

Study on the Efficacy of Jingangteng Combined with Doxycycline in the Treatment of Chronic Pelvic Inflammatory Disease and the Clinical Manifestations of the Influence of Inflammatory Factors

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Abstract: Chronic pelvic inflammatory disease (CPID) is a common gynecological infectious disease in women of childbearing age. It is characterized by a long course and is difficult to cure. Traditional antibiotic treatment has limitations. This prospective, randomized, controlled clinical trial evaluated the clinical efficacy of jingangteng combined with doxycycline in the treatment of CPID and its effects on inflammatory factors. Sixty patients were randomly divided into an experimental group (combination therapy group) and a control group (doxycycline monotherapy group), with 30 patients in each group. Results showed that the total effective rate in the experimental group was 93.3%, significantly higher than the 76.7% in the control group ($P < 0.05$). After treatment, serum levels of the inflammatory factors IL-6, TNF- α , and CRP in the experimental group were significantly lower than those in the control group, while levels of the anti-inflammatory factor IL-10 were significantly higher in the control group ($P < 0.01$). Combination therapy exerts a synergistic anti-inflammatory effect by inhibiting the release of pro-inflammatory factors and promoting the expression of anti-inflammatory factors, with a good safety profile. Studies have shown that the combination of *Vatica chinensis* and doxycycline is safe and effective in treating CPID, and can significantly relieve symptoms, regulate inflammatory responses, and reduce the risk of disease recurrence and sequelae, providing a clinical basis for the integrated treatment of CPID with traditional Chinese and Western medicine.

Keywords: Chronic Pelvic Inflammatory Disease; *Rhizoma Cynanchifoliae*; Doxycycline; Inflammatory Factors; Integrated Traditional Chinese and Western Medicine; Clinical Efficacy.

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I. INTRODUCTION

Chronic pelvic inflammatory disease (CPID) is a common gynecological infectious disease in women of childbearing age. It is characterized by a long and persistent course, characterized by lower abdominal distension and dull pain, accompanied by increased vaginal discharge and menstrual irregularities. In severe cases, it can lead to sequelae such as infertility, ectopic pregnancy, and chronic pelvic pain. Its incidence has been increasing in recent years, driven by factors such as the rise in sexually transmitted infections and increased abortions. Traditional treatment relies primarily on empirical broad-spectrum antibiotics, but Western medicine has limitations: efficacy is poor when the

pathogen is unclear, and long-term, repeated antibiotic use can lead to drug resistance and bacterial imbalance, increasing the risk of recurrence. Therefore, antibiotic therapy alone is often ineffective in treating CPID, resulting in high rates of recurrence and long-term complications. The search for new therapies that can inhibit chronic inflammatory responses and reduce recurrence is of great clinical significance.

Traditional Chinese Medicine (TCM) demonstrates unique advantages in the prevention and treatment of chronic pelvic inflammatory disease (CPID). TCM often classifies chronic pelvic inflammatory disease (CPID) as a syndrome of "damp-heat stasis," with the pathogenesis being the

stagnation of damp-heat toxic pathogens, resulting in scorched bones, and blood stasis blocking the Chong and Ren meridians. Jingangteng (Golden Vinegar Thunb.) is a commonly used TCM compound preparation containing multiple bioactive ingredients (such as alkaloids, flavonoids, polyphenols, and saponins), which possess the effects of clearing heat and detoxifying, promoting dampness and inflammation, and promoting blood circulation and removing blood stasis. Modern pharmacological studies have demonstrated that Jingangteng (Golden Vinegar Thunb.) possesses significant anti-inflammatory and immunomodulatory properties. Its flavonoids can block inflammatory responses by modulating TLR4-mediated signaling pathways, inhibiting lipopolysaccharide-induced monocyte interleukin-1 β expression, and reducing the production of proinflammatory mediators. Furthermore, it can regulate adhesion molecule expression, reducing inflammatory adhesion formation in pelvic tissues. Clinical studies have also shown that combining Jingangteng preparations with antibiotics for CPID improves clinical efficacy and safety, improves symptoms, and promotes the recovery of inflammatory cytokine levels. Meta-analysis results suggest that compared with antibiotics alone, combination therapy with jingdangteng significantly improves the overall clinical efficacy of CPID (RR = 1.19, 95% CI: 1.15-1.23) and reduces the incidence of adverse reactions (RR = 0.70, 95% CI: 0.51-0.95). Furthermore, combination therapy has advantages in reducing proinflammatory cytokines such as IL-6, IL-8, and TNF- α and increasing anti-inflammatory cytokines such as IL-10, potentially leading to more effective control of chronic pelvic inflammatory disease.

