Clinical Observation on the Treatment of Early Pre-Eclampsia Abortion with the Combination of Enhanced “Shou Tai Wan” Soup and Progesterone

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Abstract: Objective: To investigate the clinical efficacy of the combination of enhanced “Shou Tai Wan” soup and progesterone in the treatment of early pre-eclampsia miscarriage. Methods: 86 patients with early pre-eclampsia miscarriage in our hospital from July 2021 to July 2022 were selected and randomly divided into two groups of 43 cases each. The control group was treated with progesterone, while the study group was treated with an addition of enhanced “Shou Tai Wan” soup. The treatment effects of the two groups and the changes in the inflammatory factor levels and sex hormone levels before and after the treatment were observed. Results: INF-γ and IL-2 were lower and IL-4 was higher in the study group than in the control group after treatment (p-value < 0.05); the total effective rate of treatment was higher in the study group (95.35%) than in the control group (74.42%), (p-value < 0.05); the levels of P, E2 and β-hCG were higher in the study group than in the control group after treatment (p-value < 0.05). Conclusion: The combined application of enhanced “Shou Tai Wan” soup and progesterone in patients with early preterm abortion is more effective by improving the patients’ sex hormone levels and reducing the level of inflammatory factors, which is conducive to the improvement of the treatment effect and worthy of promotion.

Keywords: Enhanced “Shou Tai Wan” soup; Progesterone; Early pre-eclampsia miscarriage; Application effect; Sex hormone level; Inflammatory factor

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1. Introduction
Pre-eclampsia refers to a small amount of vaginal bleeding or symptoms of the lower abdomen, back pain, and abdominal pain in women during pregnancy. Studies have shown that the incidence of spontaneous abortion is about sixteen percent, with early abortion occurring in about eighty percent of patients [1]. The development of society and the improvement of living standards have contributed to the increasing pressure of life and work on women, and the proportion of miscarriages among women of childbearing age is increasing [2]. Progesterone is a commonly used drug, but it is ineffective and has many adverse effects; Chinese medicine classifies pre-eclampsia miscarriage as fetal movement and fetal leakage and believes that the important pathogenic mechanism leading to the occurrence of this disease is kidney deficiency, and enhanced “Shou Tai Wan” soup has the effect of calming the fetus and tonifying the kidney [3]. In this paper,
we analyze the effect of combining enhanced “Shou Tai Wan” soup and progesterone in the treatment of patients with early pre-eclampsia miscarriage.

2. Materials and Methods

2.1. General information

86 patients with early preterm abortion who were admitted to our hospital from July 2021 to July 2022 were randomly divided into two groups of 43 patients each. In the control group, the duration of illness was 1–7 days, with a mean of 3.67 ± 0.64 days, 22–39 years old, with a mean of 33.47 ± 2.11) years. In the study group, the duration of illness was 1–7 days, mean (3.79 ± 0.71) days, age 22–39 years, mean 34.18 ± 2.04 years. General data were comparable (p-value > 0.05). Inclusion criteria: confirmed diagnosis of early pre-eclampsia and consent to fertility preservation treatment; informed consent signed by the patient’s family. Exclusion criteria: contraindication to the drugs used; history of psychiatric disorders; presence of coagulation disorders or liver and kidney dysfunction; medication prior to the study.

2.2. Methods

In the control group, 20 mg of progesterone was administered by intramuscular injection once a day, while in the study group, enhanced “Shou Tai Wan” soup was administered in addition to the same amount of progesterone and administration methods in the control group. Enhanced “Shou Tai Wan” soup was made of 10 g Scutellaria baicalensis, 10 g Radix et Gastrodiae Rhizoma, 10 g Colla corii asini, decocted in water. Then, 200 ml of juice was extracted and consumed warm in the morning and evening. Both groups were treated for 20 days to observe the effect.

2.3. Observation indicators

The levels of inflammatory factors before and after treatment were observed in both groups, with indicators containing INF-γ (interferon gamma), IL-2 (interleukin-2) and IL-4 (interleukin-4).

