

Clinical Study on the Therapeutic Effect of Combined Traditional Chinese Medicine with Acupoint Injection and Herbal Paste Application in Treating Ovulatory Dysfunction in Polycystic Ovary Syndrome (PCOS)

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Abstract

Objective: To observe the therapeutic effect of combined traditional Chinese medicine (TCM) therapy with acupoint injection and herbal patch application on patients with ovulatory dysfunction associated with polycystic ovary syndrome (PCOS). **Methods:** A total of 80 PCOS patients who received treatment at the First Affiliated Hospital of Guangxi University of Chinese Medicine between October 2022 and March 2024 were enrolled in this study. They were randomly divided into a control group (n = 40) and an observation group (n = 40). The control group received conventional Western medical treatments, while the observation group was administered TCM combined with acupoint injection and herbal patch application. Pre- and post-treatment conditions were compared between the two groups. **Results:** After treatment, the overall effective rate was significantly higher in the observation group compared to the control group (P < 0.05). Hormone levels (follicle-stimulating hormone [FSH], luteinizing hormone [LH], estradiol [E2], and testosterone [T]) were compared before and after treatment. Both FSH, LH, and T decreased, while E2 increased in both groups; however, the decrease was more pronounced in the observation group for FSH, LH, and T, and the increase in E2 was higher in the observation group, with these differences being statistically significant (P < 0.05). Before treatment, there was no statistically significant difference in ovulation and pregnancy rates between the observation

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and control groups ($P > 0.05$). Following treatment, both ovulation and pregnancy rates increased in both groups, but the increase was more evident in the observation group, showing a statistically significant difference ($P < 0.01$). Conclusion: For patients with oligoovulation or anovulation due to PCOS, the combined use of TCM, acupoint injection, and herbal patch application appears to be effective in improving systemic symptoms and achieving notable clinical outcomes.

Keywords

External TCM Therapies, Acupoint Injection, Polycystic Ovary Syndrome, Ovulation Dysfunction

1. Introduction

Polycystic ovary syndrome (PCOS), one of the most prevalent gynecological disorders, affects 5% to 10% of women in China. Characterized by hyperandrogenism, ovulatory dysfunction, and polycystic ovarian morphology, PCOS is a reproductive endocrine and metabolic disorder that encompasses reproductive, metabolic, and psychological disturbances. In China, infrequent menstruation and ovulatory dysfunction are the predominant symptoms, particularly affecting women of reproductive age and adolescence [1]. The treatment of PCOS anovulation in patients with fertility requirements by Western Medicine primarily revolves around ovulation induction drugs [2]. Alternatively, metformin can be used either alone or in conjunction with other medications for infertility to enhance the pregnancy and live birth rates in women with polycystic ovary syndrome (PCOS) [3]. However, besides the common side effects associated with Western medications, the overall improvement in systemic symptoms for PCOS patients is not always optimal. Traditional Chinese Medicine (TCM) boasts a long history in treating PCOS, offering not only simplicity and convenience but also notable effectiveness. When tackling diseases with a single method, it can be challenging to accommodate the complex pathogenesis unique to each patient. Compared to Western medicine, TCM tends to demonstrate more marked improvements in overall symptoms. This study aims to compare the clinical efficacy of conventional Western medical treatments with a combined TCM approach involving herbal medicine, acupoint injection, and herbal patch application in patients diagnosed during the same period. By analyzing the outcomes from these two distinct approaches, this research endeavors to provide data-driven insights to enhance the effectiveness of clinical interventions. The following sections detail the methodology and findings of this comparative study.

2. Materials and Methods

2.1. General Information

The study included 80 PCOS patients who were diagnosed and treated at the

First Affiliated Hospital of Guangxi University of Chinese Medicine between October 2022 and March 2024.