Based on this background, this study hypothesized that jingdangteng combined with antibiotics could exert a synergistic anti-inflammatory effect, thereby more effectively treating chronic pelvic inflammatory disease. We conducted a randomized controlled clinical trial to evaluate the clinical efficacy of jingdangteng combined with doxycycline in the treatment of CPID, specifically its effects on the expression of inflammatory cytokines (interleukin-6 (IL-6), interleukin-10 (IL-10), tumor necrosis factor- α (TNF- α), and C-reactive protein (CRP)).

II. DESIGN AND METHODS

➤ Study Design:

This study was a prospective, randomized, controlled clinical trial. Patients with chronic pelvic inflammatory disease who visited the gynecology department of this hospital between January 2023 and June 2024 were enrolled. Eligible patients were randomly divided into two groups: an experimental group (combination treatment group) and a control group, 30 cases each. The experimental group received combined treatment with "King Kong Teng + doxycycline," while the control group received doxycycline alone. This study was approved by the ethics committee of this hospital, and all patients and their families provided informed consent and signed a written informed consent form.

➤ Inclusion Criteria:

Western medicine diagnosis of chronic pelvic inflammatory disease (CPID) met the criteria for chronic pelvic inflammatory disease (CPID) in the Journal of Obstetrics and Gynecology, primarily based on a history of acute pelvic inflammatory disease, symptoms such as chronic pelvic pain, and pelvic examination and ultrasound imaging findings. Furthermore, the criteria for damp-heat and stasis syndrome (D-heat) in the Journal of Traditional Chinese Medicine Gynecology (D-Gynecology) were met, including lower abdominal distension and pain, profuse yellow vaginal discharge, red tongue with a greasy yellow coating, and a slippery and rapid pulse. The TCM syndrome type was determined by a senior physician of TCM gynecology with extensive clinical experience. Patients aged 18 to 50 years with a history of marriage, childbearing, or sexual activity were eligible. No antibiotics or other medications that could affect the study results were used in the two weeks prior to enrollment. Patients demonstrated good compliance, volunteered to participate in the trial, and agreed to regular follow-up.

➤ Exclusion Criteria:

Pregnant or lactating women; patients with concomitant diseases such as endometriosis that affect the assessment of pelvic pain; patients with severe heart, brain, liver, or kidney dysfunction; patients with concomitant pelvic tumors or other gynecological diseases requiring additional treatment; patients with allergies to study drugs; and patients with psychiatric illness or cognitive impairment who are unable to cooperate with treatment. Patients who experienced acute exacerbations during the trial and required other emergency treatment were required to withdraw from the trial.

➤ Treatment:

The control group received oral doxycycline (manufactured by Guangxi Huibao Pharmaceutical Co., Ltd., 100 mg/tablet) twice daily for 28 days. The experimental group received 0.7 g (1 tablet) of jingangteng chewable tablets (manufactured by a certain pharmaceutical company in Jiangxi Province, each tablet containing 0.7 g of jingangteng extract) three times daily for 28 days in addition to the control group's treatment. During treatment, both groups were advised to abstain from sexual intercourse and maintain good personal hygiene. Symptomatic supportive care (such as analgesia and physical therapy) was administered as needed, but other anti-inflammatory or anti-infective medications were avoided. Treatment was supervised by a dedicated individual to ensure compliance. After the completion of treatment, all patients underwent efficacy evaluation and laboratory testing.

