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Modified Shaofu Zhuyu Decoction Oral Administration Combined with Sequential Herbal Compress Therapy for Sequelae of Pelvic Inflammatory Disease with Cold-Dampness Stagnation: A Clinical Efficacy Study

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Abstract: ***Objective:*** *To investigate the clinical efficacy and impact on patients' quality of life of the combined treatment of modified Shaofu Zhuyu Decoction for oral administration and sequential herbal compress therapy in treating sequelae of pelvic inflammatory disease (SPID) characterized by cold-damp stagnation.* ***Methods:*** *A total of 80 patients with cold-damp stagnation-type SPID who visited Xi'an People's Hospital (Xi'an Fourth Hospital) from January 2024 to January 2026 were selected and divided into a control group and an observation group (40 patients each) using a random number table. The control group received levofloxacin combined with metronidazole, while the observation group received the same regimen plus oral administration of modified Shaofu Zhuyu Decoction combined with sequential herbal compress therapy (Tazhi). Both groups underwent treatment for 4 weeks. Clinical efficacy, TCM syndrome scores, local physical signs scores, Visual Analogue Scale (VAS) for pain, McCormack scores, SF-36 quality of life scores, and adverse reactions were compared between the two groups.* ***Results:*** *The overall response rate in the observation group was 92.50%, higher than the 75.00% in the control group ($P < 0.05$). After treatment, the TCM syndrome scores, local physical signs scores, VAS scores, and McCormack scores in the observation group were all lower than those in the control group ($P < 0.05$); the SF-36 scores for bodily pain, physical functioning, role-physical, and general health were higher in the observation group than in the control group ($P < 0.05$). There was no statistically significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$).* ***Conclusion:*** *The sequential therapy combining oral administration of modified Shaofu Zhuyu Decoction with herbal compress therapy demonstrates significant efficacy in treating SPID of the cold-damp stagnation pattern. It effectively improves patients' clinical symptoms, physical signs, and quality of life, alleviates pain, and is safe and reliable.*

Keywords: Shaofu Zhuyu Decoction, Herbal compress therapy, Sequelae of pelvic inflammatory disease, Quality of life.

1. Materials and Methods

1.1 General Information

This study included 80 patients with SPID of the cold-damp stagnation pattern who received outpatient or inpatient treatment at Xi'an People's Hospital (Xi'an No. 4 Hospital) from January 2024 to January 2026. They were randomly divided into two groups, with 40 patients in each group. This study protocol was approved by the hospital's Medical Ethics Committee (Ethics Approval No.: KJLL-Z-K-2026008).

1.2 Diagnostic Criteria

1.2.1 Western Medical Diagnostic Criteria

Established in reference to Obstetrics and Gynecology (9th Edition) [1] and Guidelines for the Diagnosis and Treatment of Pelvic Inflammatory Disease (2019 Revised Edition) [2]: (1) A clear history of acute pelvic inflammatory disease; (2) Lower abdominal or lumbosacral pain, often exacerbated by physical exertion, sexual intercourse, or around the menstrual period; (3) Gynecological examination reveals uterine tenderness, restricted mobility, or fixation; cord-like thickening or masses may be palpable in the adnexal region; and the uterosacral ligaments are thickened with tenderness; (4) Symptoms have persisted for ≥6 months; (5) Pelvic ultrasound shows fluid accumulation or inflammatory masses.

1.2.2 Traditional Chinese Medicine Diagnostic Criteria

Based on the relevant criteria for the pattern of cold-dampness stagnation in the Guidelines for Clinical Research on New Traditional Chinese Medicines (Trial) [3] and Integrated Traditional Chinese and Western Obstetrics and Gynecology [4]. Primary symptoms: (1) Cold or stabbing pain in the lower abdomen, fixed and unmoving, relieved by warmth; (2) Cold pain in the lumbosacral region; (3) Profuse, white, and thin vaginal discharge. Secondary Symptoms: (1) Delayed menstruation or scanty menstrual flow; (2) Worsening of lower back and abdominal pain during menstruation; (3) Aversion to cold and cold extremities; (4) Fatigue and weakness; (5) Frequent urination. Tongue and Pulse: Dark tongue body, white and greasy coating, deep and string-like or tight and string-like pulse. A diagnosis can be established if two or more primary symptoms and two or more secondary symptoms are present, combined with the tongue and pulse findings.

