Acupuncture combined with Chinese and western medicine in the treatment of polycystic ovary syndrome

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Summary
The present study aimed to evaluate the clinical effect of acupuncture combined with western medicine and Chinese medicine to tonify the kidney, promote blood circulation, and eliminate sputum in the treatment of polycystic ovary syndrome (PCOS). The 156 patients with PCOS who met the diagnostic criteria were randomly divided into the western medicine group who received Diane-35 (n = 40), the Chinese and western medicine group who received Diane-35 plus Chinese medicine to tonify the kidney, promote blood circulation, and eliminate sputum (n = 60), and the acupuncture and medicine group who received Chinese and western medicine plus acupuncture (n = 56). The groups received continuous treatment for three menstrual cycles. The pre- and post-treatment levels of serum testosterone (T) and fasting insulin (FINS), luteinizing hormone (LH)/follicle stimulating hormone (FSH) ratio, and ovulation rate were compared within the three groups. Compared with before treatment, all three groups showed decreases in the serum T and FINS levels and LH/FSH ratio (all \( P < 0.05 \)). Moreover, the post-treatment decreases in serum T and FINS levels, LH/FSH ratio, and ovulation rate were superior in the acupuncture and medicine group compared with the western medicine group (\( P < 0.05 \)) and Chinese and western medicine group (\( P < 0.05 \)). The concomitant use of acupuncture, Diane-35, and Chinese medicine to tonify the kidney, promote blood circulation, and eliminate sputum is effective in treating PCOS.

Key words: Polycystic ovary syndrome; Acupuncture; Chinese medicine; Western medicine; Treatment efficacy.

Introduction
Polycystic ovary syndrome (PCOS) is the most common endocrine and metabolic disease in adolescent females and women of childbearing age. PCOS is characterized by anovulation and hyperandrogenism [1]. Clinical manifestations of PCOS include menstrual disorders, infertility, excess body hair, obesity, acne, acanthosis nigricans, and multiple ovarian cysts. The incidence of PCOS is 5% to 10% in women of childbearing age, and 30% to 60% in women with anovulatory infertility [2]. There is currently no ideal treatment for PCOS. The present study aimed to evaluate the clinical effect of acupuncture combined with western medicine and Chinese medicine in the treatment of PCOS.

Subjects and Methods
Subjects
The study cohort comprised 156 patients with PCOS who were treated at our hospital from March 2015 to December 2017. In accordance with the syndrome differentiation of traditional Chinese medicine, these patients were diagnosed with kidney deficiency, blood stasis, and phlegm dampness. The patients were randomly divided into the western medicine group, Chinese and western medicine group, and acupuncture and medicine group. In the western medicine group (n = 40), the average patient age was 27 years (range 20–38 years), and the disease duration ranged from 3 months to 7 years. In the Chinese and western medicine group (n = 60), the average patient age was 26 years (range 18–36 years), and the disease duration ranged from 2 months to 6 years. In the acupuncture and medicine group (n = 56), the average patient age was 28 years (range 19–40 years), and the disease duration ranged from 4 months to 8 years. The study was approved by the ethics committee of Hubei Provincial Maternal and Child Health Hospital, written informed consent was obtained from all patients.

Diagnostic Criteria

Western medicine diagnostic criteria
In accordance with current guidelines [3–5], the diagnostic criteria were: age 18–40 years; menstrual disorder, infertility, excess body hair, obesity, acne, and acanthosis nigricans; laboratory tests showing low serum follicle stimulating hormone (FSH) level, luteinizing hormone (LH)/FSH ratio \( \geq 2.5 \), and increased serum testosterone (T) level on day 2 to 3 of the menstrual cycle; polycystic changes in the bilateral ovaries on B-scan ultrasonography.

Traditional Chinese medicine syndrome differentiation

Kidney deficiency, blood stasis, and phlegm dampness were diagnosed in accordance with current guidelines [6], based on symptoms such as a small amount of menstruation, early menstruation, late menstruation, or amenorrhea, menstrual blood clots, waist and knee soreness, dizziness and tinnitus, a plump body, an obese hairy body, being upset...
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and irritable, gloomy tongue, echymosis, petechiae, greasy fur, and a smooth pulse.

Inclusion criteria

The study cohort comprised patients who were 18–40 years old, met the abovementioned diagnostic criteria of western medicine and traditional Chinese medicine syndrome differentiation standards, and did not take other medications.

Exclusion criteria

The exclusion criteria were: organic damage of the genital organs; severe primary diseases of the cardiovascular, liver, kidney, and/or hematopoietic systems; mental illness; allergy to the research drugs; inability to tolerate acupuncture.

