Clinical study on Chuanxiong Hualiu Mixture in the treatment of blood stasis and phlegm stagnation type of ovarian cyst

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ABSTRACT

Objective: To observe the clinical efficacy of Chuanxiong Hualiu Mixture in the treatment of blood stasis and phlegm stagnation type of ovarian cyst and the effects on physical and chemical indicators. Methods: A total of 80 patients with blood stasis and phlegm stagnation type of ovarian cyst were randomly divided into two groups, research group (n=40) took Chuanxiong Hualiu Mixture, control group (n=40) took Guizhi Fuling Capsule, 3 months was a course of treatment, and the curative effect was compared between two groups. Results: (1) The overall response rate of Chuanxiong Hualiu mixture group after 3 months of treatment was 82.5%, that of Guizhi Fuling Capsule group was 62.5%, the overall response rate of Chuanxiong Hualiu mixture group was higher than that of control group, and the difference was statistically significant; (2) before and after treatment, sex hormone and hemorheology index E2 of both groups decreased significantly, whole blood viscosity, whole blood reduced viscosity and plasma viscosity decreased significantly, the results were statistically significant, but there was no difference between two groups; (3) rank sum test of TCM symptom efficacy between two groups before and after treatment showed that the overall response rate of Chuanxiong Hualiu mixture group was 95%, the overall response rate of Guizhi Fuling Capsule group was 85%, the overall response rate of research group was better than that of control group, and the difference was statistically significant. Conclusion: Chuanxiong Hualiu mixture has good curative effect for the treatment of ovarian cyst, it can effectively improve the patients’ blood stasis and phlegm stagnation constitution, and its mechanism of action is associated with lowering estrogen levels and improving hemorheology.

1. Introduction

Ovarian cyst is the clinical common disease of gynecology, which belongs to the "abdominal mass" category of traditional Chinese medicine, and often occurs in women between 20 and 50 years old[1]. In recent years, its incidence has been gradually increasing and accounts for 15 percent of women in the reproductive stage. It is one of the main causes of abdominal pain, menstrual abnormalities and infertility[2]. It has become a clinical common gynecological disease. Patients usually have no obvious symptoms, it is mostly discovered occasionally during physical examination[3], and as the cyst increases, it can be mainly characterized by lower abdominal discomfort and menstrual disorders. In severe cases, torsion ovarian pedicle, ovarian rupture and infection may occur, even change malignantly and become life-threatening. Surgical resection was usually used to relieve patients’ illness by western medicine in the treatment of ovarian cyst, but the surgical trauma is likely to cause huge impact on patients’ physical, psychological and spiritual aspects. The disease is easy to relapse. Therefore, it is important to find effective non-surgical therapy for benign ovarian cysts. Traditional Chinese medicine (TCM) holds that the disease can be intervened by oral administration and external application of Chinese medicine, enema or acupuncture to prevent the disease from aggravating[4]. In the following research, the efficacy of Chuanxiong Hualiu Mixture in the treatment of ovarian cyst and its effects on sex hormone levels and hemorheological features were analyzed.
2. Information and methods

2.1 General information

A total of 80 patients with ovarian cyst who were treated in Gynecological Clinic of Xiangshan Hospital of Traditional Chinese Medicine in Huangpu District Shanghai between June 2014 and December 2016 were selected and divided into two groups. Chuanxiong Huailiu Mixture group (research group) included 40 cases, they were 27-51 years old, and the course of disease was 0.5-4 years and (1.4±1.0) years in average; Guizhi Fuling Capsule group (control group) included 40 cases, they were 24-52 years old, and the course of disease was 0.5-4 years and (1.5±1.0) years in average; there was no significant difference in the age and course of disease between the two groups of patients (P>0.05), and they were comparable.

2.2 Diagnostic criteria of traditional Chinese and western medicine

2.2.1 Diagnostic criteria of traditional Chinese and western medicine in Practical Obstetrics and Gynecology[5]

(1) B ultrasound indicated ovarian simple cyst; (2) touchable ovary cystic enlargement by physical examination; (3) no significant change in ovarian cysts in 2 months.

2.2.2 Chinese medical syndrome differentiation standards in Gynecology of Chinese Medicine[6]

according to the syndrome differentiation of “abdominal mass”, those with blood stasis and phlegm stagnation had the following features: (1) the lower abdomen mass was soft and mobile, there was swelling pain now and then; abundant, white and sticky leucorrhea, or fullness in chest and stomach duct; (2) more or less menstrual blood volume, or with blood clots, menstrual period in advance or delay; (3) dark tongue nature or petechiae in the edge, ecchymosis, white tongue fur, deep unsmooth pulse or thready pulse.