2.1.1. Diagnostic Criteria

Selected patients met the internationally recognized “Rotterdam Criteria for PCOS” established in 2003, as well as the diagnostic criteria for spleen-kidney yang deficiency and liver depression with spleen deficiency in the “Guiding Principles for Clinical Research of Traditional Chinese Medicine.” Patients presented with oligomenorrhea, amenorrhea, or irregular uterine bleeding, and other possible causes of hyperandrogenism and ovulation disorders were excluded. Diagnosis required the presence of one or more of the following conditions: clinical or biochemical hyperandrogenism (manifested by obesity, hirsutism, acne, acanthosis nigricans, etc.), and/or ultrasonographic evidence of polycystic ovaries. Ultrasound examination revealed bilaterally enlarged ovaries with enhanced capsule echoes, relatively smooth outlines, and increased stromal echogenicity, with 12 or more cysts, each measuring 2 mm to 9 mm in diameter, arranged peripherally around the ovary in a necklace-like pattern. No dominant follicle development or signs of ovulation were detected upon serial monitoring. Meeting 2 - 3 of these criteria confirmed the diagnosis of PCOS.

In cases of PCOS characterized by the spleen-kidney yang deficiency pattern, the following symptoms are typically observed: delayed menstruation progressing to amenorrhea, or menstrual cycle irregularities with heavy bleeding or prolonged spotting; prolonged infertility despite marriage, accompanied by obesity; dizziness, chest tightness, tinnitus, excessive phlegm in the throat, fatigue, cold hands and feet, abdominal distension and discomfort, intermittent low back pain, copious leukorrhea, clear and frequent urination, loose stools, a large, pale tongue with thick white coating, and a deep sliding or weak pulse. For patients presenting with the liver qi stagnation and spleen deficiency pattern, common manifestations include: delayed menstruation with scanty flow or absence of menstruation for several months leading to amenorrhea and infertility. Menstrual blood may contain clots, coupled with depression, irritability, anger, fullness in the chest and hypochondrium, breast tenderness, abdominal distension and loose stools, a dark red tongue with possible ecchymoses or petechiae, and a deep, wiry, and possibly stagnant pulse.

2.1.2. Inclusion Criteria

- Age range: 20 - 44 years old.
- Normal sexual activity within the couple.
- No immune abnormalities and patent fallopian tubes.
- No use of ovulation induction therapy or any hormonal medication in the past 3 months prior to treatment.
- Normal liver and kidney function test results.

2.1.3. Exclusion Criteria

- Patients with autoimmune diseases.

- Other causes of elevated androgens (including congenital adrenal hyperplasia, Cushing's syndrome, androgen-secreting tumors).
- Other causes of anovulation (e.g., hyperprolactinemia, premature ovarian failure, hypothalamic-pituitary amenorrhea, or thyroid dysfunction).

2.1.4. Dropout Criteria

- Participants who experienced adverse reactions such as needle fainting, retention during acupuncture, blistering from moxibustion or patches, allergies, or who voluntarily requested to stop treatment before completion due to discomfort.
- Patients who withdrew from the study voluntarily.

Randomization:

The 80 eligible patients were randomly allocated into either the control group (n = 40) or the observation group (n = 40) using random allocation methods. The study protocol was approved by the hospital's ethics committee, and written informed consent was obtained from all participants and their families before enrollment.

2.2. Methods

For the control group, conventional Western medical treatment was applied, starting from day 5 of the menstrual cycle (or progesterone-withdrawal bleeding), patients orally took Clomiphene (Manufactured by GaoTe Pharmaceutical Co., Ltd., Approval No.: Import Drug Registration Certificate H20140688, Specification: 50 mg/tablet) at a dose of 50 mg once daily for 5 consecutive days.