➤ Observational Measures:

The primary outcome measure was serum inflammatory cytokine levels before and after treatment, including IL-6, IL-10, TNF- α , and CRP. Five mL of fasting venous blood was collected in the morning before and at the end of treatment. Serum was separated by centrifugation at 3,000 rpm for 10 minutes and stored at -80°C until analysis. Serum IL-6, IL-10, and TNF- α concentrations were quantitatively measured using enzyme-linked immunosorbent assay (ELISA), and

serum CRP levels were measured using immunoturbidimetric assay. The kits were provided by Wuhan Boster Biological Co., Ltd., and the instructions were strictly followed. Secondary efficacy indicators include: ① Changes in TCM syndrome scores: Referring to the scoring standards of the "Guidelines for Clinical Research of New Chinese Medicines", the TCM syndromes of patients before and after treatment were scored based on the degree of symptoms (lower abdominal pain, lumbar pain, leucorrhea color, menstrual disorders, fatigue, etc.), and the improvement rate was calculated; ② Total clinical efficacy: According to the improvement of symptoms and signs, the efficacy was divided into four levels: cured, markedly effective, effective, and ineffective. Cured + markedly effective + effective was counted as the total effectiveness, among which the cure standard was the disappearance of symptoms and signs, no pelvic tenderness during gynecological examination, and the dissipation of inflammatory masses; ③ Symptom relief time: The time required for the main symptoms (abnormal leucorrhea, lower abdominal pain, abdominal pain) to disappear or be significantly relieved after treatment, as well as the time required for the pelvic mass to disappear, was recorded; ④ Adverse reactions: During the treatment, drug-related adverse reactions, such as gastrointestinal discomfort, rash, abnormal liver function, etc., were closely observed, and the incidence and severity were recorded.

➤ *Statistical Methods:*

All data were analyzed using SPSS 23.0 statistical software. Continuous data were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$). Data normality was assessed using the Kolmogorov-Smirnov test. Normally distributed data were compared between groups using the independent sample t-test, and paired comparisons before and after treatment within a group using the paired t-test. Non-normally distributed data were analyzed using the rank-sum test. Enumeration data were expressed as number of cases and percentages, and intergroup comparisons were performed using the chi-square test or Fisher's exact test. All tests were two-sided, and the significance level was set at $P < 0.05$.

III. RESULT

➤ *General Data:*

A total of 68 eligible patients were screened, of whom 5 did not meet the TCM syndrome criteria and 3 declined participation. A total of 60 patients were enrolled, with 30 in the experimental group and 30 in the control group. There were no statistically significant differences between the two groups in demographic characteristics (age, marital status), duration of illness, or history of acute pelvic inflammatory disease (API) ($P > 0.05$). Baseline inflammatory markers were similar between the two groups before treatment, with no significant differences (e.g., serum IL-6 levels before treatment were 55.0 ± 15.0 pg/mL in the experimental group and 53.0 ± 14.0 pg/mL in the control group, $P > 0.05$), indicating comparability.

➤ *Clinical Efficacy:*

According to the above efficacy evaluation criteria, the total effective rate was 93.3% (28/30) in the experimental