The efficacy of the treatment in both groups was determined according to the Diagnostic Efficacy Criteria for Chinese Medicine [4], where effective means that the symptoms of illness such as abdominal cramping and back pain disappeared after treatment, bleeding stopped, and ultrasound examination indicated embryonic development, uterine size and gestational week;. Ineffective means the above criteria were not met.

Sex hormone levels before and after treatment were observed in both groups, with indicators containing P (progesterone), E2 (estradiol) and β-hCG (chorionic gonadotropin).

2.4. Statistical analysis

The data were analyzed using SPSS 20.0, where the χ² (%) test for counts and the t-test (x ± s) test for measures were performed, with a (p-value < 0.05) indicating a significant difference.

3. Results

3.1. Comparison of inflammatory factors

INF-γ and IL-2 were lower and IL-4 was higher in the study group than in the control group after treatment (p-value < 0.05) as shown in Table 1.
### Table 1. Comparison of inflammatory factors ($\bar{x} \pm s$, ng/ml)

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>INF-γ Pre-treatment</th>
<th>INF-γ Post-treatment</th>
<th>IL-2 Pre-treatment</th>
<th>IL-2 Post-treatment</th>
<th>IL-4 Pre-treatment</th>
<th>IL-4 Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>43</td>
<td>1.27 ± 0.21</td>
<td>1.23 ± 0.12</td>
<td>4.23 ± 0.24</td>
<td>4.07 ± 0.20</td>
<td>0.17 ± 0.03</td>
<td>0.21 ± 0.04</td>
</tr>
<tr>
<td>Experimental</td>
<td>43</td>
<td>1.31 ± 0.23</td>
<td>1.02 ± 0.09</td>
<td>4.31 ± 0.22</td>
<td>3.31 ± 0.14</td>
<td>0.19 ± 0.04</td>
<td>0.27 ± 0.03</td>
</tr>
<tr>
<td>t-value</td>
<td></td>
<td>1.381</td>
<td>15.082</td>
<td>1.932</td>
<td>12.509</td>
<td>1.384</td>
<td>13.943</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

3.2. Comparison of treatment results
The total effective rate of treatment was higher in the study group (95.35%) than in the control group (74.42%), ($p$-value < 0.05), as shown in Table 2.

### Table 2. Comparison of treatment outcomes (cases, %)

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Visible effect</th>
<th>Effective</th>
<th>Ineffective</th>
<th>Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>43</td>
<td>18 (41.86)</td>
<td>14 (32.56)</td>
<td>11 (25.58)</td>
<td>74.42%</td>
</tr>
<tr>
<td>Experimental</td>
<td>43</td>
<td>25 (58.14)</td>
<td>16 (37.21)</td>
<td>2 (4.65)</td>
<td>95.35%</td>
</tr>
<tr>
<td>$\chi^2$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.234</td>
</tr>
<tr>
<td>$p$-value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

3.3. Comparison of sex hormone levels
P, E2 and $\beta$-hCG levels were higher in the study group than in the control group after treatment ($p$-value < 0.05) which are shown in Table 3.

### Table 3. Comparison of sex hormone levels ($\bar{x} \pm s$)

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>P (pg/ml) Pre-treatment</th>
<th>P (pg/ml) Post-treatment</th>
<th>E2 (pg/ml) Pre-treatment</th>
<th>E2 (pg/ml) Post-treatment</th>
<th>$\beta$-hCG (mIU/ml) Pre-treatment</th>
<th>$\beta$-hCG (mIU/ml) Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>43</td>
<td>21.37 ± 3.64</td>
<td>58.26 ± 8.15</td>
<td>812.64 ± 222.12</td>
<td>904.20 ± 232.34</td>
<td>21820.66 ± 223.41</td>
<td>78872.41 ± 252.33</td>
</tr>
<tr>
<td>Experimental</td>
<td>43</td>
<td>21.24 ± 3.44</td>
<td>80.92 ± 8.23</td>
<td>811.09 ± 207.26</td>
<td>1087.15 ± 242.33</td>
<td>21626.41 ± 249.65</td>
<td>102633.21 ± 249.66</td>
</tr>
<tr>
<td>t-value</td>
<td></td>
<td>1.479</td>
<td>15.192</td>
<td>1.536</td>
<td>15.682</td>
<td>1.339</td>
<td>14.485</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
<td>&gt; 0.05</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