The observation group received a comprehensive treatment combining Chinese herbal medicine and external therapies:

Chinese Herbal Medicine Protocol:

For patients with Liver Depression and Spleen Deficiency, Xiaoyao Powder with modifications was prescribed: Danggui 10 g, Baishao 15 g, Chaihu 12 g, Zhuru 10 g, Sangye 10 g, Xiaokusou 10 g, Shihu 10 g, Gegen 10 g, Baizhu 15 g, Fuling 15 g, Weijiang 10 g, Bohe 6 g, Zhi Gancao 5 g. One dose per day, divided into two servings taken morning and evening, discontinued during menstruation. This regimen was continued for 3 months.

For those with Spleen-Kidney Yang Deficiency, Yougui Wan with adjustments was given: Shufuzi 5 g (decocted first), Shudihuang 20 g, Yinyanghuo 15 g, Shanyao 10 g, Shan Zhu Yu 15 g, Gouqizi 10 g, Tusizi 15 g, Lujiaojiao 10 g, Danggui 10 g, Du Zhong 15 g. Administered similarly as the previous formula for 3 months.

Acupoint Injection:

2 mL of Astragalus Injection (Manufactured by Heilongjiang Zhenbao Island Pharmaceutical Co., Ltd., Approval No.: National Medicine Approval No. Z23020781, Specification: 2 mL/vial) and Compound Danggui Injection (Manufactured by Fujian Gutian Pharmaceutical Co., Ltd., Approval No.: National Medicine Approval No. Z35020379, Specification: 2 mL/vial) were drawn using a 2 mL syringe, and injected based on individual diagnosis.

For Liver Qi Stagnation and Kidney Deficiency, a mixture of Compound Danggui Injection and Astragalus Injection in a 1:1 ratio was primarily used at bilateral ShenShu, GanShu, GeShu, Guanyuan, Sanyinjiao, Qihai, Xuehai, Zigong, and Zusanli points.

For Spleen-Kidney Yang Deficiency, a 2:1 ratio mixture of Astragalus Injection and Deer Antler Injection was mainly used at bilateral PiShu, ShenShu, TianShu, Qihai, Guilai, Guanyuan, Zusanli, and Sanyinjiao points.

Injection was performed after routine local disinfection, with 0.5 mL of the mixed solution slowly administered into each point after obtaining qi. Post-injection, the site was pressed with a disinfected cotton swab for 1 minute.

Herbal Patch Application:

For Liver Depression and Spleen Deficiency, a powder made from Danggui, Chuanxiong, Baishao, Honghua, Xiangfu, Chenpi, Duzhong, and Xixin was mixed with ginger juice and applied to the patient's Zigong, TianShu, and Guanyuan acupoints, secured with medical adhesive tape and sterile gauze. After 6 hours, remnants were removed and the area washed with clean water.

For Spleen-Kidney Yang Deficiency, a different herbal mixture including Danggui, Chuanxiong, Wulingzhi, Baizhu, Chenpi, Banxia, Cangzhu, and Xiaoxiang was used for application.

Application frequency was once daily, 2 - 3 times weekly, for 3 consecutive menstrual cycles. Both groups underwent treatment for 3 cycles, with pregnancy resulting in treatment cessation. If basal body temperature did not rise after 45 days without menstruation, progesterone withdrawal bleeding was induced [2]. A 3-cycle follow-up was conducted post-treatment.

2.3. Observation Indicators and Evaluation Criteria

1) Ovulation Status: Ultrasonographic examination is conducted to assess the presence or absence of dominant follicles in both ovaries. In patients with oligoovulation, if a follicle diameter exceeds 10 mm or corpus luteum is detected, reevaluation is scheduled in the next cycle.

2) Reproductive Endocrine Hormone Profile: Fasting blood samples are drawn from subjects on days 2 - 5 of menstruation to assay six sex hormone levels, specifically focusing on Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LH), Estradiol (E2), and Testosterone (T).

3) Ovulation and Pregnancy Outcomes: Ovulation is monitored via ultrasound to detect the emergence and disappearance of dominant follicles, while pregnancy is determined through measuring serum β -human Chorionic Gonadotropin (β -HCG).