group and 76.7% (23/30) in the control group, with a statistically significant difference ($\chi^2 = 4.20$, $P = 0.040$). In the experimental group, 12 patients (40%) were cured, 10 patients (33.3%) had marked effects, 6 patients (20%) had effective effects, and 2 patients (6.7%) had no effect. In the control group, 8 patients (26.7%) were cured, 9 patients (30%) had marked effects, 6 patients (20%) had effective effects, and 7 patients (23.3%) had no effect. Patients treated with combined treatment with jingangteng tung showed more significant symptom improvement, with a higher rate of resolution of refractory pelvic tenderness and masses. The TCM syndrome scores in both groups decreased significantly after treatment (symptoms were significantly alleviated), with the decrease greater in the experimental group than in the control group. The time required for major symptom resolution was also shorter (e.g., the average time for lower abdominal pain resolution was 7.3 ± 2.1 days in the experimental group and 10.5 ± 3.4 days in the control group, $P < 0.05$). Throughout the treatment, no patients experienced serious adverse events. Some patients reported mild gastrointestinal discomfort (2 in the experimental group and 3 in the control group) and transient mild elevations in liver function tests (1 in the experimental group and 1 in the control group), all of which resolved without requiring special treatment. There was no statistically significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$).

➤ *Changes in Inflammatory Factor Levels:*

The results of inflammatory factor testing before and after treatment in the two groups are shown in Table 1. Before treatment, there were no significant differences in serum IL-6, IL-10, TNF- α , and CRP levels between the experimental and control groups (all $P > 0.05$). After treatment, these inflammatory markers showed significant changes in both groups compared with pre-treatment levels: IL-6, TNF- α , and CRP levels were significantly decreased, while IL-10 levels were significantly increased (compared with pre-treatment levels in the same group, $P < 0.001$). However, the degree of improvement in inflammatory factors in the experimental group was greater than that in the control group. After treatment, the absolute values of serum IL-6, TNF- α , and CRP in the experimental group were significantly lower than those in the control group, while the IL-10 level was significantly higher than that in the control group (all $P < 0.01$ for intergroup comparisons). For example, after treatment, IL-6 levels in the experimental group decreased to 20.0 ± 8.0 pg/mL, a decrease of approximately 64% compared to pre-treatment levels. In the control group, IL-6 levels were 32.0 ± 9.0 pg/mL, a decrease of only approximately 40% compared to pre-treatment levels. The difference between the two groups was statistically significant ($P < 0.001$). Similarly, the increase in the anti-inflammatory factor IL-10 in the experimental group (from 5.2 ± 1.8 to 12.5 ± 3.0 pg/mL) was greater than in the control group (from 5.0 ± 1.5 to 9.0 ± 2.5 pg/mL, $P < 0.01$). These results suggest that the addition of jingangteng tung oil can more effectively inhibit the expression of inflammatory mediators in patients with chronic pelvic inflammatory disease and promote the resolution of inflammation.

Table 1 Comparison of Serum Inflammatory Factor Levels ($\bar{x} \pm s$) and Differences Between the Two Groups of Patients with Chronic Pelvic Inflammatory Disease before and after Treatment (Experimental Group: Jingangteng Combined with Doxycycline, n=30; Control Group: Doxycycline Alone, n=30)

index	Before treatment in the experimental group	After treatment in the experimental group	Control group before treatment	After treatment in the control group	P_{withi n the experimental group}	P_{withi n control group}	P_{Comparison between groups} (after treatment)
IL-6 (pg/mL)	55.0 $\pm$ 15.0	20.0 $\pm$ 8.0	53.0 $\pm$ 14.0	32.0 $\pm$ 9.0	<0.001	<0.001	<0.001
IL-10 (pg/mL)	5.2 $\pm$ 1.8	12.5 $\pm$ 3.0	5.0 $\pm$ 1.5	9.0 $\pm$ 2.5	<0.001	<0.001	0.003
TNF- α (ng/mL)	0.25 $\pm$ 0.07	0.10 $\pm$ 0.03	0.24 $\pm$ 0.06	0.15 $\pm$ 0.04	<0.001	<0.001	<0.001
CRP (mg/L)	15.0 $\pm$ 5.0	6.0 $\pm$ 2.0	15.5 $\pm$ 5.5	9.0 $\pm$ 3.0	<0.001	<0.001	0.002

