

Clinical Observation of Zhuang Medicine Yangxue Xiaozheng Decoction in Treating the Combined Endometriosis of Dampness and Blood Stasis in Guangxi

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Abstract: Objective: To explore the clinical effects of Zhuang Medicine Yangxue Xiaozheng Decoction in treating the combined Ems of dampness and blood stasis in Guangxi; **Methods:** 100 patients with endometriosis treated in Lili Clinic of Famous Doctor, Guangxi International Zhuang Medicine Hospital from Mach 2016 to May 2017 were chosen as the research object. According to the random grouping method, patients were randomly divided into the treatment group (The Zhuang Medicine Yangxue Xiaozheng Decoction (ZYF) Group) and the control group (Chinese patent medicine SanJieZhenTongJiaoNang (SJZT) group with 50 cases in each group. After treatment, the TCM syndrome score, changes in pelvic mass size, hepatocyte growth factor (HGP) levels, and clinical effects before and after treatment were evaluated. **Results:** After two courses of treatment, the total effective rate of patients in the ZYF group was 88%, which were significantly better than 70% of the SJZT group. The difference was statistically significant ($P < 0.05$). **Conclusion:** With a significant effect on patients with the combined Ems of dampness and blood stasis in Guangxi, Zhuang Medicine Yangxue Xiaozheng Decoction can improve the uterine cavity mass and reduce serum HGP level.

Keywords: Zhuang Medicine Yangxue Xiaozheng

Decoction; Combined Ems of dampness and blood stasis; Hepatocyte growth factor (HGF); Clinical observation; Random grouping Introduction

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The main clinical manifestation of endometriosis (Ems) is chronic pelvic pain^[1], named “Jing Yin” in Zhuang medical disease and involved in the category of “dysmenorrhea” and “abdominal mass” in Chinese medicine; and its incidence is increasing year by year. However, its pathogenesis is still unclear, and the effect of clinical treatment is also not satisfactory. Thus, it is still a hot disease for basic and even clinical research, and Chinese medicine treatment of Ems also become one of the hot discussion for its good clinical effect^[2]. Studies^[3] have shown that the severity of Ems lesions is positively correlated with abnormal expression of serum HGF.

In the subtropical zone Guangxi, most local women always suffer from the syndrome of the combined Ems of dampness and blood stasis. In recent years, great progress has been made in research on the treatment of Ems with traditional Chinese medicine. However,

no systematic research has been carried out among those patients on which Zhuang medicine Yangxue Xiaozheng Decoction with Zhuang medicine as the main component has shown significant improvement of their clinical symptoms.

Therefore, 100 patients with combined Ems of dampness and blood stasis in Guangxi for a long time were screened according to the standard. Through the control test, clinical symptom improvement of Ems patients treated with Zhuang Medicine Yangxue Xiaozheng Decoction and Chinese patent medicine SanJieZhenTongJiaoNang was observed and the HGF levels before and after the treatment were compared to explore the possible mechanism and clinical effects of HGF in the treatment of the combined Ems of dampness and blood stasis in Guangxi.

1 Data & Methods

1.1 Data

1.1.1 General data

100 patients with Ems treated in Lili Clinic of Famous Doctor, Guangxi International Zhuang Medicine Hospital from Mach 2016 to May 2017 were chosen as the research object. According to the random grouping method, patients were randomly divided into the treatment group (The Zhuang Medicine Yangxue Xiaozheng Decoction (ZYF) Group) and the control group (Chinese patent medicine SanJieZhenTongJiaoNang (SJZT) group with 50 cases in each group. All patients were informed about the content of this study and signed the consent. In the treatment group, patients aged 21-45, averagely 27.94 ± 2.87 , had the course of disease of 3 to 53 months. In the control group, patients aged 22-45, averagely 28.76 ± 3.21 , had the course of disease of 5 to 52 months. Comparing the general data between the two groups, the difference was not statistically significant ($P > 0.05$) and was comparable.

1.1.2 Inclusion criteria

(1) Those with 5 years of residence in the Guangxi Zhuang Autonomous Region;

(2) Those who conform to the diagnostic criteria for Western medicine^[4] (Formulated by referring to the *Guiding Principles for Clinical Research of Traditional Chinese Medicine New Drugs* of the Ministry of Health) complies with the diagnostic criteria of Ems;

(3) Those who conform to the diagnostic criteria

for Zhuang medicine^[5] (Formulated by referring to the Comment-soliciting Draft DB45 of Guangxi Local Standard *Name Specification of Diseases in Zhuang Medicine* and *Diagnostics in Zhuang Medicine* published by *Guiding Principles for Clinical Research of Traditional Chinese Medicine New Drugs* of the Ministry of Health) complies with the diagnostic criteria of “Jing Yin” of Zhuang Medicine;

(4) Those who conform to the standard of differentiation of symptoms and signs^[6] (Formulated by referring to the relevant content of *TCM Diagnostic Standard for Endometriosis* revised by Obstetrics and Gynecology Professional Committee, Chinese Association of Integrative Medicine (CAIM) in the 3rd academic conference in 1990 as well as the traditional Chinese medicine teaching materials for general higher education *Gynecology of TCM*) complies with the diagnostic criteria of patients with combined Ems of dampness and blood stasis.