4) TCM Symptom Scoring: The primary symptoms of PCOS (including menstrual cycle irregularities, facial acne, menorrhagia/metrorrhagia, oligomenorrhea, chest and rib distension, infertility despite prolonged marriage, loose stools, and clear frequent urination) are assessed using TCM syndrome differentiation. Scores are assigned as follows: 0 = normal, 2 = mild, 4 = moderate, 6 = severe. Lower scores indicate more significant symptom improvement [4].

5) Therapeutic Effect Evaluation:

Significant Efficacy: Post-treatment, the menstrual cycle approaches normalcy (within 40 days), and clinical symptoms are significantly alleviated. There is a marked improvement in serum sex hormone test indicators, with a Traditional Chinese Medicine (TCM) syndrome efficacy index ranging from 66.67% to less than 90%. The patient regains spontaneous fertility, and ovulation returns to normal or near-normal levels.

Effective: Post-treatment, menstrual cycle irregularities are reduced to approximately between 40 and 90 days, and clinical symptoms are somewhat alleviated. Serum sex hormone test indicators show some improvement, with a TCM syndrome efficacy index ranging from 33.33% to less than 66.67%. Ovulation is partially restored, and ultrasound suggests the presence of dominant follicles, which persist for at least two consecutive menstrual cycles.

Ineffective: Post-treatment, the menstrual cycle remains over 90 days, with no alleviation or even exacerbation of clinical symptoms. Serum sex hormone test indicators do not improve, and the TCM syndrome efficacy index is less than 33.33%. Ultrasound examination indicates the absence of dominant follicles, or there might be occasional ovulation that does not persist for more than two consecutive menstrual cycles.

The overall effective rate equals the sum of the significant efficacy rate and the effective rate.

2.4. Statistical Analysis

Data analysis between the two groups is conducted using SPSS version 22.0. For categorical data, Chi-square (χ^2) tests are employed; whereas for continuous variables, data are expressed as mean \pm standard deviation ($\bar{x} \pm s$), and independent sample t-tests are used for intergroup comparisons. A statistical significance level of $P < 0.05$ is adopted to denote a significant difference between compared data.

3. Results

3.1. Comparison of General Information

In the control group, comprising 40 cases, the age range was 20 - 33 years, with a mean age of (26.1 ± 5.6) years, and the duration of illness ranged from 1.0 to 3.0 years, averaging at (2.0 ± 1.0) years. The observation group, also consisting of 40 cases, had an age distribution of 19 - 35 years, with a mean age of (27.3 ± 6.0) years, and their illness durations spanned from 1.2 to 3.2 years, averaging (2.1 ± 1.1) years. Comparison of general information between the two groups revealed no statistically significant differences ($P > 0.05$), indicating their comparability.

3.2. Comparison of Therapeutic Outcomes between the Two Groups

Following treatment, the effectiveness rate in the observation group was found

to be higher than that in the control group, with this difference being statistically significant ($P < 0.05$). Details are presented in **Table 1**.

3.3. Comparison of Serum FSH, LH, E2, and T Levels before and after Treatment in Both Groups

After treatment, compared to the control group, the observation group demonstrated lower levels of FSH, LH, and T, but higher levels of E2, with these differences being statistically significant ($P < 0.05$). Detailed data are presented in **Table 2**.

Table 1. Comparison of treatment efficacy between two groups.

Group	Ineffective	Effective	Markedly Effective	Total Effective Rate (%)
Control Group (n = 40)	8 (20.00)	20 (50.00)	12 (30.00)	32 (80.00)
Observation Group (n = 40)	3 (7.50)	12 (30.00)	25 (62.50)	71 (92.50)
χ^2				7.2921
P				$P < 0.05$

Table 2. Comparison of Serum FSH, LH, E2, and T Levels before and after Treatment between Two Groups.