Methods

 Patients in the western medicine group were treated with Diane-35 from day 5 of menstruation or withdrawal of bleeding until menstruation; the dosage was one pill once daily for 21 consecutive days.

In the Chinese and western medicine group, the patients received therapy to tonify the kidney, promote blood circulation, and eliminate sputum, as well as the same Diane-35 treatment as the western medicine group. The traditional Chinese medicine was administered in accordance with the phases of the menstrual cycle. In the follicular phase (days 5 to 11 of the menstrual cycle), the method of tonifying the kidney and filling the essence was used; the basic prescription comprised prepared Rehmannia root 15 g, common yam rhizome 15 g, Asiatic cornelian cherry fruit 12 g, tree peony bark 10 g, Indian bread 10 g, Chinese angelica 10 g, fried red and white peony alba each 12 g, Achyranthes pseudobulb 10 g, and kelp 10 g. In the ovulatory phase (days 12 to 16 of the menstrual cycle), the method of tonifying the kidney, warming yang, regulating qi, and activating blood circulation was used; the basic prescription comprised prepared Rehmannia root 15 g, Chinese teasel root 15 g, Asiatic cornelian cherry fruit 12 g, tree peony bark 10 g, Indian bread 10 g, Malaytea Scurpea fruit 12 g, dodder seed 12 g, Chinese honeylocust spine 12 g, Faeces Trogopterori 10 g. In the luteal phase (days 17 to 25 of the menstrual cycle), the method of warming the kidney and invigorating yang was used; the basic prescription comprised common curculigo rhizome 12 g, palmleaf raspberry fruit 12 g, human placenta 3 g, Epimedium herb 10 g, Himalayan teasel root 10 g, prepared Rehmannia root 10 g, common yam rhizome 10 g, Cremastra appendiculata pseudobulb 10 g, tree peony bark 10 g, and danshen root 10 g. In the menstrual phase (from day 26 of the menstrual cycle to menstruation), the method of activating blood and promoting menstruation was used; the basic prescription comprised motherwort herb 15 g, danshen root 15 g, fried red and white peony alba each 12 g, Indian bread 10 g, Himalayan teasel root 12 g, Cyathula officinalis Kuan 15 g, thunberg fritillary bulb 10 g, and prepared Rhizoma cyperi with vinegar 10 g.

The acupuncture and medicine group received acupuncture in addition to the abovementioned Chinese and western medicine treatments. The patients received acupuncture once every other day, starting on day 5 of menstruation. In accordance with the Location of Acupoints of State Standard of People's Republic of China issued by the State Bureau of Technical Supervision, the following acupoints were selected: Qihai (RN6), Guanyuan (RN4), Zhongji (RN3), Guilai (double ST29), Zusanli (double ST36), Fenlong (ST40), and Sanyinjiao (SP6). The acupoints were added and subtracted in accordance with the symptoms present at the time of acupuncture administration. Shenhu (BL23) and Mingmen (DU4) were added for kidney-yang deficiency. Hegu (LI4) and Taichong (LR3) were added for stagnation of liver-qi. Yinlingquan (SP9) and Tianshu (ST25) were added for damp abundance due to splenic asthenia. The needle was inserted until the sensation of deqi was achieved. After the achievement of deqi, electroacupuncture was applied to Qihai (RN6) and Guanyuan (RN4) at a frequency of 16–18 times/minute as a continuous wave. The intensity was set so that the patient felt comfortable. The needles were maintained in place for 30 minutes. Acupuncture treatment was stopped during menstruation.

Treatment was continued for three menstrual cycles. During treatment, patients were advised to avoid eating cold spicy foods and staying up late, to perform appropriate exercises, and to control their diet.

Observation indexes

The menstrual volume, color, duration, and accompanying symptoms were recorded before and after treatment for all patients. The pre- and post-treatment serum levels of T, FSH, LH, and FINS were measured on days 2 to 3 of the menstrual cycle. The LH/FSH ratio was calculated. The number and size of the bilateral ovarian follicles were measured using B-scan ultrasonography, and the presence or absence of ovulation was observed. The ovulation rate was calculated.