1.1.3 Exclusion Criteria

(1) Those with less than 5 years of residence in the Guangxi Zhuang Autonomous Region;

(2) Those who fail to conform to the diagnostic criteria for Western medicine^[4] (Formulated by referring to the *Guiding Principles for Clinical Research of Traditional Chinese Medicine New Drugs* of the Ministry of Health) complies with the diagnostic criteria of Ems.

(3) Those who fail to conform to the diagnostic criteria for Zhuang medicine^[5] (Formulated by referring to the Comment-soliciting Draft DB45 of Guangxi Local Standard *Name Specification of Diseases in Zhuang Medicine* and *Diagnostics in Zhuang Medicine* published by *Guiding Principles for Clinical Research of Traditional Chinese Medicine New Drugs* of the Ministry of Health) complies with the diagnostic criteria of “Jing Yin” of Zhuang Medicine.

(4) Those who fail to conform to the standard of differentiation of symptoms and signs^[6] (Formulated by referring to the relevant content of *TCM Diagnostic Standard for Endometriosis* revised by Obstetrics and Gynecology Professional Committee, Chinese Association of Integrative Medicine (CAIM) in the 3rd academic conference in 1990 as well as the traditional Chinese medicine teaching materials for general higher education *Gynecology of TCM*) complies with the diagnostic criteria of patients with combined Ems of dampness and blood stasis.

(5) Those with the previous history of abdominal surgery, or women in pregnancy or lactation, or those who are allergic to the test drug.

1.2 Methods

1.2.1 Administration Methods

The treatment group: Patients were treated with Zhuang Medicine Yangxue Xiaozheng Decoction (Composition: 20g Polygala fallax Hemsl, 10g Centaurum sibiricum, 20g glabrous greenbrier rhizome, 6g resina draconi, 10g pseudo-ginseng, 15g Salvia miltiorrhiza, 10g Angelica sinensis, 10g Radix Paeoniae Rubra, 10g Psoralea corylifolia Linn, 10g Atractylodes, 10g lycopus lucidus, 6g Ligusticum chuanxiong hort, 6g Radix Glycyrrhizae Preparata) one dose per day with decoction twice for a total of 400ml and twice in the morning and evening on an empty stomach

The control group: SanJieZhenTongJiaoNang (Manufactured by Jiangsu Kanion Pharmaceutical Co., Ltd.). Efficacy: Softening and resolving hard mass; and removing stasis to ease pain, SFDA Approval No.: Z20030127, 4 capsules per time; 3 times per day.

Patients in the two groups started to take the medicine since the third days after menstruation till the third day of menstruation. 3 months constitute for a course of treatment and a total of 2 courses were observed. During the treatment period, other drugs with a therapeutic effect on the main symptom should be stopped and the feelings and symptoms of discomfort during medication shall be recorded timely.

1.2.2 Observation Indexes

(1) The effect score of TCM syndromes used to compare the changes before and after treatment.

(2) Gynecologic B-ultrasound: Size change of pelvic mass before and after treatment (Checked and compared at the same period after menstruation is clean).

(3) Detection and analysis of hepatocyte growth factor (HGP) levels in the two groups of patients before and after treatment. The serum HGP content of the

fasting venous blood drawn from those observation objects on the 4th day (8 AM-9 AM) of the menstrual cycle before and after the treatment was detected with ELISA.

(4) Comparison of clinical effects between the two groups.

1.2.3 Judgement standard for clinical effect

It can be formulated according to the relevant curative effect standards in reference to *the Guidelines for the Clinical Research of Chinese Medicine New Drugs*. Cured: Patients with dysmenorrhea and lower abdominal pain, etc. have been cured, and no nodules and masses in the attachment examination were found; Significantly effective: The symptoms of dysmenorrhea and TCM syndromes and others have been significantly alleviated, and the mass and nodules significantly reduced; Effective: The symptoms have been eased, but there was still acceptable recurrence; invalid: no improvement; Ineffective: No improvement was observed. Total effective rate = (The cured+ The significantly effective+ The effective) Number of Cases/ The Total Number of Cases × 100%

1.3 Statistical methods

SPSS23.0 software was used for statistical analysis, measurement data was expressed as ($\bar{X} \pm s$), t was used for the test, and the count data were expressed as a rate (%), χ^2 was used for the test, and $P < 0.05$, indicating that it was statistically significant.

2 Results

2.1 TCM syndrome score

Before the treatment, the difference between the two groups was not statistically significant ($P > 0.05$); After the treatment, the symptoms of the combined Ems of dampness and blood stasis in Guangxi in the ZYF group were significantly improved, better than that in the SJZT group ($P < 0.05$). See Table 1.

Table 1. Comparison of TCM syndrome scores of two groups of patients

| Group | Number of cases | Before the treatment | After the treatment |
|----------------|-----------------|----------------------|---------------------|
| The ZYF group | 50 | 21.77±6.13 | 12.59±2.84 |
| The SJZT group | 50 | 21.86±6.37 | 16.15±4.24 |

Note: Compared with the SJZT group, * $P < 0.05$.

