

Original Article

Therapeutic effect of compound Cangchai Tiaozhong decoction on polycystic ovary syndrome with phlegm-dampness block and its effect on sex hormone levels

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Abstract: Objective: This study aimed to investigate the therapeutic effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome (PCOS) with phlegm-dampness block and its effect on sex hormone levels. Methods: One hundred and twenty PCOS patients with phlegm-dampness block were randomized into a control group (n=60) for clomiphene treatment and a Compound Cangchai Tiaozhong Decoction group (n=60) for Compound Cangchai Tiaozhong Decoction therapy. The levels of follicle stimulating hormone (FSH), estradiol (E₂), luteinizing hormone (LH), testosterone (T) and procalcitonin (PCT), as well as pregnancy status, endometrial pulsation index (PI) and resistance index (RI) were measured. The treatment effective rate and the incidence of adverse reactions were calculated. Results: Compared with control group, PCT, FSH, LH, LH/FSH and T levels and ovarian volume were lower in Compound Cangchai Tiaozhong Decoction group after treatment, while E₂ was higher (all P<0.01). The post-treatment PI and RI values of endometrial blood flow in Compound Cangchai Tiaozhong Decoction group were lower than those in control group (P<0.01). Compound Cangchai Tiaozhong Decoction group had more dominant follicles, shorter ovulation induction days, and higher effective rate than control group (P<0.01). The incidence of adverse reactions in Compound Cangchai Tiaozhong Decoction group was lower than that in control group (P<0.01). Conclusion: Compound Cangchai Tiaozhong Decoction is markedly effective in the treatment of PCOS with phlegm-dampness block in that it can improve endocrine and sex hormone levels and promote ovulation in patients, which is worthy of clinical promotion.

Keywords: Compound Cangchai Tiaozhong Decoction, polycystic ovary syndrome with phlegm-dampness block, sex hormone level, clomiphene

Introduction

Polycystic ovary syndrome (PCOS), mainly characterized by chronic anovulation and hyperandrogenemia, is a common reproductive dysfunction and metabolic disorder among women of childbearing age, with a high degree of heterogeneity and clinical diversity [1]. PCOS is the main cause of female infertility in China. Without timely treatment, its pathology and physiology will affect each other, triggering a series of complications and seriously affecting the quality of life of patients. The key to treat PCOS is to improve the ovulation rate [2].

Currently, symptomatic treatments such as improving hyperandrogenemia, adjusting menstrual cycle and promoting ovulation are the main treatment methods of western medicine; but generally, the compliance of drug treatment is unfavorable, with strong toxicity and side effects, resulting in poor clinical tolerance the clinical tolerance of patients [3]. Compound Cangchai Tiaozhong Decoction is mainly used for regulating Qi-flowing for removing blood stasis and invigorating the spleen for eliminating dampness and phlegm, and has the effects of tonifying Qi and regulating middle energizer, as well as invigorating the circulation of Qi, which

can be used clinically to treat PCOS. Today, with the change of people's living environment, the incidence of PCOS is increasing year by year, which has become a common clinical gynecological disease. Mainly manifested as menstrual cycle disorder, ovulation disorder and amenorrhea, as well as secretion abnormalities of related sex hormone levels such as estrone and androgen, this disease usually occurs in women of childbearing age, which seriously affects their ovulation function, and even leads to obesity and infertility in severe cases [4]. Clinically, ovulation-promoting drugs such as clomiphene citrate are applied to reduce the secretion of luteinizing hormone, increase the secretion of follicle stimulating hormone (FSH), decrease the synthesis and release of androgen, and promote follicular development, however, with high incidence of adverse reactions [5].