1.3 Inclusion Criteria

(1) Simultaneous fulfillment of the aforementioned Western and Traditional Chinese medical diagnostic criteria; (2) Age 22–45 years; (3) History of sexual activity; (4) Disease

duration ≥6 months; (5) Generally regular menstrual cycle.

1.4 Exclusion Criteria

(1) Patients with concomitant gynecological conditions such as uterine fibroids, endometriosis, or ovarian tumors; (2) Patients with severe primary diseases of the heart, liver, kidneys, or hematopoietic system; (3) Pregnant or lactating women; (4) Patients who have participated in other clinical trials within the past 3 months; (5) Patients with allergies to the study drug; (6) Patients with concomitant psychiatric disorders or cognitive impairment; (7) Patients with acute or chronic pelvic tuberculosis.

1.5 Criteria for Withdrawal and Exclusion

(1) Participants who were inadvertently enrolled despite not meeting the inclusion criteria; (2) Participants unable to adhere to the prescribed medication regimen; (3) Participants who voluntarily withdrew or were lost to follow-up during treatment; (4) Participants who developed severe hepatic or renal dysfunction or significant adverse reactions; (5) Participants with a history of allergies.

1.6 Treatment Methods

1.6.1 Control Group

Received standard Western medical treatment. Levofloxacin tablets 0.5 g per dose, taken orally once daily; metronidazole tablets 0.4 g per dose, taken orally three times daily. Treatment was administered continuously for 4 weeks and discontinued during menstruation.

1.6.2 Observation Group

In addition to the treatment in the control group, patients received oral administration of modified Shaofu Zhuyu Decoction combined with sequential herbal compress therapy.

1) Modified Shaofu Zhuyu Decoction for oral administration:

Ingredients: Foeniculum vulgare (Xiaohuixiang) 10 g, Fried Ginger (Pao Jiang) 6 g, Corydalis yanhusuo (Yanhusuo) 20 g, Myrrh (Mo Yao) 10 g, Angelica sinensis (Danggui) 10 g, Ligusticum chuanxiong (Chuanxiong) 12 g, Cinnamomum cassia (Rougui) 6 g, Paeonia rubra (Chishao) 15 g, Pollen Typhae (Puhuang) 10 g, Faeces Trogopterori (Wulingzhi) 10 g, Cynanchum paniculatum (Xu Changqing) 12 g, Achyranthes bidentata (Niuxi) 15 g.

Administration: Decoct in water and take 150 mL per dose, divided into two doses (morning and evening) taken warm. One dose per day. Continue for 4 weeks.

2) Herbal compress therapy (Tazhi): After decocting the oral medication, add water to the remaining herbal residue and simmer for 30 minutes. Strain the liquid, then take an appropriate amount of gauze and fully soak it in the liquid. Remove after 3 minutes and set aside. The patient lies supine with the lower abdomen fully exposed. Place the soaked, damp (but not dripping) gauze (at 40°C) over the lower abdomen in two layers, approximately 20 cm × 15 cm in size. Spread the herbal residue evenly over the gauze to a thickness of approximately 3 cm. Cover with plastic wrap and apply localized irradiation using a TDP therapy device. Position the lamp approximately 15 cm from the skin; adjust the intensity to ensure patient comfort as needed. Treatment duration is approximately 20 minutes, twice weekly. Begin on the second day after menstruation has ceased and continue for 4 consecutive weeks.

1.7 Observation Indicators

1.7.1 Traditional Chinese Medicine Syndrome Score

The SPID Traditional Chinese Medicine Syndrome Scoring Scale was developed in accordance with the Guidelines for Clinical Research on New Traditional Chinese Medicines (Trial) [3]. Primary symptoms (lower abdominal pain, lumbosacral pain, abnormal vaginal discharge) were scored as 0, 2, 4, or 6 points for “none,” “mild,” “moderate,” and “severe,” respectively; secondary symptoms (menstrual irregularities, aversion to cold with cold extremities, fatigue and weakness, and urinary abnormalities) were scored as 0, 1, 2, and 3 points for “none,” “mild,” “moderate,” and “severe,” respectively. Tongue and pulse findings were used for reference only and were not included in the total score. A higher total score indicates more severe symptoms.

1.7.2 Local Physical Signs Scoring

Referring to the literature [5,6], a local physical signs scoring scale for SPID patients in this study was developed, including uterine mobility and uterine tenderness. Each item is scored on a scale of 1 to 4 (1 indicates normal, 4 indicates severe abnormality); a higher score indicates more severe local physical signs. See the footnote in Table 2 for specific scoring criteria.