Efficacy standards

The efficacy was assessed in accordance with the Guiding Principles for Clinical Research of New Traditional Chinese Medicine. Cure was defined as the return to a normal menstrual cycle, disappearance of concurrent symptoms, normal serum levels of T, FSH, LH, and FINS, presence of ovulation, biphasic basal body temperature, and pregnancy within 3 months in patients who had previously received infertility treatment or within 1 year in patients who had not received infertility treatment. Effectiveness was defined as a basically normal menstrual cycle (within 45 days), improvement of symptoms (such as excess body hair and acne), almost normal levels of serum T, FSH, LH, and FINS, and the presence of regular or occasional ovulation. The therapy was defined as invalid when continuous treatment for 3 months resulted in no change in clinical symptoms and examination findings, and there was no ovulation.
mental factors. The long-term complications of PCOS include type 2 diabetes, cardiovascular and cerebrovascular diseases, and endometrial cancer, and this condition seriously decreases the physical and mental health of patients [7-8]. Therefore, PCOS should be actively treated. Western medicine treatment of PCOS comprises the administration of oral contraceptive medications. In clinical practice, Diane-35 is a commonly used short-acting contraceptive that not only inhibits excessive secretion of gonadotropin, but also reduces androgen activity, improves endocrine levels [9], and adjusts menstrual disorders. However, as the sex hormone levels and clinical indicators return to pretreatment levels 6 months after withdrawal of treatment, there is a need to identify better treatment options.

In accordance with the symptoms and manifestations of PCOS, the disease is categorized as menopause, late menstruation, infertility, and abdominal mass. In traditional Chinese medicine theory, PCOS is strongly associated with dysfunction of the kidney, spleen, and liver, blood stasis, and phlegm stagnation. The pathogenesis of PCOS is based on kidney deficiency. Kidney deficiency easily causes yin-yang qi-blood disorders, blocks the Chong and Ren meridians and uterus, and causes qi stagnation and blood stasis, making the ovaries enlarge. Thus, it is difficult for the ovum to be discharged. A variety of pathological changes are caused by the changes in qi, blood, yin, and yang that occur during the menstrual cycle. Modern studies have showed that Bushen Huoxue Decoction improves the hemodynamic parameters of the uterus and ovarian arteries, and reduces serum LH and T levels, thereby effectively improving clinical efficacy [10-13]. In accordance with the changes in qi, blood, yin, and yang in the kidney during the follicular, ovulatory, luteal, and menstrual phases, the Chinese

Table 1. — Comparison of clinical efficacy in the three groups after treatment (number of cases, %)

<table>
<thead>
<tr>
<th>Group</th>
<th>Cure</th>
<th>Effective</th>
<th>Invalid</th>
<th>Effective rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture and medicine (56)</td>
<td>18(32.1%)</td>
<td>35(62.5%)</td>
<td>3(5.4%)</td>
<td>94.6%*</td>
</tr>
<tr>
<td>Chinese and western medicine (60)</td>
<td>13(21.7%)</td>
<td>41(68.3%)</td>
<td>6(10.0%)</td>
<td>90.0%*</td>
</tr>
<tr>
<td>Western medicine (40)</td>
<td>5(12.5%)</td>
<td>25(62.5%)</td>
<td>10(25.0%)</td>
<td>75.00%</td>
</tr>
</tbody>
</table>

Note: *P < 0.05, **P < 0.05, vs. the western medicine group; ***P < 0.05, vs. the Chinese and western medicine group.

Table 2. — Changes in T and FINS levels, LH/FSH ratio and ovulation rate among the three groups before and after treatment (mean ± SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>T (ng/mL)</th>
<th>LH/FSH (mIU/mL)</th>
<th>FINS (mIU/L)</th>
<th>Ovulation rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture and medicine group</td>
<td>Before treatment 0.85 ± 0.37</td>
<td>4.02 ± 3.01</td>
<td>9.04 ± 3.25</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>After treatment 0.22 ± 1.74*</td>
<td>0.52 ± 3.47*</td>
<td>4.97 ± 3.44*</td>
<td>82.40*</td>
</tr>
<tr>
<td>Chinese and western medicine group</td>
<td>Before treatment 0.89 ± 0.36</td>
<td>3.87 ± 4.17</td>
<td>8.52 ± 3.29</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>After treatment 0.41 ± 1.28*</td>
<td>1.34 ± 0.92*</td>
<td>5.16 ± 3.36*</td>
<td>60.5**</td>
</tr>
<tr>
<td>Western medicine group</td>
<td>Before treatment 0.89 ± 0.28</td>
<td>3.47 ± 2.33</td>
<td>8.47 ± 3.03</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>After treatment 0.67 ± 3.33*</td>
<td>2.28 ± 1.60*</td>
<td>6.29 ± 3.82*</td>
<td>17.25*</td>
</tr>
</tbody>
</table>

Note: *P < 0.05, vs. before treatment; **P < 0.05, vs. the acupuncture and medicine group after treatment.