PCOS falls into the categories of "infertility", "abdominal mass" and "amenorrhea" in traditional Chinese medicine, which is primarily induced by stagnation of liver Qi, endogenous turbid dampness, dysfunction of thoroughfare vessel, Qi-blood disharmony and vascular obstruction of uterine collaterals, as well as dysfunction of internal organs and impairment of Chong and Ren Channels, and is mainly manifested as phlegm dampness block, kidney deficiency and liver Qi stagnation [6, 7]. In Compound Cangchai Tiaozhong Decoction, dried tangerine peel can eliminate dampness and phlegm, and regulate Qi-flowing for strengthening spleen; Largehead Atractylodes Rh can dry dampness and promote diuresis, and prevent miscarriage; Codonopsis pilosula can nourish the blood and promote the production of body fluid, and tonify middle-Jiao and Qi; Poria cocos can calm the heart, clear damp and promote diuresis; Angelica sinensis can regulate menstruation and stop bleeding, and promote blood circulation; Radix bupleuri can raise Yang and lift prolapsed Zang-Fu organs, and reconcile exterior and interior; Atractylodes lancea can expel wind and remove cold, dry damp and strengthen spleen; Astragalus membranaceus can promote granulation, and invigorate Qi for strengthening superficies; Rhizoma cimicifugae can clear away heat and remove detoxify, relieve the exterior and expose the exanthema; Ligusticum wallichii can activate blood for acesodyne, promote Qi circulation and remove

obstruction in the collateral; Rhizome of rehmannia can tonify blood and nourish Yin, and supplement body essence and marrow; Herba epimedii can dispel wind and eliminate dampness, invigorate kidney and strengthen Yang; Rhizoma cyperi can regulate menstruation and relieve pain, and regulate Qi to sooth the middle; Cistanche deserticola can tonify kidney Yang, enrich and benefit essence and blood; Rehmannia glutinosa can nourish blood and Yin; and Glycyrrhiza can resolve phlegm to relieve cough, clear heat and remove toxicity [8, 9]. This study explored the therapeutic effect of Compound Cangchai Tiaozhong Decoction on PCOS with phlegm-dampness block and its effect on sex hormone levels.

Materials and methods

Data

Research participants: One hundred and twenty PCOS patients with phlegm-dampness block treated in The Sixth People's Hospital of Zhuji from March 2015 to March 2018 were randomized into two groups: control group (n=60) and Compound Cangchai Tiaozhong Decoction group (n=60). In control group, patients were aged 26-37 years, with an average age of 31.5 ± 3.5 years old and a mean body mass index (BMI) of 24.71 ± 2.32 kg/m². Patients in Compound Cangchai Tiaozhong Decoction group were 25-37 years old, with an average age of 31.4 ± 3.4 years old and a mean BMI of 24.38 ± 2.65 kg/m². Diagnostic criteria of traditional Chinese medicine (TCM): The patients were selected by referring to the standards of the *Diagnostic Criteria of TCM Syndrome* issued by the State Administration of Traditional Chinese Medicine in 1994. Primary symptoms: delayed menstrual cycle, reddish and sticky menstruation, hypomenorrhea, long-term infertility, and gradual amenorrhea; Secondary symptoms: chest and abdomen tightness, nausea and vomiting, physical obesity; tongue and pulse: light-colored and fat tongue with whitish greasy coating. This study was approved by the Ethics Committee of The Sixth People's Hospital of Zhuji and all patients signed the informed consent.

Inclusion criteria: All the enrolled patients 1) met the relevant diagnostic criteria in the diagnostic criteria and guidelines for polycystic

Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

ovary syndrome published by Journal of International Reproductive Health/Family Planning in 2011; 2) with unobstructed oviduct as confirmed by hysterosalpingography; 3) with normal endometrium and at least unobstructed unilateral fallopian tube.

Exclusion criteria: patients with 1) severe liver disease; 2) other serious gynecological diseases; 3) other endocrine diseases; 4) thyroid or gonadal dysfunction; 5) allergies to the drugs used in this study.