2.2 Changes in the pelvic mass size before and after the treatment

Before the treatment, the difference between the two groups was not statistically significant ($P > 0.05$);

After the treatment, the pelvic mass size changes of the combined Ems of dampness and blood stasis in Guangxi in the ZYF group were significantly improved, better than that in the SJZT group ($P < 0.05$). See Table 2.

Table 2. The biggest diameter of the pelvic mass before and after treatment in the two groups (cm)

| Group | Number of cases | Before the treatment | After the treatment |
|----------------|-----------------|----------------------|---------------------|
| The ZYF group | 50 | 4.31±0.15 | 2.39±1.04* |
| The SJZT group | 50 | 4.25±0.17 | 3.15±1.24 |

Note: Compared with the SJZT group, * $P < 0.05$.

2.3 Changes in the serum HGP levels in patients of the two groups before and after the treatment

Before the treatment, the difference between the two groups was not statistically significant ($P > 0.05$);

After the treatment, the pelvic mass size changes of the combined Ems of dampness and blood stasis in Guangxi in the ZYF group were significantly improved, better than that in the SJZT group ($P < 0.05$). See Table 3.

Table 3. Comparison of the serum HGP levels between patients in two groups (ng/mL)

| Group | Number of cases | Before the treatment | After the treatment |
|----------------|-----------------|----------------------|---------------------|
| The ZYF group | 50 | 0.77±0.21 | 0.28±0.11 |
| The SJZT group | 50 | 0.75±0.25 | 0.38±0.23 |

Note: Compared with the SJZT group, * $P < 0.05$.

2.4 Comparison of clinical effects between the two groups

After two courses of treatment, the total effective rate

of patients in the ZYF group was 88%, which were significantly better than 70% of the SJZT group. The difference was statistically significant ($P < 0.05$). See Table 4.

Table 4. Comparison of clinical effects between the two groups (n)

| Group | The cured | The effective | The ineffective | Total effective rate |
|----------------|-----------|---------------|-----------------|----------------------|
| The ZYF group | 29 | 15 | 6 | 88%* |
| The SJZT group | 18 | 17 | 15 | 70% |

Note: Compared with the SJZT group, * $P < 0.05$.

3 Discussion

The clinical manifestation of Ems, a frequent chronic disease for women of childbearing age mainly includes chronic pelvic pain and infertility with the characteristics of the hormone-reactive endometrial tissue growth outside the uterine cavity. Since the pathological mechanism has not been completely clarified, there is still a lack of effective methods in the treatment, which seriously affects the quality of life of patients^[8]. In recent years, the clinical application of traditional Chinese medicine and ethnic medicine has been hugely increased with remarkable clinical effects. Therefore, traditional Chinese medicine and ethnic medicine may be a novel method for Ems. There were no records of

Ems in traditional Chinese medicine. According to its clinical manifestations, it belongs to the category of “dysmenorrhea” and “abdominal mass”, in which blood stasis was believed as the main pathogenesis and dampness as the main aetiology. For doctors of the Zhuang nationality, Ems was called as “Jing Yin” and caused by the disorder of Qi and blood, blocks of the “three passages and two channels” as well as dysfunctions of “uterus”.

The hot and humid climate and geographical environment of the Guangxi Zhuang Autonomous Region determine the susceptibility and frequency of the damp-heat syndrome in the area. Also, locals’ preference for hot and sour food causes spleen and stomach injuries, as well as damp turbidity. All these

factors lead to the uniqueness of Guangxi's physique. Tang Hanqing *et al*^[10] found that, in the classification of Zhuang medical constitution in Guangxi Zhuang population, the wet constitution and depressed constitution accounted for 31.4% and 13.94% respectively. Xie Sheng *et al*^[11] found that the number of women aged 18 to 50 in Guangxi for a long time with blood stasis and depressed Qi was significantly higher than men. And women are very susceptible to dampness, hotness and turbidity, which cause the danger of dampness, hotness and blood stasis. Based on the theory of "Dampness & Stasis" for Guangxi Ems, Professor Xiuwen Ban, a master class of traditional Chinese medicine, put forward that most Ems patients in Guangxi were characterized by the pathogenesis of the "mutual combination of dampness and stasis blocks the uterus and uterine collateral", in which the dampness accumulated the phlegm and further combined with the stasis, which blocked the vitality. Therefore, the disease became much difficult to be cured. Thus, it is of great medical and sociological significance to study the patients with the combined Ems of dampness and blood stasis in Guangxi.

Doctors of the Zhuang nationality originated in Guangxi and have a good knowledge of local climate, customs, lifestyle and the incidence of the disease. Zhuang Medicine Yangxue Xiaozheng Decoction was created in the clinical research of long-term treatment of Ems. This study has found significant clinical effects of Zhuang Medicine Yangxue Xiaozheng Decoction in treating patients with the Combined Endometriosis of Dampness and Blood Stasis in Guangxi, and the serum HGP levels and improving the uterine cavity mass.

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