2.3 Inclusion criteria

(1) participating in this clinical study voluntarily, and signing informed consent; (2) with age range between 20 and 65 years old; (3) conforming to the diagnostic criteria of western medicine; (4) conforming to the standard of differentiation of symptoms and signs.

2.4 Exclusion criteria

(1) patients associated with severe heart, liver, kidney, blood or endocrine diseases; (2) patients who had taken contraceptives, ovulatory drugs and other hormone drugs in the past 3 months; (3) the diameter of the ovarian cyst greater than 10 cm; (4) pregnant and breast-feeding women; (5) those with serum CA125>35 IU/mL.

2.5 Methods

(1) research group took Chuanxiong HuaiLiu mixture with drug compositions: angelica, rhizoma corydalis (processed by vinegar), dragon's blood, trogopterus dung (fried), ligusticum wallichii, poria cocos, processed pinellia tuber, radix paoniea rubra, rhizoma cypere (processed), radix rubiae (carbon), fennel fruit, myrrh (processed), concha arcae (calcined), thlaspi herba and cassia twig. The above 15 drugs were extracted into solution and taken orally, 20 mL each time, 3 times a day, 3 months as a course of treatment; (2) control group took Guizhi Fuling Capsule orally, 3 pills each time, 3 times a day, 3 months as a course of treatment; (3) during the treatment, both groups of patients were told to sleep regularly, take normal and light diet, refuse the spicy and fat, and refuse stimulating food[7].

2.6 Observation indicators

The clinical symptoms in both groups were observed before and after treatment, including the change of symptoms and signs of traditional Chinese medicine, B ultrasound was used to examine ovarian cyst volume change, and serum was collected during menstrual period to determine follicle stimulating hormone (FSH), estradiol (E2), luteinizing hormone (LH), progesterone (P), testosterone (T), prolactin (PRL), whole blood viscosity, whole blood reductive viscosity, plasma viscosity and hematocrit value.

The clinical efficacy of the two groups were determined according to clinical symptoms, syndromes and signs of traditional Chinese medicine, the changes of ovarian cysts and the related physical and chemical indexes.

2.7 Curative effect evaluation standard

2.7.1 The main curative effect standards were drawn up according to those in Obstetrics and Gynecology[8]

(1) recovery: B ultrasound review indicated that ovarian cysts disappeared, and clinical symptoms and signs disappeared; (2) excellent: the B ultrasound showed that the ovarian cyst shrank by 1/2, and the clinical symptoms were eliminated or significantly decreased; (3) effective: B ultrasound review indicated that the ovarian cyst shrank by 1/3, and the clinical symptoms were reduced; (4) invalid: B ultrasound review showed the ovarian cyst was without significant change or increased, and the clinical symptoms were without significant change.

2.7.2 Scoring standard of TCM symptoms

Lower abdomen pricking: none: 0 point; occasional and tolerable: 1 point; common and still tolerable: 2 points; menstruation: normal: 0 point; occasional irregularity: 1 point; irregular: 2 points; infertility: asymptomatic: 0 point; symptoms: 1 point; complexion: normal: 0 point; pale: 1 point; lacklustre: 2 points; fullness in chest and abdomen: none: 0 point; occasional fullness in stomach duct: 1 point; fullness in stomach duct and abdomen: 2 points; leucorrhea amount: normal: 0 point; slight increase: 1 point; significant increase: 2 points; tongue fur: white: 0 point; thin, white and greasy: 1 point; thick, white and greasy: 2 points; light purple tongue nature, and with petechiae and ecchymosis: none: 0 point; light and dark tongue nature: 1 point; light purple tongue nature, without ecchymosis: 2 points;
points; light and dark tongue nature, with petechiae and ecchymosis: 3 points; thready pulse or deep unsmooth pulse: normal: 0 point; thready: 1 point; deep unsmooth: 2 points.

2.7.3 Diagnostic criteria for curative effect of TCM syndrome
The evaluation criteria of symptoms: the overall curative effect of the syndrome was judged by integral method; the curative effect index = (integral before treatment - integral after treatment)/integral before treatment *100%; recovery: n ≥ 90%; excellent: 66.7 ≤ n < 90%; effective: 33.3% n < 66.7%; invalid: n < 33.3%.

2.8 Statistical analysis
SPSS 19.0 software was used to input data, measurement data were by t test, count data were by chi-square test and P<0.05 indicated statistical significance in differences.