Drug source: Clomiphene (Shanghai Hengshan Pharmaceutical Co., Ltd., H31021107, China, specification 50 mg); dried tangerine peel, Largehead Atractylodes Rh, Poria cocos, Radix bupleuri, Codonopsis pilosula, Herba epimedii, Atractylodes lancea, Angelica sinensis, Rhizoma cyperi, Astragalus membranaceus, Ligusticum wallichii, Rhizoma cimicifugae, Rhizome of rehmannia, Cistanche deserticola, Rehmannia glutinosa, Glycyrrhiza, Chinese Honeylocust Spine, Achyranthes bidentata, Semen Sinapis Albae, Beautiful Sweetgum Fruit (Shanghai Traditional Chinese Medicine Co., Ltd., Zhejiang Zhuji Huatai Group Co., Ltd.).

Methods

Treatment methods: Instead of raw, cold and greasy food, all the included patients adopted a light diet during the treatment. Patients in control group were given clomiphene citrate (50 mg/day) on the fifth day of the menstrual cycle for 5 days. While those in Compound Cangchai Tiaozhong Decoction group were given Compound Cangchai Tiaozhong Decoction, which was composed of dried tangerine peel 10 g, Largehead Atractylodes Rh 15 g, Poria cocos 8 g, Radix bupleuri 15 g, Codonopsis pilosula 12 g, Herba epimedii 15 g, Atractylodes lancea 20 g, Angelica sinensis 9 g, Rhizoma cyperi 10 g, Astragalus membranaceus 20 g, Ligusticum wallichii 12 g, Rhizoma cimicifugae 10 g, Rhizome of rehmannia 8 g, Cistanche deserticola 15 g, Rehmannia Glutinosa 10 g, Glycyrrhiza 9 g, Chinese Honeylocust Spine 20 g, Achyranthes bidentata 10 g, Semen Sinapis Albae 6 g, and Beautiful Sweetgum Fruit 12 g. Every day, one dose of Compound Cangchai Tiaozhong Decoction was fried with water to extract 400 mL of decoction for patients to administered warm twice, once each in the morning and in the evening. Patients in both groups

were treated continuously for 3 menstrual cycles.

Detection of follicle stimulating hormone (FSH), luteinizing hormone (LH), LH/FSH, testosterone (T), estradiol (E₂), procalcitonin (PCT) levels and ovarian volume: Fasting venous blood (5 mL) was extracted from each patient on the day of admission and 3 menstrual cycles after treatment, and placed in the disposable vacuum vessel without anticoagulant. After standing at 20°C-25°C for 60 min, the blood samples were centrifuged at 3000× g for 10 min, and the obtained serum was separated and stored at -20°C. The levels of FSH, LH, LH/FSH, T and E₂ were detected by chemiluminescence kits (Siemens Healthcare Diagnostics (Shanghai) Co., Ltd.). ELISA kits (Shanghai Enzyme-linked Biotechnology Co., Ltd.) were used to detect the levels of PCT on the day of admission and 3 menstrual cycles after treatment. Pelvic ultrasound (EPIQ type-B ultrasonic, Philips) was used to detect the ovarian volume (calculated as ovarian volume (mm³) = 1/2 × length diameter (mm) × width (mm) × thickness (mm)) on the day of admission and 3 menstrual cycles after treatment, and the dominant follicles and ovulation induction days were monitored.

Detection of pulsation index (RI) and resistance index (PI) values of endometrial blood flow: Color Doppler flow imaging (Philips) was used to observe the blood flow of the uterine artery and its branches. After obtaining 3 or more consistent blood flow graphs of cardiac cycles, spectral image analysis was performed. Endometrial RI and PI were measured.

Pregnancy rate: Patients in both groups were followed up for 1 year after treatment, and the pregnancy status was recorded and compared between the two groups. Pregnancy rate = number of pregnancy cases/total cases × 100%.

