

# ***Mechanism Study on the Treatment of Pelvic Pain in Endometriosis by Qu Yu Jie Du Xiao Zheng Decotion in Combination with Dextroprogesterone***

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**Abstract:** This study aimed to evaluate the clinical efficacy and effect on serum levels of PGE2, NGF and TNF- $\alpha$  of the combination of Qu Yu Jie Du Xiao Zheng Decotion and Dydrogesterone in treating pelvic pain in patients with endometriosis. Sixty patients were randomly divided into three groups: Chinese medicine group, Western medicine group, and combination group. After treatment, the combination group showed significant relief of pain, and the apparent efficacy of menstrual pain, pelvic pressure pain, and palpable nodules was 70%, 83.33%, and 61.54%, respectively, which was significantly higher than that of the other two groups. There were significant differences in serum TNF- $\alpha$ , NGF and PGE2 levels among the three groups after treatment. The conclusion was that the combination of Qu Yu Jie Du Xiao Zheng Decotion and Dydrogesterone could significantly improve the immune function of patients with endometriosis, regulate levels of nerve growth factor, tumor necrosis factor, and prostaglandin E2, thereby relieving pain.

## **1. Introduction**

Endometriosis (EMs) is a gynecological disease caused by endometrial growth in the uterus and other extra-uterine parts, which mostly occurs in women aged 20-45 years old, and the incidence of this disease has been on the rise in recent years [1]. EMs can infiltrate other organs in the patient's pelvic cavity, and has the characteristics of proliferation, hyperplasia, and metastasis, with clinical manifestations such as pelvic pain and infertility, which seriously affect the patient's health and quality of life [2]. For the treatment of EMs, Western medicine mainly adopts sex hormone therapies such as progesterone, contraceptive pills, and mifepristone to achieve the purpose of relieving pain by inhibiting ovulation, which has a better effect on symptomatic improvement in the short term, but is prone to drug resistance, and the symptoms are easy to recur after discontinuing the drug [3]. In Chinese medicine, this disease belongs to the category of "dysmenorrhea" and "symptoms". In recent years, many scholars believe that the pathogenesis of EMs is stasis of blood, evil blood congestion in the uterus and veins of the uterus, which becomes toxic over time and is transformed into stasis of toxins, and advocate that this disease should be treated with the method of eliminating

stasis of blood and removing toxins [4]. In the present study, in order to enhance the efficacy of EMs, the treatment of Qu Yu Jie Du Xiao Zheng decoction was added on the basis of conventional western medicine treatment, which is now reported as follows.

## 2. Information and Methods

In this study, a total of sixty patients diagnosed with EMs were selected from the gynecology outpatient clinic of Xi'an Hospital of Traditional Chinese Medicine between January 2022 and December 2022. The random assignment of patients to different treatment groups, namely A: Traditional Chinese medicine group, B: Western medicine group, and C: Combination of Chinese and Western medicine group, was conducted using the random number generation algorithm in SPSS22.0 statistical software. The age range of the traditional Chinese medicine group was between 25 and 44 years, with an average age of  $33.95 \pm 4.23$  years. The duration of the disease varied from 0.4 to 5 years, with an average duration of  $2.07 \pm 1.15$  years. The body mass index ranged from 19.8 to 26, with a mean body mass index of  $22.28 \pm 1.34$ . In the western medicine group, the age range was between 22 and 25 years, with a mean age of  $32.55 \pm 6.75$  years. The disease duration varied from 0.5 to 4 years, with an average duration of  $1.85 \pm 1.18$  years. The body mass index ranged from 18.9 to 27, with a mean body mass index of  $22.72 \pm 1.95$ . In the group combining Chinese and Western medicines, the age range was between 25 and 45 years, with a mean age of  $33.5 \pm 5.63$  years. The disease duration varied from 1 to 6 years, with an average duration of  $2.35 \pm 1.31$  years. The body mass index ranged from 19 to 26, with a mean body mass index of  $22.32 \pm 1.49$ . After conducting a  $\chi^2$  test, the difference between the baseline data of the three groups was not statistically significant ( $P > 0.05$ ), and was considered comparable.