IV. DISCUSSION

This study, conducted in a randomized controlled trial, investigated the clinical efficacy of Jingangteng capsule combined with doxycycline in the treatment of chronic pelvic inflammatory disease (CPID). Results demonstrated that the combined group achieved superior symptom remission rates and inflammatory factor reduction compared with the antibiotic monotherapy group. The overall efficacy rate in the experimental group reached 93.3%, significantly higher than the 76.7% in the control group, suggesting that integrated Chinese and Western medicine offers significant advantages in improving efficacy. This is consistent with previous studies reporting that Jingangteng capsule combined with antibiotics significantly improves the clinical efficacy and shortens the duration of symptom remission in patients with CPID. More importantly, we found that combined therapy can more effectively regulate the inflammatory response in patients. After treatment, serum IL-6, TNF- α , and CRP levels in the experimental group were significantly lower than those in the control group, while IL-10 levels were significantly higher, indicating that Jingangteng capsule plays a positive role in inhibiting the release of proinflammatory mediators and promoting the expression of anti-inflammatory factors. Previous studies have reported that Jingangteng capsule combined with conventional therapy can promote the recovery of inflammatory factors and T lymphocyte counts, contributing to the resolution of inflammation.

A study by Hao Xia et al. also showed that in patients with chronic pelvic inflammatory disease who received jingangteng vine treatment, serum levels of inflammatory markers such as CRP and IL-6 were significantly lower than those in the antibiotic-only group. Furthermore, levels of the anti-inflammatory factor IL-10 and matrix metalloproteinase-2 (MMP-2) were better regulated. These results are consistent with the current study and further support the synergistic anti-inflammatory effects of jingangteng vine.

The mechanisms underlying the superior efficacy of gypsophila gracile combined with doxycycline over

monotherapy may be multifaceted. First, antibiotics primarily eliminate bacteria and other pathogens but lack a direct effect on the inflammatory response and tissue damage caused by chronic infection. Patients with chronic pelvic inflammatory disease (CPID) often experience persistent, low-grade inflammatory stimulation. The endotoxin (LPS) produced by pathogens can activate the TLR4 receptor, initiating the downstream NF- κ B signaling pathway and inducing the release of a cascade of proinflammatory cytokines, including TNF- α and IL-6. This persistent inflammatory activation not only causes pelvic tissue adhesions and scarring but also makes symptoms recurrent and difficult to resolve. gypsophila gracile can modulate the inflammatory response at its source. In vitro and animal studies have demonstrated that the active components of gypsophila gracile can inhibit overactivation of the TLR4/NF- κ B pathway, thereby reducing the production of multiple downstream inflammatory mediators. Qin Hongzhen et al. found that gypsophila gracile polysaccharide significantly reduced serum TNF- α and IL-6 levels, inhibited inflammatory factor-mediated apoptosis, and improved T lymphocyte subset dysfunction in a rat model of CPID. This suggests that Vinegar Thunb. regulates the body's immune balance and achieves anti-inflammatory effects by affecting the innate immune recognition receptor TLR4 and the classic NF- κ B transcription factor. In addition, Vinegar Thunb. may also help enhance the body's endogenous anti-inflammatory mechanism. IL-10 is an important anti-inflammatory cytokine that can negatively feedback and inhibit excessive inflammatory responses. We observed that the IL-10 level after combined treatment was significantly higher than that in the control group. It is speculated that Vinegar Thunb. may promote the secretion of IL-10 by monocytes and macrophages or enhance its effect, thereby further calming the inflammatory response. This inference needs to be confirmed by further mechanistic studies. Secondly, the multi-target action mode of Vinegar Thunb. may have a comprehensive regulation on the pathological process of chronic pelvic inflammatory disease.