3. Results
3.1 Comparison of curative effect of ovarian cyst between two groups of patients before and after treatment
After research group received 3 months of treatment, the results showed that there were 17 recovery cases (42.5%), 10 excellent cases (25.0%), 6 effective cases (15.0%) and 7 invalid cases (17.5%), and the overall effective rate was 82.5%; after control group received 3 months of treatment, the results showed that there were 12 recovery cases (30.0%), 7 excellent cases (17.5%), 6 effective cases (15.0%) and 15 invalid cases (37.5%), and the overall effective rate was 62.5%. Compared with that of control group, the overall effective rate of Chuanxiong HuaLiu mixture group increased significantly (P<0.05).

3.2 Comparison of sex hormones and hemorheology indexes between two groups of patients before and after treatment
E2 of Chuanxiong Huali u mixture group and Guizhi Fuling Capsule group significantly decreased after treatment, and the difference was statistically significant (P<0.01), but there was no difference between two groups. The results showed that both Chuanxiong Huali mixture and d Guizhi Fuling Capsule were able to reduce the estrogen levels, and the results were shown in Table 1. Whole blood viscosity, whole blood reducing viscosity and plasma viscosity of both groups decreased significantly after treatment, and the difference was statistically significant (P<0.01), but there was no difference between two groups. The results showed that both Chuanxiong Huali mixture and d Guizhi Fuling Capsule were able to reduce blood viscosity and improve hemorheology, and the results were shown in Table 2.

3.3 Comparison of curative effect of TCM syndrome
After research group received 3 months of treatment, there were 1 recovery case (2.5%), 20 excellent cases (50.0%), 17 effective cases (42.5.0%) and 2 invalid cases (5.0%), and the overall effective rate was 95.0%; after control group received 3 months of treatment, there were 0 recovery case (0.0%), 11 excellent cases (27.5%), 23 effective cases (57.5%) and 6 invalid cases (15.0%), and the overall effective rate was 85.0%. After rank sum test, P<0.05, the two were different, and research group were better than control group. The results showed that Chuanxiong Huali mixture could improve the body constitution of blood stasis and phlegm stagnation and thus shrink or cure ovarian cyst.

Table 1.
Effect of two therapies on sex hormones.

<table>
<thead>
<tr>
<th>Sex hormone items</th>
<th>Time</th>
<th>FSH</th>
<th>LH</th>
<th>E2</th>
<th>P</th>
<th>T</th>
<th>PRL</th>
</tr>
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<tr>
<td>Research group</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Before treatment</td>
<td>6.9±3.1</td>
<td>6.1±2.6</td>
<td>117±36.7</td>
<td>0.5±0.1</td>
<td>22.1±5.5</td>
<td>13.8±3.6</td>
<td></td>
</tr>
<tr>
<td>After treatment</td>
<td>7.1±3.7</td>
<td>6.3±3.0</td>
<td>105±35.5</td>
<td>0.5±0.1</td>
<td>22.1±4.9</td>
<td>13.6±3.1</td>
<td></td>
</tr>
<tr>
<td>t</td>
<td>-1.46</td>
<td>-1.64</td>
<td>5.71</td>
<td>-2.00</td>
<td>1.43</td>
<td>0.87</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&lt;0.01</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
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<tr>
<td>Control group</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Before treatment</td>
<td>7.7±4.6</td>
<td>6.3±3.4</td>
<td>109.8±39.6</td>
<td>0.5±0.1</td>
<td>22.4±6.7</td>
<td>13.3±3.8</td>
<td></td>
</tr>
<tr>
<td>After treatment</td>
<td>7.8±4.9</td>
<td>6.5±3.6</td>
<td>96.8±31.8</td>
<td>0.5±0.1</td>
<td>22.2±6.2</td>
<td>13.1±4.0</td>
<td></td>
</tr>
<tr>
<td>t</td>
<td>1.35</td>
<td>0.35</td>
<td>5.61</td>
<td>0.03</td>
<td>0.86</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&lt;0.01</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

Note: compared with before treatment, **P<0.01.

Table 2.
Effect of two therapies on hemorheology.

<table>
<thead>
<tr>
<th>Hemorheology items</th>
<th>Time</th>
<th>Whole blood viscosity high shear</th>
<th>Whole blood reducing viscosity high shear</th>
<th>Hematocrit value</th>
<th>Plasma viscosity</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Research group</td>
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<td></td>
</tr>
<tr>
<td>Before treatment</td>
<td>5.0±0.3</td>
<td>7.9±0.9</td>
<td>0.35±0.02%</td>
<td>1.6±0.1</td>
<td></td>
</tr>
<tr>
<td>After treatment</td>
<td>4.7±0.4</td>
<td>7.3±0.9</td>
<td>0.35±0.02%</td>
<td>1.5±0.1</td>
<td></td>
</tr>
<tr>
<td>t</td>
<td>11.96</td>
<td>12.20</td>
<td>12.20</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before treatment</td>
<td>5.0±0.4</td>
<td>8.1±1.0</td>
<td>0.37±0.01%</td>
<td>1.6±0.1</td>
<td></td>
</tr>
<tr>
<td>After treatment</td>
<td>4.7±0.4</td>
<td>7.4±1.0</td>
<td>0.37±0.02%</td>
<td>1.5±0.1</td>
<td></td>
</tr>
<tr>
<td>t</td>
<td>9.24</td>
<td>10.90</td>
<td>10.90</td>
<td>1.27</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td></td>
</tr>
</tbody>
</table>