The inclusion criteria for this study were as follows: ① Patients with endometriosis who met both the clinical diagnostic criteria of Western medicine [5] and the Chinese medicine diagnosis of "stasis, toxicity, dampness and turbidity" [6]; ② Patients who did not have plans for pregnancy within the next year; ③ Patients who voluntarily agreed to participate in the study and signed the informed consent form; ④ Patients who had previously undergone treatment with hormonal drugs or conservative surgical treatments, and had ceased usage for a minimum of three months; or patients who had received traditional Chinese medicine (TCM) treatment for at least three months; or patients who had previously received TCM treatment, but had stopped using the medicine for at least one month and still met the aforementioned diagnostic criteria.

The exclusion criteria for this study encompass various medical conditions, which include severe uterine fibroids, cardiovascular and cerebrovascular diseases, hepatic and renal diseases, as well as hematopoietic system diseases. Additionally, patients with psychiatric disorders and those who have demonstrated allergies to the drug being tested, as well as the control drug, are also excluded. Furthermore, individuals who fail to meet the inclusion criteria, fail to adhere to the drug usage criteria, or have incomplete data that may hinder the assessment of therapeutic efficacy and safety are also excluded.

Treatment ① The oral Qu Yu Jie Du Xiao Zheng decoction in the Traditional Chinese medicine group consists of various herbal ingredients. These include 30g of Sargentgloryvine Stem , 30g of Hedyotis diffusa, 30g of Coix seed, 30g of Astragalus membranaceus, 15g of Corrugated wood, 15g of Litchi seed (broken), 10g of Pseudobulbus Cremastrae seu Pleiones (broken), 9g of Agastache rugosus (after the lower part of the head), 2 Centipede (with head and feet removed), 6g of Resina draconis, 6g of Eupolyphaga, 6g of Olibanum, 6g of Myrrha, and 6g of Radix Glycyrrhizae Preparata[7]. The Xi'an Hospital of Traditional Chinese Medicine's Pharmacy Center prepared a decoction, while the Traditional Chinese Medicine Decoction Room provided the broth, in the amount of 200mL per bag. The recommended dosage is one bag, two times a day, in the morning

and evening. It is important to note that no other medications should be taken for this condition during the treatment period. Additionally, the consumption of cold drinks, oily foods, and stimulating foods should be minimized while taking this medication. If a cold is contracted, the medication should be immediately discontinued. In the event of pregnancy during treatment, the medication should also be stopped immediately. Individuals with allergies to Chinese medicine are prohibited from using this medication, and those who are allergic should exercise caution. ② Western medicine group: Daflon (Diflucan tablets Abbott Biologicals B.V. (Netherlands)) should be administered at a dosage of 10mg per intake, twice daily, starting from the fifth day of the menstrual cycle and continuing for a duration of 20 days. It is necessary to undergo a consecutive treatment regimen for three menstrual cycles. It is important to note that the concomitant use of other medications with similar effects is strictly contraindicated during the treatment period. ③ Combination of Chinese and Western medicines group: the administration method of oral Chinese medicine is similar to that of the Chinese medicine group. Additionally, dydrogesterone tablets are orally administered starting on the 5th day of menstruation, following the dosage and administration method of the Western medicine group. There is no combined medication involved. Observation indicators

Pelvic pain scores: The "Pelvic Pain Assessment Scale" [8] was utilized by patients to document various aspects of their pain. These included menstrual pain, encompassing abdominal and breast pain, as well as lumbar pain before and after menstruation, and symptoms of anal irritation during menstruation. Additionally, scores were assigned to other pelvic pain symptoms, such as non-menstrual pelvic pain, pain during intercourse, and anal cramps. The severity of menstrual pain and non-menstrual pelvic pain was measured using the Visual Analog Scale (VAS) before and after treatment for all three patient groups.

Serum factor levels: ELISA was used to detect the levels of nerve growth factor (NGF), prostaglandin E2 (PGE2) and tumor necrosis factor-alpha (TNF- $\alpha$ ) in the peripheral blood in the serum before and after treatment, and the experimental process was carried out in strict accordance with the instructions.

In this experiment, percent efficacy was used to assess the treatment effect. The formula for calculating the percentage of efficacy was  $(\text{pre-treatment points} - \text{post-treatment points})/\text{pre-treatment points} \times 100\%$ . According to the calculated percentage of efficacy, the efficacy was categorized into four grades: cured, obvious, effective and ineffective. The specific efficacy evaluation criteria are as follows:

① Cured: after drug intervention, various clinical symptoms disappeared, such as pelvic masses, tender nodules and other local signs basically disappeared. The percentage of efficacy (N) is greater than or equal to 95% [9].