In addition to TLR4/NF- κ B signaling, literature reports indicate that Chinese herbal medicine monomers (including jing jing tung extract) can also act on multiple inflammatory pathways, including MAPK, JAK-STAT, Nrf2/HO-1, and the NLRP3 inflammasome. This multi-pathway regulation helps inhibit the inflammatory cascade, reduce tissue oxidative stress and fibrosis, and protect pelvic tissue function. For example, studies suggest that jing jing tung total flavonoids can inhibit excessive activation of the NLRP3 inflammasome and reduce the release of proinflammatory mediators such as IL-1 β . Furthermore, recurrent chronic pelvic inflammatory disease often leads to problems such as fallopian tube adhesions and pelvic masses. Jing jing tung, through its blood-activating and blood-stasis-removing effects, can improve local microcirculation and promote the absorption of inflammatory exudates and fibrous adhesions. Therefore, combined use of jing jing tung not only enhances anti-infective and anti-inflammatory effects but also may reduce tissue damage and the risk of sequelae, thereby improving overall patient prognosis.

From a Traditional Chinese Medicine (TCM) perspective, combining jinggangteng with Western medicine embodies the principle of treating both the symptoms and the root cause. Doxycycline clears heat and detoxifies, eliminating residual damp-heat pathogens at the "symptom" level; jinggangteng strengthens the body's vital energy and dispels pathogens at the "root" level, improving the local environment and dissolving blood stasis. The two synergistically address the pathogenesis of chronic pelvic inflammatory disease (CPID) more comprehensively. Combining TCM and Western medicine not only alleviates symptoms and eliminates inflammation in the short term but also may reduce the incidence of long-term complications. In this study, no new acute exacerbations were observed in the experimental group during a three-month follow-up period after treatment, and the recurrence rate of pelvic pain was also lower than in the control group (although the follow-up period was limited and statistical analysis was not performed). This suggests that combined therapy may also have advantages in reducing disease recurrence. Reports indicate that combined TCM treatment can reduce the incidence of sequelae of pelvic inflammatory disease (PID) and improve patients' quality of life. Therefore, combining TCM herbs such as jinggangteng with standard antibiotics is an effective and safe strategy for recurrent and persistent chronic pelvic inflammatory disease.

It should be pointed out that this study still has certain limitations. First, the sample size is relatively small and the follow-up time is short, so changes in long-term reproductive prognosis (such as the incidence of infertility) cannot be observed. This limits the evaluation of long-term efficacy to a certain extent. Secondly, although we detected typical inflammatory factors, the immunopathological process of chronic pelvic inflammatory disease is complex, with the participation of multiple cytokines and pathways, and the mechanism of action of Vajrabella truncatula still needs more experimental research support. This study did not monitor more in-depth immunological indicators (such as the function of different subpopulations of lymphocytes, expression of cell

signaling molecules, etc.). In the future, in randomized controlled studies with larger samples, the monitoring of the immune-inflammatory network can be increased, and follow-up can be extended to evaluate the recurrence rate and reproductive outcomes, so as to more comprehensively verify the clinical value of Vajrabella truncatula combination therapy.

V. CONCLUSION

The combination of jinggangteng (Shengangteng) and doxycycline is safe and effective for the treatment of chronic pelvic inflammatory disease (PID), significantly alleviating symptoms and improving overall clinical efficacy. One mechanism of action is synergistic inhibition of chronic pelvic inflammatory responses: combined treatment reduces the expression of proinflammatory cytokines IL-6, TNF- α , and CRP, while increasing the level of the anti-inflammatory cytokine IL-10, thereby alleviating inflammation-mediated tissue damage.

This may be related to jinggangteng's anti-inflammatory effects through modulation of inflammatory signaling pathways such as TLR4/NF- κ B. Integrated traditional Chinese and Western medicine (TCM) therapy has the potential to complement the shortcomings of antibiotic therapy alone, controlling infection while improving the internal environment and reducing the risk of recurrence and sequelae. This study provides clinical evidence for the combination of jinggangteng (Shengangteng) and other traditional Chinese medicines with antibiotics for the treatment of chronic PID. Given the limited sample size of this study, further large-scale, multicenter clinical trials and related mechanistic studies are needed to further confirm its efficacy and clarify its mechanism of action, thereby promoting the application of integrated TCM and Western medicine in PID.

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