Shuiling et al., the "internal and external treatment" method of taking Dan Bie capsules orally and applying Sihuang powder externally can effectively improve the treatment effect of chronic pelvic pain [5]. The research of Binyang et al. showed that when oral Chinese patent medicine is used as an auxiliary treatment for chronic pelvic pain syndrome, the efficacy is closely related to the route of drug administration and the effect of the drug reaching the affected area [6]. This experiment uses a randomized controlled method to explore the comparative effect of enema and oral administration of Red Vine Decoction on inflammatory indicators and pelvic microenvironment, aiming to provide empirical support for the optimization of treatment plans.

1 Subjects and Methods

1.1 Basic Data

A review of 120 cases of chronic pelvic inflammatory disease admitted to our hospital between March 2021 and March 2023 was conducted. The inclusion criteria were as follows: diagnosis based on the diagnostic criteria for chronic pelvic inflammatory disease in the Journal of Obstetrics and Gynecology [7]. Age range: 18 to 50 years old. Voluntary participation in this experiment and signing of informed consent. Exclusion criteria: patients with severe liver and kidney failure. Individuals allergic to the ingredients of Hongteng Decoction. Pregnant and lactating women. Cases who had recently received antibiotics and immunosuppressants. According to the random number table method, they were divided into enema group and oral group. The age distribution ranged from 20 to 48 years old, with an average age of 32.56 years old and a standard deviation of 5.21 years old. The duration of the disease ranged from half a year to five years, with an average duration of 2.31 years and a standard deviation of 0.87 years. The age range was between 19 and 49 years old, with an average age of 33.12 years old and an age fluctuation range of ±5.34 years old. The duration of the disease ranged from 5 months to 6 years, with an average duration of 2.45 years and a coefficient of variation of ±0.92 years. The basic data of the two groups were examined, $P>0.05$, and the comparison results were not statistically significant, and the data of the two groups were comparable.

1.2 Treatment Methods

Both groups received Hongteng Decoction, consisting of: Hongteng 30g, Patrinia 30g, Taraxacum mongolicum 30g, Viola yedoensis 20g, Lonicera japonica 20g, Forsythia suspensa 15g, Paeonia lactiflora 15g, Paeonia suffruticosa 15g, Prunus persica 10g, Carthamus tinctorius 10g, Corydalis yanhusuo 15g, and Licorice root 6g. The decoction was prepared uniformly by our hospital's Chinese medicine pharmacy, with each dose containing 400mL of decoction.

Enema Group: Patients were placed in the left lateral decubitus position, and the temperature of the decoction was maintained between 38 and 40°C. A 50mL syringe was connected to the anal canal and gradually advanced to a point 15 to 20cm into the anus. The decoction was then slowly injected, maintaining a retention period of at least 30 minutes. Treatment continued for four weeks.

Oral Group: 200mL was taken twice daily for four weeks.

1.3 Observation Indicators

① Inflammatory markers: Before and after treatment, 5 mL of fasting venous blood was drawn from the patients, and the serum was centrifuged. IL-6 and TNF-α were quantitatively analyzed using enzyme-linked immunosorbent assay (ELISA) and CRP levels were evaluated using immunoturbidimetric methods. The kits used in this study were purchased from Shanghai ELISA Biotechnology Co., Ltd. and were strictly followed in accordance with the kit instructions. ② Pelvic microenvironment indicators: Before and after treatment, a specific color Doppler ultrasound detection system (Philips IU22) was used to detect pelvic blood flow resistance index and effusion volume. ③ Clinical efficacy: The evaluation was conducted in accordance with the "Guidelines for Clinical Research of New Chinese Medicines" [8]. Cured: Symptoms and signs have completely disappeared, and the pelvic ultrasound examination result is negative. Significantly effective: The condition and signs are significantly relieved, and the pelvic effusion volume has decreased by more than 70%. Effective: The condition and signs show positive changes, and the pelvic effusion volume has decreased by 30% to 69%. Ineffective: Symptoms have not improved, or have worsened, and the amount of pelvic effusion has decreased by less than 30%. The total effective rate is calculated as follows: Total effective rate = (number of cured cases + markedly effective cases + effective cases) / total number of cases × 100%.

1.4 Statistic Analysis

SPSS 22.0 software was used to perform statistical analysis of the data. The results were presented in the format of ($x \pm s$). Paired *t*-tests were used for internal comparisons, and independent sample *t*-tests were used to test differences between groups. Data were counted in the format of [n (%)], and differences between data were analyzed using the χ^2 test. A *P* of less than 0.05 was considered the critical point for determining statistical significance.

2 Results

2.1 Comparison of inflammatory marker levels between the two groups before and after treatment

Before treatment, there was no statistically significant difference in IL-6, TNF-α, and CRP levels between the two groups ($P>0.05$). After treatment, IL-6, TNF-α, and CRP levels were lower in both groups, with those in the enema group lower than those in the oral group ($P<0.05$). See Table 1.