② Significant effect: clinical symptoms basically disappeared and pelvic mass was reduced (compared with gynecological examination and pelvic ultrasound examination at the same time of menstrual cycle). The percentage of efficacy is 95% greater than N greater than or equal to 70%.

③ Effective: Symptoms are relieved and pelvic lesions are not significantly enlarged or slightly reduced. The percentage of efficacy is 70% greater than N greater than or equal to 30%.

Ineffective: no change or aggravation of the main symptoms, local lesions have a tendency to aggravate. The percentage of efficacy (N) is less than 30%.

According to the above criteria, patients can be categorized into different levels according to the efficacy percentage to assess the effectiveness of treatment.

Statistical methods In this experiment, SPSS 22.0 statistical software was used to process the obtained data. For the general data of the three groups of patients, the chi-square test was used to analyze the count data, while for the measurement data, the variance chi-square test was performed first, and then the independent samples t-test was used to compare the differences between the

groups, while the paired samples t-test was used to compare the differences between the groups. When the p-value is less than 0.05, it means that the difference is statistically significant.

### 3. Results

#### 3.1 Comparison of VAS Scores among the 3 Groups See Table 1.

Table 1. Comparison of VAS scores in 3 groups ( $\bar{x} \pm s$ , points)

Group	Number of cases	Before treatment	After treatment	Before and after difference (D value)
Chinese medicine group	20	5.83±1.95	2.8±1.05	3.03±1.55
Western medicine group	20	5.60±2.14	3.05±1.36	2.55±1.75
Chinese and Western medicine Combined group	20	6.10±1.80	1.95±1.05	4.15±1.43

As can be seen from Table 1, the VAS scores of the three groups had different decreases after treatment. After t-test, the difference between the points of the combined Chinese and Western medicine group compared with the Chinese medicine group and the Western medicine group was extremely significant ( $p < 0.01$ ), and the difference of the combined Chinese and Western medicine group  $>$  the difference of the Chinese medicine group  $>$  the difference of the Western medicine group, which indicated that in terms of the effect of pain relief, the combined Chinese and Western medicine group had a better effect than the other two groups.

#### 3.2 Comparison of Pelvic Pain Efficacy after Treatment in the 3 Groups See Table 2.

Table 2. Comparison of the effective rate of pelvic pain treatment among 3 groups of patients

Symptoms	Group	Number of cases	Disappearance rate
Menstrual abdominal pain	Chinese medicine group	19	9 (47.36%)
	Western medicine group	17	7 (41.11%)
	Chinese and Western medicine Combined group	20	14(70.00%)
Lumbosacral pain	Chinese medicine group	15	7 (46.67%)
	Western medicine group	18	8 (44.44%)
	Chinese and Western medicine Combined group	15	10(66.67%)
Pelvic pressure pain	Chinese medicine group	18	10(55.56%)
	Western medicine group	19	9(47.37%)
	Chinese and Western medicine Combined group	18	15(83.33%)
Sexual intercourse pain	Chinese medicine group	11	7(63.64%)
	Western medicine group	14	8(57.14%)
	Chinese and Western medicine Combined group	12	10(83.30%)
Anal pain	Chinese medicine group	13	8(61.54%)
	Western medicine group	11	6(54.55%)
	Chinese and Western medicine Combined group	14	11(78.57%)
Tender nodules	Chinese medicine group	12	5(41.67%)
	Western medicine group	15	7(46.67%)
	Chinese and Western medicine Combined group	13	8(61.54%)

As can be seen from Table 2, after treatment, the apparent efficacy rates of menstrual abdominal pain, pelvic pressure pain, and tender nodules of the patients in the combination of Chinese and Western medicines group were 70%, 83.33%, and 61.54%, respectively, which were higher than those of the rest of the two groups, and the difference between the apparent efficacy rates of pelvic pain of the combination of Chinese and Western medicines treatment group compared with the Chinese medicine treatment group and the Western medicine treatment group was extremely significant after the  $\chi^2$  test ( $p < 0.01$ ); after treatment, the apparent efficacy rates of intercourse pain, lumbosacral pain, anal pain of patients in the After the treatment, the apparent efficiency of sexual intercourse pain, lumbosacral cramps and anal cramps of the patients in the combined group was also higher than that of the remaining two groups, but the difference was not statistically significant, which indicated that the combination of traditional Chinese and Western medicines group could achieve effective relief of pelvic pain.