1.7.3 Pain Assessment

The Visual Analogue Scale (VAS) [7] was used to assess the severity of lower abdominal pain in patients. The scoring range is 0–10, where 0 indicates no pain and 10 indicates severe pain; a higher score indicates more severe pain. The McCormack score [8] was used to assess patients’ pelvic tenderness, with a scoring range of 0–3, where 0 indicates no pain and 3 indicates a reaction of extreme distress.

1.7.4 Quality of Life Assessment

The SF-36 Health Status Survey [9] was used to assess patients’ quality of life. This survey comprises eight dimensions: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. Each dimension is scored on a scale of 0–100, with higher scores indicating better quality of life.

1.8 Criteria for Determining Efficacy

Efficacy evaluation criteria were established in accordance with the Guidelines for Clinical Research on New Traditional Chinese Medicines (Trial) [3]. Clinical Cure: All symptoms and signs have disappeared, and the reduction in TCM syndrome scores is no less than 90%; Marked Improvement:

Clinical symptoms and signs have improved significantly, with a reduction in scores of 70%–<90%; Improvement: Symptoms and signs have improved somewhat, with a reduction in scores of 30%–<70%; No Effect: The above criteria were not met, or symptoms and signs worsened, with a reduction in scores of less than 30%.

1.9 Statistical Methods

Data analysis was performed using SPSS 26.0 statistical software. Quantitative data conforming to a normal distribution are expressed as mean ± standard deviation ($\bar{x} \pm s$). Paired t-tests were used for intra-group comparisons, and independent samples t-tests were used for inter-group comparisons; categorical data are expressed as cases (%) and were compared between groups using the chi-square (χ^2) test; ordinal data were compared between groups using the rank-sum test. A P-value < 0.05 was considered statistically significant.

2. Results

2.1 Baseline Comparison

Comparison revealed no statistically significant differences between the two groups in baseline characteristics such as age, duration of illness, BMI, number of pregnancies, number of deliveries, and VAS scores (P > 0.05), indicating that the two groups were comparable. See Table 1.

Table 1: Comparison of Baseline Characteristics ($\bar{x} \pm s$)

Item	Control Group (n=40)	Observation Group (n=40)	P-value
Age (years)	34.85 ± 6.32	35.12 ± 5.98	0.842
Duration of illness (months)	10.58 ± 2.36	10.72 ± 2.18	0.778
BMI (kg/m²)	21.85 ± 2.14	22.03 ± 2.06	0.703
Number of pregnancies	1.85 ± 0.76	1.92 ± 0.82	0.692
Number of deliveries	1.28 ± 0.45	1.32 ± 0.48	0.701
VAS score (points)	5.78 ± 1.24	5.85 ± 1.18	0.797
McCormack score (points)	2.85 ± 0.62	2.92 ± 0.58	0.605

2.2 Comparison of Clinical Efficacy

The overall response rate was 92.50% in the observation group and 75.00% in the control group; the difference between the two groups was statistically significant (P < 0.05). See Table 2.

Table 2: Comparison of Clinical Efficacy [Cases (%)]

Efficacy	Control Group (n=40)	Observation Group (n=40)	P-value
Clinical Cure	8 (20.00)	14 (35.00)	
Marked improvement	12 (30.00)	16 (40.00)	
Effective	10 (25.00)	7 (17.50)	
Invalid	10 (25.00)	3 (7.50)	
Total effective	30 (75.00)	37 (92.50)	0.035

2.3 Comparison of Traditional Chinese Medicine Syndrome Scores Before and After Treatment

After treatment, the scores for primary symptoms, secondary symptoms, and total scores in both groups were significantly lower than before treatment (P < 0.05), with a greater reduction observed in the observation group. All indicators were lower in the observation group than in the control group (P < 0.05). See Table 3.

Table 3: Comparison of TCM syndrome scores before and after treatment ($\bar{x} \pm s$, points)

Group	Time	Primary Symptom Score	Secondary Symptom Score	Total Score
Control group (n=40)	Before treatment	12.85 ± 2.36	7.42 ± 1.58	20.27 ± 3.42
	Post-treatment	7.68 ± 1.52#	4.35 ± 1.12#	12.03 ± 2.28#
Observation group (n=40)	Before treatment	12.92 ± 2.18	7.55 ± 1.62	20.47 ± 3.28
	Post-treatment	5.25 ± 1.28#*	2.85 ± 0.95#*	8.10 ± 1.85#*

Note: # Compared with pre-treatment values in the same group, P < 0.05; * Compared with post-treatment values in the control group, P < 0.05.