Statistical Analysis

Data were analyzed using SPSS 19.0 software. Inter-group differences were compared using the independent sample t-test. The pre- versus post-treatment differences within each group were compared using the paired sample t-test. A value of $P < 0.05$ was considered statistically significant. Data in each group were expressed as the mean ± SD.

Results

Comparison of the clinical effectiveness of treatment between the three groups

The effective rates were 94.6%, 90.0%, and 75.0% in the acupuncture and medicine group, Chinese and western medicine group, and western medicine group, respectively (all $P < 0.05$) (Table 1).

Pre- versus post-treatment T and FINS levels, LH/FSH ratio, and ovulation rate within the three groups

Compared with the pre-treatment values, all three groups showed significant post-treatment decreases in the T and FINS levels and LH/FSH ratio, and a significant increase in the ovulation rate (all $P < 0.05$) (Table 2). The reduction in the T level, LH/FSH ratio, and FINS level, and the promotion of ovulation were superior in the acupuncture and medicine group compared with the western medicine group and the Chinese and western medicine group (Table 2).

Discussion

PCOS is an endocrine disorder syndrome caused by multiple genetic factors, multiple genes, and multiple environmental factors. The long-term complications of PCOS include type 2 diabetes, cardiovascular and cerebrovascular diseases, and endometrial cancer, and this condition seriously decreases the physical and mental health of patients [7-8]. Therefore, PCOS should be actively treated. Western medicine treatment of PCOS comprises the administration of oral contraceptive medications. In clinical practice, Diane-35 is a commonly used short-acting contraceptive that not only inhibits excessive secretion of gonadotropin, but also reduces androgen activity, improves endocrine levels [9], and adjusts menstrual disorders. However, as the sex hormone levels and clinical indicators return to pretreatment levels 6 months after withdrawal of treatment, there is a need to identify better treatment options.

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Acupuncture combined with Chinese and western medicine in the treatment of PCOS, and studies have shown that it produces significant effects [14-15]. Previous studies have shown that acupuncture not only downregulates the level of corticotropin-releasing hormone in the hypothalamus, regulates LH secretion, and improves insulin resistance and hyperandrogenism [16], but also inhibits overactivity of the sympathetic nervous system and regulates the neuroendocrine activity of the ovary by regulating the sympathetic activity [17]. Qihai (RN6) belongs to the Ren meridian, is the reservoir (sea) of qi, and regulates the qi of the body. The application of acupuncture at Qihai (RN6) renews qi and regulates menstruation. Guanyuan (RN4) acupuncture is the convergent acupuncture of the Ren meridian and the three yin meridians of the foot, and is connected with the Chong meridian; it is the intersection point of yin-yang and the primordial qi of the human body, and has the functions of nourishing primordial qi and regulating the Chong and Ren meridians. Zhongji (RN3) is the convergent acupuncture of the Ren meridian and the Foot-Taiyin meridian. Gualai (double ST29) is a local acupuncture used to treat diseases of the reproductive system. Zusanli (double ST36) strengthens the spleen, renews qi, and coordinates qi and blood. Fenglong (ST40) is the collateral point of the stomach channel of the Foot-Yangming, belongs to the spleen channel of the Foot-Taiyin, and strengthens the spleen and dissipated phlegm. Sanyinjiao (SP6) regulates the liver, spleen, and kidney, regulates qi, and promotes blood circulation. Overall, the application of acupuncture at the above-mentioned acupoints used in the present study invigorates primordial energy, renews qi, activates blood circulation, resolves phlegm, and regulates the Chong and Ren meridians.

Our results demonstrated that acupuncture combined with Diane-35 and Chinese medicine to tonify the kidney, promote blood circulation, and eliminate sputum effectively improves reproductive disorders in PCOS, promotes the regularization of menstruation, enables some infertile patients to conceive by reducing LH and T levels in the treatment of hyperandrogenic syndrome, and reduce the FINS level and improves insulin resistance. The present results suggest that acupuncture combined with Chinese medicine and Diane-35 plays a role in adjusting the glucose and lipid metabolism in patients with PCOS. This treatment combination may also be used as preventive treatment for the long-term complications of PCOS, such as diabetes, obesity, and heart disease. Acupuncture combined with Chinese medicine (to tonify the kidney, promote blood circulation, and eliminate sputum) and Diane-35 is an effective method for the treatment of PCOS, and should be applied in the clinical setting.

Conflict of Interest

The authors declare no competing interests.

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