### **3.3 Comparison of Serum TNF- $\alpha$ , NGF and PGE2 Levels before and after Treatment in the 3 Groups See Table 3.**

Table 3. Comparison of serum TNF- $\alpha$ , NGF and PGE2 levels before and after treatment in 3 groups of patients

Item	Chinese medicine group (n=20)	Western medicine group (n=20)	Chinese and Western medicine Combined group(n=20)	F value	P value
TNF- $\alpha$					
Before treatment	11.94 $\pm$ 1.33	11.86 $\pm$ 2.54	11.52 $\pm$ 1.96	0.268	0.767
Post-treatment	10.54 $\pm$ 1.75	9.15 $\pm$ 3.58	7.87 $\pm$ 3.30	3.416	0.038
NGF					
Before treatment	89.97 $\pm$ 9.39	80.81 $\pm$ 17.31	90.62 $\pm$ 10.60	2.140	0.134
Post-treatment	72.15 $\pm$ 12.56	66.23 $\pm$ 14.06	64.07 $\pm$ 26.40	4.901	0.014
PGE2					
Before treatment	95.318 $\pm$ 8.790	95.01 $\pm$ 12.77	98.04 $\pm$ 9.43	0.307	0.738
Post-treatment	81.620 $\pm$ 15.33	79.87 $\pm$ 18.07	63.51 $\pm$ 26.68	6.453	0.004

As shown in the above table, the difference in serum TNF- $\alpha$ , NGF and PGE2 levels between the three groups before and after treatment was statistically significant ( $p < 0.05$  or  $p < 0.01$ ), in addition, the difference in TNF- $\alpha$ , NGF and PGE2 levels after treatment between the western medicine group and the combination of western and traditional Chinese medicines group was statistically significant ( $p < 0.05$ ), and the difference between the Chinese and western medicine group after treatment TNF- $\alpha$ , NGF and PGE2 levels after treatment in the Chinese medicine group and the combination of Chinese and Western medicines group, the difference was statistically significant ( $P < 0.05$ ), while the difference was not statistically significant in the comparison of TNF- $\alpha$ , NGF and PGE2 levels after treatment in the Chinese medicine group and the combination of Chinese and Western medicines group ( $P > 0.05$ ).

#### 4. Discussion

Effect of Qu Yu Jie Du Xiao Zheng decotion in Combination with Dydrogesterone Tablets on Pelvic Pain The results of this study showed that after the intervention of Qu Yu Jie Du Xiao Zheng decotion in Combination with Dydrogesterone Tablets, the patients' pelvic pain was significantly improved, and the significant scores of dysmenorrhea, pelvic tenderness and palpable nodules were higher than those of dysmenorrhea, pelvic pain, and palpable nodules of the rest of the two groups with a statistically significant difference ( $P<0.05$ ), which confirms that Qu Yu Jie Du Xiao Zheng decotion can also effectively relieve other symptoms such as pain during sexual intercourse and anal pain.

Effects of Qu Yu Jie Du Xiao Zheng decotion in combination with Difluprednate Tablets on the levels of TNF- $\alpha$ , NGF and PGE2 in the serum of the patients Modern medicine believes that endometriosis is a kind of intractable disease, and the mechanism of its pathogenesis is extremely complex, which has not been completely clarified, and is currently dominated by the retrograde flow of menstrual blood and the implantation theory [10], that is, the fragments of the endometrium retrograde flow of menstrual blood and enter the pelvic cavity via the fallopian tubes, and then are planted in the ovary or other parts of the pelvic cavity [11]. or other parts of the pelvis [11]. Pelvic pain is one of the main symptoms of endometriosis, and the mechanism by which it arises is a complex process. Studies have shown that immunoinflammatory factors, estrogen levels, nerve growth factors, and serum prostaglandins are closely related to the occurrence of endometriosis-related pain. It has been found that ectopic endothelial tissue can secrete nerve growth factor (NGF) [12], and activated macrophages can produce a large amount of tumor necrosis factor (TNF-) and increase the level of cyclooxygenase-2 (COX2), which in turn increases the level of prostaglandins, which in turn increases the level of prostaglandins. The activated mast cells can degranulate and secrete TNF- and PGs [13]. Therefore, the serum levels of TNF-, NGF and PGE2 are higher in patients with endografts. According to the results of this experiment, the levels of TNF- $\alpha$ , NGF and PGE2 in the serum of patients in the combined Chinese and Western medicine group were significantly lower after treatment compared with those before treatment, and the difference was statistically significant ( $P < 0.01$ ). Meanwhile, there were significant differences between the Western medicine group and the combined Chinese and Western medicine group in the levels of TNF- $\alpha$ , NGF and PGE2 after treatment ( $P < 0.05$ ). Significant differences also existed between the TCM group and the combined TCM and Western medicine group in the levels of TNF- $\alpha$ , NGF and PGE2 after treatment ( $P < 0.05$ ), however, the differences between the TCM group and the Western medicine group in the levels of TNF- $\alpha$ , NGF and PGE2 after treatment were not statistically significant ( $P > 0.05$ ). This suggests that the combination of Qu Yu Jie Du Xiao Zheng decotion and Difenocoumarol Tablets was able to regulate the levels of TNF- $\alpha$ , NGF and PGE2 in the serum of the patients, which significantly alleviated the pain of pelvic pain in patients with endogamy.