2.4 Comparison of Local Physical Examination Scores Before and After Treatment

After treatment, both groups showed a significant decrease in uterine mobility and tenderness compared to pre-treatment levels (P < 0.05), and the observation group showed significantly lower scores than the control group (P < 0.05). See Table 4.

Table 4: Comparison of Local Physical Examination Scores Before and After Treatment ($\bar{x} \pm s$, points)

Group	Time	Uterine Mobility	Uterine Tenderness
Control group (n=40)	Pre-treatment	3.12 ± 0.68	3.05 ± 0.72
	Post-treatment	2.35 ± 0.62#	2.28 ± 0.65#
Observation group (n=40)	Pre-treatment	3.08 ± 0.72	3.12 ± 0.68
	Post-treatment	1.85 ± 0.58#*	1.72 ± 0.55#*

Note: # Compared with pre-treatment values within the same group, P < 0.05; * Compared with post-treatment values in the control group, P < 0.05.

2.5 Comparison of Pain Scores Before and After Treatment

After treatment, both the VAS scores and McCormack scores in both groups decreased significantly compared to pre-treatment levels (P < 0.05), and the observation group's scores for these indicators were lower than those of the control group (P < 0.05). See Figure 1.

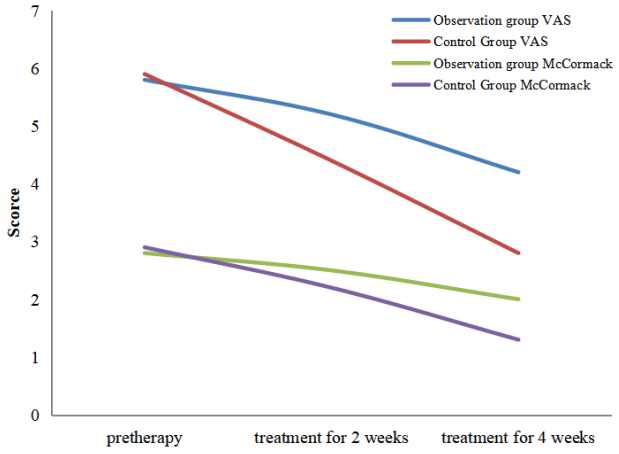

Figure 1: Trends in pain scores before and after treatment

2.6 Comparison of Quality of Life Scores Before and After Treatment

After treatment, the scores for all dimensions of the SF-36 in both groups increased compared to pre-treatment levels (P <

0.05), and the observation group's scores for bodily pain, physical functioning, role-physical, and general health were all higher than those of the control group ($P < 0.05$). See Figure 2.

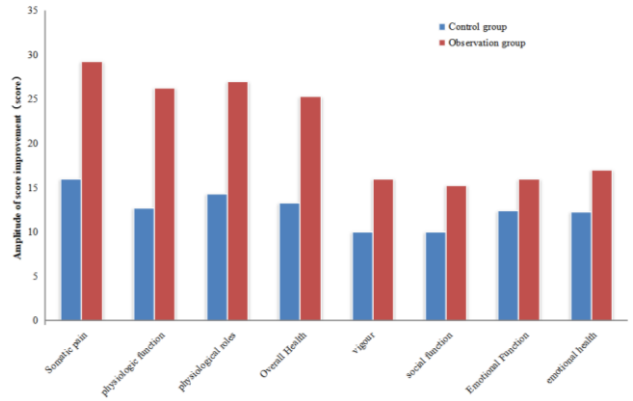

Figure 2: Comparison of improvements in SF-36 quality of life scores before and after treatment

2.7 Safety Evaluation

During treatment, the control group experienced gastrointestinal discomfort in 3 cases (7.50%) and rash in 1 case (2.50%), with an adverse reaction incidence rate of 10.00% (4/40); the observation group experienced gastrointestinal discomfort in 2 cases (5.00%) and mild skin itching in 1 case (2.50%), resulting in an adverse reaction incidence rate of 7.50% (3/40). Comparison of adverse reaction incidence rates between the two groups showed no statistically significant difference ($P > 0.05$). Adverse reactions in both groups were mild and resolved spontaneously without special treatment or discontinuation of medication.