Table 1 Comparison of inflammatory marker levels between the two groups before and after treatment ($x \pm s$)

Group	Number of cases	time	IL-6 (pg /mL)	TNF-α (pg /mL)	CRP (mg/L)
Enema group	60	Before treatment	35.21±5.67	28.34±4.21	25.67±4.89
		After treatment	12.34±3.12	10.21±2.34	8.76±2.15
Oral group	60	Before treatment	34.89±5.43	27.98±4.05	24.98±4.67
		After treatment	18.76±3.89	15.67±2.89	13.45±2.67

2.2 Comparison of pelvic microenvironment indicators between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the pelvic blood flow resistance index and pelvic effusion volume between the two groups (P>0.05) . After treatment, the pelvic blood flow resistance index and pelvic effusion volume in both groups were lower than before treatment, and the enema group showed greater improvement than the oral group (P<0.05). See Table 2.

Table 2 Comparison of pelvic microenvironmental indicators before and after treatment between the two groups (x±s)

Group	Number of cases	time	Pelvic blood flow resistance index	Pelvic fluid volume (mL)
Enema group	60	Before treatment	0.78±0.12	35.67±8.21
		After treatment	0.52±0.08	10.21±3.12
Oral group	60	Before treatment	0.77±0.11	34.98±7.89
		After treatment	0.63±0.09	18.76±4.21

2.3 Comparison of clinical efficacy between the two groups

The total effective rate of the enema group was 93.33%, higher than the 80.00% of the oral group (P < 0.05). See Table 3.

Table 3 Comparison of clinical efficacy between the two groups [n (%)]

Group	Number of cases	get well	Significant effect	efficient	invalid	Total efficiency
Enema group	60	25 (41.67)	20 (33.33)	11 (18.33)	4 (6.67)	56 (93.33)
Oral group	60	18 (30.00)	16 (26.67)	14 (23.33)	12 (20.00)	48 (80.00)

3 Discussion

Chronic pelvic inflammatory disease has a long course and is a major challenge in clinical treatment. Its pathological core lies in the persistent inflammatory response and chronic damage to the pelvic microenvironment [9]. This study compared the efficacy of different routes of administration of Hongteng Decoction, further revealing the unique advantages of local administration in the treatment of chronic inflammatory diseases.

From the perspective of traditional Chinese medicine theory, the pathological core of chronic pelvic inflammatory disease is the pathological changes of "damp-heat and blood stasis", and the disease is located in the lower pelvic cavity. Hongteng Decoction contains herbs such as Hongteng and Patrinia. It clears away heat and detoxifies the "damp-heat" evil spirit, and herbs such as red peony root and peach kernel that activate blood circulation and remove blood stasis directly attack the root cause of the "blood stasis" pathology. By implementing enteral administration, the drug is absorbed through the rectal mucosa and acts directly on the pelvic lesions, which is consistent with the treatment principle of "adjacent administration" in traditional Chinese medicine. Modern pharmacological studies have confirmed that the emodin contained in red vine and the oleanolic acid contained in Patrinia serrata have the effect of inhibiting bacterial biofilm formation and reducing macrophage overactivation. The concentration of the components in the pelvic cavity can be significantly increased, reducing the reduction in bioavailability caused by the first-pass effect in the liver after oral administration [10].。

The reduction in inflammatory markers was particularly significant in the enema group. The potential mechanism of this effect may be derived from the anatomical characteristics of the rectal venous plexus. The blood from the lower rectal vein directly enters the pelvic venous plexus, allowing the drug components to quickly reach the site of inflammation, limiting the activation of the NF-κB signaling pathway and reducing the secretion of

inflammatory inducing factors such as IL-6 and TNF-α. The local application of high-concentration drugs has a significant effect on the repair of peritoneal damage and enhances the absorption capacity of inflammatory exudates. It can be inferred that the phenomenon of enema treatment significantly reducing pelvic effusion can be explained. Color Doppler ultrasound examination showed a decrease in the pelvic blood flow resistance index, which may enhance the function of pelvic microcirculation, optimize the local tissue oxygen delivery mechanism, correct chronic hypoxia, and thus reverse the vicious cycle of "inflammation-hypoxia-fibrosis".

The difference in efficacy may be related to patient compliance. The bitter taste of the oral formulation of Hongteng Tang (Red Vine Decoction) and the wide range of dosages required may have forced some patients to discontinue treatment due to gastrointestinal discomfort. Although enema treatment is somewhat invasive, this study meticulously optimized the anal insertion depth (15-20 cm) and the temperature of the solution (38-40°C), significantly reducing patient pain. All subjects successfully completed the four-week treatment cycle. Notably, the four patients who did not respond to enema treatment all had a history of pelvic adhesions, with a duration of more than three years and severe fibrosis. Combining enema with oral medication is recommended, or physical therapy may be used to enhance efficacy.

This study did not verify the actual difference in drug concentrations in the blood and pelvic fluid, and the observation period was too short, and the recurrence rate of the two routes of administration was not examined. The use of pharmacokinetic methods is expected to accurately outline the relationship between the dose and efficacy of enema administration, and conduct long-term follow-up to analyze the matching between inflammatory markers and the risk of disease recurrence, providing a more accurate basis for the individualized treatment of chronic pelvic inflammatory disease.

4 Conclusion

In summary, in the treatment of chronic pelvic inflammatory disease, Hongteng decoction enema stands out for its proven efficacy, rapid results, and high safety. It regulates the inflammatory response and pelvic microenvironment in a multi-target manner, contributing a core reference to the optimization of chronic pelvic inflammatory disease treatment options. Primary care and TCM gynecology fields should adopt this therapy for promotion, further expand the research sample size, integrate pharmacokinetic analysis and long-term follow-up data sets, and provide more accurate evidence-based medicine for the development of individualized treatment plans.

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