Legislative basis for the treatment of endometriosis by Qu Yu Jie Du Xiao Zheng decotion in combination with dextroprogesterone tablets Endometriosis is an estrogen-dependent disease, for which Western medicine drug therapy is mainly given as hormonal therapies (progestins, birth control pills, sex hormones such as mifepristone). Deferiprogestrone is a progestin, which can inhibit endometrial hyperplasia, shrink the ectopic endometrium, and further inhibit the development of ectopic foci [14]. Endometriosis belongs to the category of "dysmenorrhea" and "obstruction in the abdomen" in traditional Chinese medicine (TCM). TCM believes that the core of this disease is "blood stasis", so the treatment is based on activating blood circulation and eliminating blood stasis. In recent years, some scholars believe that the basic pathology of EMs is not only "blood stasis", but also "turbid fluid", and that both of them can not only be brewed into

stasis toxin and dampness toxin for a long period of time, but also fumigate with each other and turn into heat toxin. In the previous project, we have formulated Qu Yu Jie Du Xiao Zheng decoction, which has the function of dispelling blood stasis, resolving toxins and removing turbidities, and eliminating crushing and dispersing lumps and knots, to treat dysmenorrhea and obstruction in the abdomen of internal heterotaxy, and it has achieved good therapeutic effect. In this experiment, in order to improve the efficacy of EMS, the formula of Qu Yu Jie Du Xiao Zheng decoction was added on the basis of oral administration of dydrogesterone tablets, in which all the medicines in the formula were combined together to eliminate and remit the evil toxins in an all-rounded way and at various levels, such as clearing away heat and detoxification, dispelling blood stasis, removing dampness and resolving turbidities and toxins, clearing up the channels of the worms and eliminating the toxicity and alleviating the toxicity by benefiting the qi to support the toxins and relieving toxicity through the glycates and the toxins, so as to eliminate blood stasis and clear up channels of the worms and resolving turbidities and eliminating symptoms and alleviating pain [15]. The results of this study also proved that the difference in VAS scores before and after treatment between Qu Yu Jie Du Xiao Zheng decoction in combination with dydrogesterone tablets was more obvious compared with the traditional Chinese medicine group and the western medicine group ( $P<0.05$ ), and the improvement of pelvic pain in the combination of traditional Chinese medicine and western medicine group was more significant than that in the rest of the two groups, which suggests that the addition of Qu Yu Jie Du Xiao Zheng decoction in combination with dydrogesterone tablets can enhance the effect of improving pelvic pain. The difference in serum TNF- $\alpha$ , NGF and PGE2 levels between the Chinese and Western medicine combination group before and after treatment was statistically significant ( $P < 0.01$ ), confirming that the combination of Qu Yu Jie Du Xiao Zheng decoction and dydrogesterone tablets could regulate the serum levels of TNF- $\alpha$ , NGF and PGE2 in patients with endogenous syndrome.

In conclusion, the combination of Qu Yu Jie Du Xiao Zheng decoction with dydrogesterone tablets can regulate the serum levels of TNF- $\alpha$ , NGF and PGE2 in patients, effectively improve the symptoms of pelvic pain in patients with endometriosis, and the effect is remarkable, which provides a new way of thinking for the treatment of endometriosis pain.

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