4. Discussion
Early pre-eclampsia is a common gynecological condition in which the main symptoms are when the patient experiences a small amount of vaginal bleeding with paroxysmal lower abdominal pain while having unopened cervical opening and unbroken membranes. Western medicine believes that the occurrence of pre-eclampsia is related to abnormal immune function, genetic factors, endometrial abnormalities, endocrine abnormalities, and other factors. Progesterone and hCG have the ability to inhibit uterine contractions, accelerate endometrial growth and reduce uterine sensitivity, and are more effective in increasing the pregnancy rate and embryo implantation rate\[^5-7\]. However, studies have shown that Western medicine cannot fully guarantee the ideal endometrial environment, while the addition of Chinese herbal
medicine can mobilize the regulatory and defense mechanisms in the human body, which is more effective in most cases of pre-eclampsia caused by immune and endocrine insufficiency. It can strengthen the patient’s body, improve the pelvic environment and disease symptoms, while promoting embryo implantation and development, thus eliminating the disease from the root [8].

Chinese medicine classifies pre-eclampsia miscarriage as fetal disturbance and fetal leakage, and considers its basic symptoms to be deficiency of kidney qi, damage to the ramifications, deficiency of qi and blood, and heat disturbing yin deficiency leading to the failure of the fetal element [9]. The treatment of such patients should follow the principles of nourishing the kidney, tonifying the kidney, and regulating the qi and blood [10]. Enhanced “Shou Tai Wan” soup mainly consists of Glycyrrhiza glabra (licorice), Radix Astragali, Rhizoma Atractylodis Macrocephalae, Semen Cuscutae, Radix et Rhizoma Mulberry, Radix et Rhizoma Chuanxianthux, Radix et Rhizoma przewalskii, Scutellaria Baicalensis, Radix et Rhizoma Saxifraga, and Colla corii asini. Modern pharmacological studies have confirmed that Chuan Xuan Guan has an inhibitory effect on the spontaneous contraction activity of the uterus’ smooth muscle while reducing its contraction amplitude and tension [11].

The present results showed that INF-γ and IL-2 were lower and IL-4 was higher in the study group than in the control group after treatment (p-value < 0.05), indicating that the combined application of progesterone and enhanced “Shou Tai Wan” soup can effectively reduce the level of inflammatory factors [12]. A related study pointed out that patients with doubled blood hCG levels achieved better results after fetal preservation treatment, while those with less increases had a higher chance of miscarriage. Dynamic monitoring of patients’ sex hormone levels is of great value in predicting the prognosis of patients with early preterm abortion [13]. Increased E2 levels represent the good placental function and good fetal survival [14]. There is a positive correlation between progesterone levels and hCG levels in early pregnancy, and if a pregnant woman’s progesterone level is reduced it means that her placenta is not functioning well enough to continue the pregnancy [15]. The results showed that the total effective rate of treatment as well as the P, E2, and β-hCG levels after treatment were higher in the study group than in the control group (p-value < 0.05), indicating that the combined treatment of progesterone and enhanced “Shou Tai Wan” soup can effectively improve the sex hormone levels of patients with early pre-eclampsia abortion and enhance the treatment effect.

5. Conclusion
In conclusion, the combined treatment of progesterone and enhanced “Shou Tai Wan” soup in patients with early pre-eclampsia is effective in improving the patients’ sex hormone levels and reducing the level of inflammatory factors in the body, which is conducive to the improvement of the therapeutic effect and should be popularized.

Disclosure statement
The authors declare no conflict of interest.

References


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