Efficacy evaluation: Markedly effective: normal ovulation or pregnancy, menstrual cycle traits close to normal, normal LH/FSH ratio; Effective: improved menstrual cycle, occasional ovulation, LH/FSH close to normal; ineffective: no improvement in clinical symptoms, nor any recovery in ovulation or pregnancy. Total effective rate = number of cases of (markedly effective + effective)/total number of cases × 100%.

Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

Table 1. Baseline data ($\bar{x} \pm sd$)

Group	Control group (n=60)	Compound Cangchai Tiaozhong Decoction group (n=60)	t	P
Age (years)	31.5±3.5	31.4±3.4	0.159	0.874
BMI (kg/m ²)	24.71±2.32	24.38±2.65	0.726	0.469

Note: BMI: body mass index.

Statistics on the incidence of adverse reactions: Stomachache, swelling and lower abdominal pain were recorded in the two groups. Incidence of adverse reactions = number of cases of (stomachache + swelling + lower abdominal pain)/total number of cases × 100%.

Statistical processing

SPSS 20.0 statistical software was used for data analysis. The counting data were described as the number of cases (percentage), and the measurement data were recorded as mean ± standard deviation ($\bar{x} \pm sd$). Paired t-test was used for intra-group comparisons before and after treatment, and independent sample t-test was applied for inter-group comparisons. χ^2 test was used for the comparison between groups. $P < 0.05$ indicated that the difference was statistically significant.

Results

Comparison of general information between the two groups

As shown in **Table 1**, there were no statistically significant differences in average age and mean body mass index (BMI) between the two groups ($P > 0.05$).

Comparison of FSH, LH, LH/FSH and T levels between the two groups before and after treatment

As shown in **Table 2**, FSH, LH, LH/FSH and T levels did not differ statistically between the two groups before treatment ($P > 0.05$). After treatment, FSH, LH, LH/FSH and T levels decreased in both groups (all $P < 0.01$), and their levels in Compound Cangchai Tiaozhong Decoction group were lower than those in control group (all $P < 0.01$).

Comparison of E_2 and PCT levels and ovarian volume between the two groups before and after treatment

As shown in **Table 3**, there were no statistically significant differences in levels of

E_2 and PCT and ovarian volume between the two groups before treatment ($P > 0.05$). After treatment, PCT and ovarian volume decreased while E_2 increased in both groups (All $P < 0.01$), and compared with control group, PCT and ovarian volume were lower while E_2 was higher in Compound Cangchai Tiaozhong Decoction group (all $P < 0.01$).

Comparison of PI and RI values of endometrial blood flow between the two groups before and after treatment

As shown in **Table 4**, there were no statistically significant differences in endometrial blood flow PI and RI values between the two groups before treatment ($P > 0.05$). After treatment, the endometrial blood flow PI and RI values reduced in the two groups (both $P < 0.01$), and their values in Compound Cangchai Tiaozhong Decoction group were lower than those in control group (both $P < 0.01$).

Comparison of dominant follicles and ovulation induction days between the two groups

As shown in **Table 5** and **Figure 1**, Compound Cangchai Tiaozhong Decoction group had more dominant follicles and shorter ovulation induction days than control group ($P < 0.01$).

Comparison of pregnancy rate between the two groups after treatment

The pregnancy rate in Compound Cangchai Tiaozhong Decoction group (81.67%) was higher than that in control group (36.67%) after treatment ($\chi^2 = 25.145$, $P < 0.01$).

Comparison of total effective rate between the two groups after treatment

As shown in **Table 6**, the total effective rate in Compound Cangchai Tiaozhong Decoction group was higher than that in control group after treatment ($P < 0.01$).

Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

Table 2. Comparison of FSH, LH, LH/FSH and T levels before and after treatment ($\bar{x} \pm sd$)

Group	FSH (μ/L)	LH (μ/L)	LH/FSH	T (mmol/L)
Control group (n=60)				
Before treatment	9.24 \pm 2.12	16.14 \pm 4.42	2.71 \pm 0.91	24.55 \pm 8.40
After treatment	8.59 \pm 1.86 ^a	14.53 \pm 2.18 ^a	2.06 \pm 0.18 ^a	19.90 \pm 4.80 ^a
Compound Cangchai Tiaozhong Decoction group (n=60)				
Before treatment	9.27 \pm 2.13	16.10 \pm 4.21	2.73 \pm 0.92	22.21 \pm 9.15
After treatment	6.11 \pm 0.73 ^{a,b}	8.47 \pm 1.05 ^{a,b}	1.58 \pm 0.10 ^{a,b}	12.15 \pm 3.20 ^{a,b}

Note: compared with the same group before treatment, ^aP<0.01; compared with the control group after treatment, ^bP<0.01. FSH: follicle stimulating hormone; LH: luteinizing hormone; T: testosterone.

Table 3. Comparison of E₂, PCT levels and ovarian volume between the two groups before and after treatment ($\bar{x} \pm sd$)

Group	E ₂ (ng/L)	PCT ($\mu g/L$)	Ovarian volume
Control group (n=60)			
Before treatment	52.14 \pm 3.42	2.51 \pm 0.81	9.27 \pm 2.85
After treatment	70.53 \pm 5.18 ^a	1.43 \pm 0.38 ^a	7.01 \pm 1.80 ^a
Compound Cangchai Tiaozhong Decoction group (n=60)			
Before treatment	52.10 \pm 3.41	2.53 \pm 0.82	9.25 \pm 2.80
After treatment	95.87 \pm 6.05 ^{a,b}	0.68 \pm 0.15 ^{a,b}	6.05 \pm 0.91 ^{a,b}

Note: compared with the same group before treatment, ^aP<0.01; compared with the control group after treatment, ^bP<0.01. E₂: estradiol; PCT: pregnancy, procalcitonin.

Table 4. Comparison of PI and RI values of endometrial blood flow between the two groups before and after treatment ($\bar{x} \pm sd$)

Group	PI	RI
Control group (n=60)		
Before treatment	0.70 \pm 0.15	1.25 \pm 0.20
After treatment	0.65 \pm 0.09 ^a	1.10 \pm 0.09 ^a
Compound Cangchai Tiaozhong Decoction group (n=60)		
Before treatment	0.71 \pm 0.14	1.26 \pm 0.19
After treatment	0.60 \pm 0.05 ^{a,b}	0.95 \pm 0.05 ^{a,b}

Note: compared with the same group before treatment, ^aP<0.01; compared with the control group after treatment, ^bP<0.01. PI: pulsation index; RI: resistance index.

Table 5. Comparison of ovulation status between the two groups ($\bar{x} \pm sd$)

Group	Dominant follicle (n)	Days of ovulation induction (d)
Control group (n=60)	1.05 \pm 0.20	20.50 \pm 1.75
Compound Cangchai Tiaozhong Decoction group (n=60)	1.85 \pm 0.60	13.60 \pm 1.35
t	9.798	24.180
P	0.001	0.001

Comparison of incidence of adverse reactions between the two groups after treatment

As shown in **Table 7**, the incidence of adverse reactions after treatment in Compound Cangchai Tiaozhong Decoction group was lower than that in control group (P<0.01).

Discussion

In Compound Cangchai Tiaozhong Decoction, *Atractylodes lancea*, Chinese Honeylocust Spine and *Astragalus membranaceus* are the monarch drugs; *Largehead Atractylodes Rh*, *Radix bupleuri*, *Herba epimedii* and *Cistanche*

Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

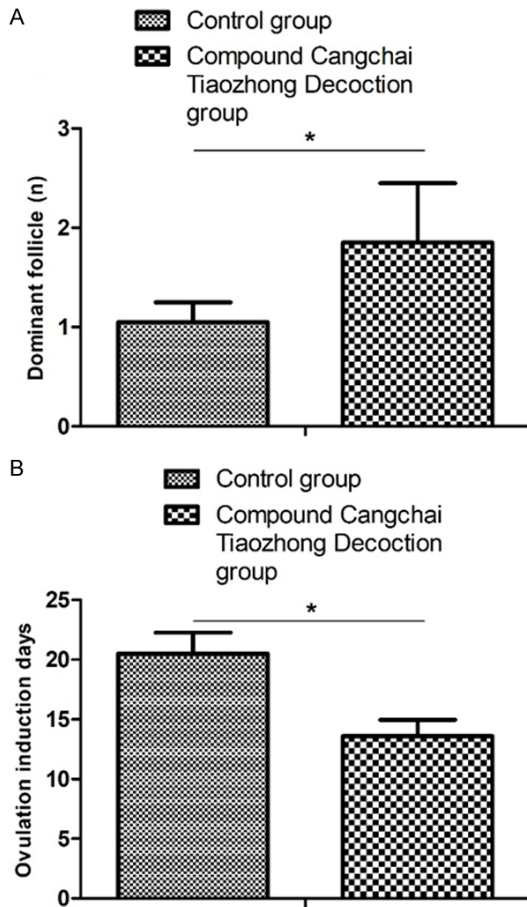


Figure 1. Comparison of ovulation status between the two groups. A. Dominant follicle; B. Days of ovulation induction. * $P < 0.001$.

deserticola are the minister drugs; *Codonopsis pilosula*, Beautiful Sweetgum Fruit, and *Ligusticum wallichii* are the assistant drugs and; dried tangerine peel, *Angelica sinensis*, *rhizoma cyperi*, *rhizoma cimicifugae*, *Rehmannia glutinosa* and *Achyranthes bidentata* are the conductant drugs. *Atractylodes lancea* and Largehead *Atractylodes Rh* can dry dampness and resolve phlegm, promote Qi and invigorate the spleen; dried tangerine peel can regulate Qi and invigorate the spleen, dry dampness and resolve phlegm; *Rhizoma cyperi* can disperse stagnated liver Qi for relieving Qi stagnation, regulate menstruation and relieve pain, as well as harmonize Qi and reconcile the middle energizer; *Ligusticum wallichii* can activate blood and promote Qi; *Herba epimedii* and *Cistanche deserticola* can nourish the kidney and strengthen the essence; *Rhizome of rehmannia* and *Rehmannia glutinosa* can nourish Yin, to-

nify serum heat and clear internal heat, supplement with *Poria cocos* to invigorate the spleen to eliminate dampness and resolve phlegm; *Astragalus membranaceus* and *Codonopsis pilosula* can invigorate spleen-stomach, replenish Qi and strengthen spleen; *Radix bupleuri* and *Rhizoma cimicifugae* promote spleen Yang and Qi, clear heat and remove toxicity; and *Glycyrrhiza* can invigorate the spleen, and neutralize and harmonize various drugs [10, 11]. On the basis of Cangchai Tiaozhong Decoction, Chinese Honeylocust Spine, *Achyranthes bidentata*, *Seman Sinapis Albae*, Beautiful Sweetgum Fruit are added, which can dredge collaterals, facilitate blood circulation and promote ovulation [12]. The interaction of various drugs is capable of removing dampness, dissolving phlegm, strengthening the spleen, promoting Qi, removing blood stasis and promoting stagnation.

FSH can inhibit the development of follicles, so that the follicles cannot develop and mature normally and cannot ovulate [13]. In patients with PCOS, the hypothalamic-pituitary-ovarian axis is maladjusted, and hyperandrogenemia affects ovulation during ovulation induction [14]. In addition, increased E_2 of PCOS patients, and elevated PI and RI values of perifollicular arteries will affect follicular maturation and seriously decrease follicle-promoting blood perfusion [15, 16]. In this study, the levels of FSH, LH, LH/FSH and T in Compound Cangchai Tiaozhong Decoction group were decreased after the treatment, indicating that Compound Cangchai Tiaozhong Decoction can improve the endocrine level of patients, thus improving the ovarian function and promoting ovulation. The increased PCT level is positively correlated with the severity of inflammation and is a secondary inflammatory factor, which can amplify and aggravate the pathological process of inflammatory response [17, 18]. PCOS patients usually suffer from Qi and blood stasis, which makes it difficult for eggs to discharge smoothly and increases the size of ovaries, resulting in infertility. In our research, Compound Cangchai Tiaozhong Decoction group presented lower FSH levels and ovarian volume while higher E_2 levels than control group after treatment, indicating that Compound Cangchai Tiaozhong Decoction could effectively improve patients' sex hormone levels and inhibit the inflammatory response.

Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

Table 6. Total effective rate of the two groups after treatment (n (%))

Group	Significantly effective	Effective	Non-effective	Total effective rate
Control group (n=60)	20	21	19	41 (68.33)
Compound Cangchai Tiaozhong Decoction group (n=60)	37	20	3	57 (95.00)
χ^2				14.249
P				<0.01

Table 7. Incidence of adverse reactions in the two groups after treatment (n (%))

Group	Stomachache	Swelling	Lower abdominal pain	Incidence of adverse reactions
Control group (n=60)	5	2	5	12 (20.00)
Compound Cangchai Tiaozhong Decoction group (n=60)	0	0	0	0 (0.00)
χ^2				13.133
P				<0.01

Compound Cangchai Tiaozhong Decoction can effectively increase follicle number and ameliorate sex hormone levels of PCOS patients with phlegm dampness block by “tonifying kidney essence, nourishing blood and regulating menstruation, as well as promoting blood circulation and removing stasis”, thereby promoting ovulation [19]. In the menstrual cycle of healthy women, there are typical periodic changes in the blood flow resistance of the ovarian interstitial artery. Related to the endocrine of patients, E_2 and LH levels are low in follicular phase, and the resistance of ovarian interstitial artery is higher. When LH reaches the peak, the blood flow of the ovarian interstitial artery increases during diastole, while RI decreases [20, 21]. The results of this study showed that the PI and RI values of endometrial blood flow of patients in Compound Cangchai Tiaozhong Decoction group were better improved, indicating that the Compound Cangchai Tiaozhong Decoction could promote blood circulation and improve pelvic microcirculation and hemodynamic status, further meliorating the uterine and ovarian blood supply of patients. Zeng et al. pointed out that the use of Bushenhuoxue Decoction in the treatment of PCOS ovulatory infertility can also improve the patient’s PI and RI values, which is consistent with the results of this study [22]. Furthermore, in Compound Cangchai Tiaozhong Decoction group, the predominant follicles increased, the ovulation induction days shortened, and the pregnancy rate increased, indicating that Compound Cangchai Tiaozhong Decoction significantly promoted ovulation and increased the pregnancy rate of PCOS patients.

Moreover, it was observed that the incidence of adverse reactions in Compound Cangchai Tiaozhong Decoction group was lower than that in control group after treatment, indicating that Compound Cangchai Tiaozhong Decoction could reduce adverse reactions in PCOS patients.

Of course, there is still room for improvement in this study. For example, the limited research time has resulted in insufficient clinical study samples and the failure to set up control groups with different treatment courses. If the observation time can be extended and the sample size can be increased, the conclusion will be more credible. In addition, we only conducted a preliminary study on the mechanism of Compound Cangchai Tiaozhong Decoction in the treatment of PCOS from a macro perspective. If relevant animal experiments can be conducted in depth, the conclusion of this study will be more reliable.

To sum up, Compound Cangchai Tiaozhong Decoction has a significant effect on the treatment of PCOS with phlegm-dampness block. It can improve sexual hormone levels of patients, promote ovulation, improve the pregnancy rate and reduce the inflammatory reaction, which is worthy of clinical promotion.

Disclosure of conflict of interest

None.

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Effect of Compound Cangchai Tiaozhong Decoction on polycystic ovary syndrome

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