3. Discussion

Sequelae of pelvic inflammatory disease (SPID) are common and frequently occurring conditions in gynecological clinical practice. They primarily refer to pathological states resulting from incomplete resolution of infectious diseases of the female upper reproductive tract following the acute phase, with chronic pelvic pain, pelvic adhesions, and infertility as the main clinical manifestations [10]. Among these, the pattern of cold-damp stagnation is one of the common syndromes of SPID. It often arises when the uterine orifice remains open during menstruation or postpartum, allowing pathogenic cold and dampness to invade the body through its vulnerability. These pathogens interact with qi and blood, causing stasis and obstruction in the Chong and Ren meridians and the uterus, leading to impaired circulation of qi and blood — a condition where obstruction results in pain [11]. Modern medicine holds that the pathogenesis of SPID is closely associated with factors such as persistent pathogen infection, inflammatory responses, immune dysfunction, pelvic tissue adhesions, and circulatory disorders [12]. Currently, Western medical treatment for SPID primarily relies on antibiotics; while these can eliminate pathogens, they fail to effectively repair the pathological damage caused by the pathogens. Furthermore, long-term use can lead to drug resistance, resulting in suboptimal therapeutic outcomes [13]. Traditional Chinese medicine (TCM) offers unique advantages in treating SPID, emphasizing syndrome differentiation and holistic regulation, and demonstrating significant efficacy in alleviating symptoms and reducing recurrence [14]. Shaofu Zhuyu Decoction originates from Wang Qingren's Corrections in Medical Forest (Yi Lin Gai Cuo) of the Qing Dynasty and is a classic formula for treating the syndrome of cold stagnation and blood stasis in the lower abdomen. In this formula, Foeniculum vulgare, Zingiber officinale, and Cinnamomum cassia warm the meridians, dispel cold, and promote blood circulation; Angelica sinensis, Ligusticum chuanxiong, and Paeonia rubra nourish and invigorate the blood, remove blood stasis, and relieve pain; Pollen Typhae and Faeces Trogopterori (from Shixiao San) invigorate blood, remove blood stasis, disperse nodules, and relieve pain; Corydalis yanhusuo and Myrrh regulate qi, invigorate blood, reduce swelling, and alleviate pain. The combined action of these herbs achieves the effects of warming the meridians and dispelling cold, invigorating blood and resolving stasis, and regulating qi to relieve pain, which aligns with the pathogenetic characteristics of the cold-damp stagnation pattern in SPID [15].

The results of this study show that the overall response rate in the observation group was 92.50%, significantly higher than the 75.00% in the control group, suggesting that the combined treatment of oral Shaofu Zhuyu Decoction with modifications and sequential herbal compress therapy is significantly effective for cold-damp stagnation type SPID. After treatment, both the TCM syndrome score and local physical signs score in the observation group were significantly lower than those in the control group, indicating that this combined therapy can effectively improve patients' clinical symptoms and physical signs. Analysis of the mechanisms suggests that the modified Shaofu Zhuyu Decoction administered orally exerts a systemic regulatory effect by warming the meridians, dispelling cold, and promoting blood circulation to resolve stasis; meanwhile, the herbal compress therapy, as an external treatment in TCM, allows the medication to act directly on the affected area through transdermal absorption, reaching the site of the disease to enhance local blood circulation, promote the resolution of inflammation, and release tissue adhesions, thereby achieving a combined internal and external treatment that addresses both the symptoms and the root cause [16]. Chronic pelvic pain is the primary clinical symptom in patients with SPID and severely impacts their quality of life. In this study, both the VAS scores and McCormack scores in the observation group were significantly lower than those in the control group, and improvements in dimensions such as bodily pain, physical functioning, role-physical, and general health on the SF-36 questionnaire were also superior to those of the control group ($P < 0.05$). This suggests that the combined therapy can effectively alleviate pain and improve quality of life, which may be related to its ability to improve local pelvic blood circulation, reduce inflammatory responses, release tissue adhesions, and promote the repair of damaged tissues [17].

In summary, the combination of oral Shaofu Zhuyu Decoction with modified formula and sequential herbal compress therapy for the treatment of SPID of the cold-damp stagnation pattern is effective. It can significantly improve patients' clinical symptoms and signs, alleviate pain, and enhance quality of life. Given the limited sample size and short observation period in this study, future research should expand the sample size and extend the follow-up period to

further validate the long-term efficacy and mechanism of action of this treatment regimen.

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Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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