Note: compared with before treatment, **P<0.01.
4. Discussion

The people's standard of living is rising with the rapid development of society, the chance for eating high cholesterol foods greatly increases, industrial technology development also brings a lot of pollution to our living environment, study shows that the incidence of ovarian cysts may be associated with high cholesterol and environmental factors, and may also have relationship with familial inheritance, as well as women's own factors, namely the endocrine factors[6]. Modern medical research shows that chronic inflammation of the reproductive system is also the main cause of the disease[7]. Ovarian cysts are common tumors in gynecology, and modern medicine has limitations in the treatment of the disease. Surgical treatment is generally chosen for bigger cyst that is more than 5 cm in diameter, the curative effect is exact, but patients will inevitably suffer from surgical trauma and bear a larger economic burden, and it is found that many patients have the signs of recurrence after surgery. A lot of clinical studies have also shown that after laparoscopic ovarian cyst decollement, the number of primary follicle in surgery side is significantly lower than that in contralateral side, which affects the female ovulation and fertility function [11]. Effective treatment is short for minor cysts, which is known as the "window period" in treatment[12].

Compared with the single surgical treatment of modern medicine, TCM has a great advantage in the treatment of ovarian cysts. At present, Chinese traditional treatment has been introduced in the course of clinical treatment of ovarian cyst, and the effect is significant[13]. Ovarian cyst belongs to the category of "intestinal tan", "abdominal mass", "accumulation" and so on in traditional Chinese medicine. From the view of clinical features such as fixed pain and failing to move when pushed, the ovarian cyst is more consistent with the concept of illness and accumulation[14]. TCM holds that the pathogenesis of this disease lies in the visceral dysfunction, the obstruction of functional activities of qi, the phlegm obstruction-induced stasis, the blood stasis dampness retention, and the intermingled phlegm and blood stasis. "Stasis" is the basic pathogenesis of the disease[15]. Thus, the method of promoting blood circulation to remove blood stasis, eliminating phlegm and removing dampness as well as resolving hard lump is adopted. Chuanxiong Hualiu mixture is the TCM mixture developed successfully by our hospital after repeated experiments and clinical verifications. Angelica, dragon’s blood, trogotropus dugu and radix rubiae promote blood circulation to remove blood stasis as well as stop pain and regulate menstruation; rhizoma cyperi, rhizoma corydalis, fennel fruit and ligusticum wallichii break blood to remove stasis and regulate menstruation; rhizoma cyperi, rhizoma corydalis, fennel fruit and ligusticum wallichii break blood to remove stasis and regulate menstruation; rhizoma cyperi, rhizoma corydalis, fennel fruit and ligusticum wallichii break blood to remove stasis and regulate menstruation. All compositions work together to achieve the effect of softening hardness and eliminating stagnation, promoting blood circulation to remove blood stasis as well as disinhibiting water and dispersing accumulation.

In the study, Chuanxiong Hualiu mixture was used to treat simple ovarian cyst, it significantly reduced the size of ovarian cyst, the overall effective rate was 82.5%, and the effect is more prominent than that of Guizhi Fuling Capsule. At the same time, the serum estrogen levels in two groups were significantly lower after treatment, which adjusted the sex gland axis and made endocrine hormone achieve balance. Although the differences between the two groups were not obvious, the effect of reducing estrogen was clear. In addition, the whole blood viscosity, whole blood reducing viscosity and plasma viscosity of the two groups decreased obviously after treatment, there was no difference between the two groups, but the effect of the two drugs is remarkable on improving the patient's blood dynamics and microcirculation. Finally, in terms of symptoms and signs of traditional Chinese medicine, the overall effective rate of Chuanxiong Hualiu mixture group was 95.0%, the effect was more significant than that of Guizhi Fuling Capsule group, and it proves that Chuanxiong Hualiu mixture can not only shrink tumors, but can also significantly improve the symptom such as menstrual disorders, lower abdomen pain and dark complexion, and improve the body constitution of phlegm stagnation. So traditional Chinese medicine is better at curing the disease, and traditional Chinese medicine treatment has better long-term effects[16]. This clinical study also provides a new drug option for treating ovarian cysts.

References