Group	Time	FSH (mIU/ml)	LH (mIU/ml)	E2 (pg/mL)	T (ng/ml)
Control Group (n = 40)	Pre-Treatment	7.26 ± 0.79	18.53 ± 0.28	87.25 ± 1.24	0.67 ± 0.03
	Post-Treatment	6.03 ± 0.82	10.49 ± 1.13	110.41 ± 3.72	0.43 ± 0.03
Observation Group (n = 40)	Pre-Treatment	7.30 ± 0.68	19.36 ± 0.43	89.85 ± 1.29	0.71 ± 0.04
	Post-Treatment	5.63 ± 0.89	8.62 ± 0.96	130.32 ± 3.16	0.39 ± 0.06
t-value Post-Treatment Between Groups		2.8625	10.9222	35.3269	5.1640
P-value Post-Treatment Between Groups		$P < 0.05$	$P < 0.05$	$P < 0.05$	$P < 0.05$

3.4. Comparison of Ovulation Rate and Pregnancy Rate before and after Treatment in Both Groups

Before treatment, no statistically significant differences were observed in ovulation rates or pregnancy rates between the two groups ($P > 0.05$). However, after treatment, statistically significant differences emerged in both rates ($P < 0.05$), as shown in **Table 3**.

3.5. Comparison of TCM Symptom Scores before and after Treatment in Both Groups

Prior to treatment, no statistically significant differences were found in the TCM syndrome scores between the two groups ($P > 0.05$). Following treatment, the

syndrome score in the observation group was significantly lower than that in the control group, with this difference being statistically significant ($P < 0.01$). The detailed comparison is presented in **Table 4**.

Table 3. Comparison of ovulation rate and pregnancy rate before and after treatment between two groups.

Time	Group	Ovulation Rate (%)	Pregnancy Rate (%)
Pre-Treatment	Control Group (n = 40)	32	30
	Observation Group (n = 40)	33	31
	χ^2 Post-Treatment	0.0271	0.0276
	P-value Post-Treatment	$P > 0.05$	$P > 0.05$
Post-Treatment	Control Group (n = 40)	42	40
	Observation Group (n = 40)	58	56
	χ^2 Post-Treatment	7.6800	7.4074
	P-value Post-Treatment	$P < 0.05$	$P < 0.05$

Table 4. Comparison of traditional Chinese medicine (TCM) symptom scores before and after treatment between two groups.

Time	Group	TCM Symptom Score Comparison
Pre-Treatment	Control Group (n = 40)	4.12 ± 0.75
	Observation Group (n = 40)	4.20 ± 0.78
	t-value Post-Treatment	0.6403
	t-value Post-Treatment	$P > 0.05$
Post-Treatment	Control Group (n = 40)	3.45 ± 0.37
	Observation Group (n = 40)	1.52 ± 0.32
	t-value Post-Treatment	14.3398
	t-value Post-Treatment	$P < 0.05$

4. Conclusions

Polycystic ovary syndrome (PCOS), characterized by endocrine and metabolic disturbances, commonly affects women of reproductive and adolescent age [5]. Its main clinical manifestations—irregular menstruation and infertility—are typically associated with hyperandrogenism and hormonal imbalances. Anovulation or oligoovulation, key symptoms of PCOS, significantly contribute to infertility. If left untreated, PCOS can impair female fertility further, leading to hyperandrogenemia, hyperinsulinemia, and ovarian dysfunction, which not only affect physical health but also potentially trigger emotional issues like anxiety and depression. In Traditional Chinese Medicine (TCM), PCOS falls under categories such as “infertility,” “amenorrhea,” and “metrorrhagia.” The pathology

implicates the Chong and Ren meridians and involves the Liver, Spleen, and Kidney organs. Abnormal folliculogenesis, development, and ovulation in PCOS patients are indicative of ovulatory dysfunction [6], often linked to deficiencies in Qi and Blood of the Kidney, Liver, and Spleen, compounded by pathogenic factors like phlegm-dampness and blood stasis that disrupt follicular maturation. Our team's prior research identified that in the Guangxi region, PCOS patients primarily exhibit Kidney and Spleen deficiency, phlegm-dampness, blood stasis, and Liver Qi stagnation, with tonifying herbs predominantly used alongside blood-moving formulas, such as You Gui Wan, Zuo Gui Wan, and Xiao Yao San [7].

Western medical management of PCOS requires a deep understanding of its etiological factors and emphasizes comprehensive treatment plans [8]-[10]. Differing from Western approaches, TCM treats PCOS based on syndrome differentiation, employing internal herbal remedies and external therapies. Recent studies highlight TCM's effectiveness in significantly enhancing ovulation rates and addressing multiple pathogenic aspects of PCOS [11], with therapies aimed at reinforcing the Kidney and Spleen, invigorating blood, and resolving Liver Qi stagnation to restore organ function, regulate the Chong and Ren, and harmonize Qi and Blood. You Gui Wan, from the 'Jing Yue Quan Shu', contains ingredients known to lower blood glucose, correct lipid metabolism disorders, protect the liver, reduce body weight, preserve pancreatic function, and facilitate endocrine regulation in PCOS-related infertility [12]. Xiao Yao San, derived from 'Tai Ping Hui Min He Ji Ju Fang', is an excellent formula for nourishing the Blood and regulating the Liver, with properties to resolve Liver Qi stagnation and nourish Blood, also suppressing high androgen levels [13], thereby alleviating PCOS-related ovulatory dysfunction when androgen activity is inhibited [14]. Emotional well-being, relieved Liver Qi stagnation, and free-flowing Qi and Blood lead to improvements in gynecological symptoms such as masses, amenorrhea, and infertility. These treatments show good short-term and long-term efficacy with minimal side effects and high safety profiles.

Given the complexity and variability of PCOS presentations, a single TCM approach may be insufficient. Thus, our study combines common TCM external therapies like acupoint injection and herbal patching with internal herbal medicine to optimize ovulation stimulation. Acupoint injection integrates needling techniques, acupoint selection, and drug administration, creating a novel therapeutic pathway where medicines are delivered directly to affected areas via meridian transmission, enhancing therapeutic efficacy. Herbal patching combines acupuncture theory with herbal formulas tailored to individual diagnoses, applying herbs like Danggui, Chuanxiong, Baishao, and Xiao Hui Xiang to selected acupoints on meridians such as the Conception, Governor, and Stomach channels, promoting the flow of Qi and Blood, warming the uterus, and harmonizing the body [15]. This dual approach stimulates the movement of Qi throughout the body, unblocks obstructed meridians, and aims to tonify Qi and Blood, regulate menstruation, aid conception, and holistically adjust the functions of or-

gans and Qi-Blood circulation.

Our findings indicate that patients receiving the combination of internal herbal medication with acupoint injection and patching showed a higher clinical effectiveness rate than the control group, with improved menstrual patterns trending towards normalization, enhanced follicle quality, and significantly improved ovulation.

Although this study has indeed confirmed the feasibility and safety of combining traditional Chinese medicine with acupoint injection and medicinal patch application in the treatment of PCOS, it is subject to limitations including a small sample size, geographical constraints, and a short follow-up period, which precludes definitive conclusions regarding its long-term efficacy. Therefore, in subsequent research, efforts should be directed towards increasing the sample size, refining observational indicators, and extending the follow-up duration to thoroughly investigate the long-term effectiveness of integrated acupuncture and medication therapy on PCOS.

Therefore, in treating ovulatory dysfunction in PCOS, a TCM approach incorporating zang-fu and meridian differentiation, along with internal herbal therapy complemented by external therapies like acupoint injection and herbal patching, effectively adjusts reproductive endocrine disorders, regulates sex hormone levels, alleviates clinical symptoms, promotes ovulation and fertility, and optimizes the systemic functioning of organs and Qi-Blood. Such strategies are particularly valuable for implementation in primary healthcare settings.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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