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## The impact of the herbal formula Qing Bao Zhu Yu Tang in the treatment of endometriosis

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### ABSTRACT

Retrospective chart review research method was employed to analyze data from 120 cases of women who were treated for endometriosis using an herbal formulation known as Qing Bao Zhu Yu Tang. The cases were analyzed in three categories as per the most common condition accompanying endometriosis. The three groups included those where endometriosis was associated with infertility (n=53), those with polycystic ovarian syndrome (PCOS) (n=7) and those with ovarian cysts (n=38). Data from the charts were analyzed in terms of the impact of the Qing Bao Zhu Yu Tang formula on endometriosis and the accompanying conditions. The results evidenced the positive impact of the formula. The pain effectiveness level survey rating for the entire sample of 120 patient charts shows that 116 patients (96.7% responded with indication of some level of effectiveness. From the total sample of 120 patients, the satisfaction survey shows that 111 patients (92/5%) responded in the "satisfied" range. The results were discussed regarding implications for practice, and recommendations were made for future related research.

**Keywords:** Endometriosis, herbals, traditional Chinese medicine; fertility, reproduction

### 1. Introduction

The prevailing theory about the development of endometriosis is that the condition occurs when menstrual blood backflows through the fallopian tubes, carrying with it endometrial cells that are then transplanted to ectopic sites, such as the peritoneal cavity, the ovaries, the uterosacral ligaments, or the pouch of Douglas, where they implant, proliferate and develop. It is a gynecological disorder with clinical symptoms of menstrual pain, pelvic pain and infertility, and is one of the most complex and least understood diseases. The pain of endometriosis is severe and debilitating and can cause significant health problems for women during their reproductive years<sup>[6]</sup>. Endometriosis is the number one cause of infertility; 38% of women who are infertile and 70-80% of women with chronic pain have endometriosis<sup>[1]</sup>. More than 10 million women have endometriosis in the United States<sup>[2]</sup>. Furthermore, in the U.S., annual healthcare costs and costs of productivity loss associated with endometriosis were estimated at \$22 billion in 2002<sup>[3]</sup>.

In a review of Western Medicine theories about the causation of endometriosis theories include: the involvement of hormones, the immune system of the body, inherited immune deficiency, menstrual blood containing endometrial cells flowing back through the fallopian tubes, apoptosis which helps maintain cellular homeostasis during the menstrual cycle, protein expression, sexual intercourse during menstrual period, immunologic abnormalities and antinuclear antibodies (ANA) in the blood of women<sup>[4]</sup>.

The only way to identify, for certain, that a patient has endometriosis is to look inside her abdomen (direct visualization) for signs of endometrial tissue. This is accomplished during a laparoscopy, which is a minor surgical procedure. For several decades laparoscopy has been the gold standard for the diagnosis of endometriosis<sup>[5]</sup>. A definite diagnosis of endometriosis only can be made through histology of lesions removed at surgery. Neither serum makers nor imaging studies have been able to supplant diagnostic laparoscopy for the diagnosis of endometriosis.

The objective of this study is to discern and describe the effectiveness of the Qing Bao Zhu Yu Tang formula on the condition of endometriosis. The discussion will proceed with an overview of the Traditional Chinese Medicine perspectives regarding the etiology and treatment of endometriosis.

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### 1.1 Endometriosis from a Traditional Chinese Medicine Perspective

Traditional Chinese Medicine does not recognize endometriosis as a disease, but instead as a cluster of symptoms. It is referred to as menstrual pain due to accumulation of menstrual blood in the lower abdominal cavity (Classic Fu Ren Kyu Pang). The primary pattern, or mechanism, that causes endometriosis is blood stasis. Blood stasis can be caused by emotional disturbance, chronic illness, exposure to cold temperatures, surgery, and genital infections. When the pattern of disease is blood stasis, the objective of the treatment is to invigorate blood and remove stasis, using both acupuncture and Chinese herbal medicine. In addition to blood stasis, there are often other disease-causing factors which are part of the patterns of endometriosis. Cold, heat, deficiency, or excess patterns are frequently part of the mix, and are differentiated based on the clinical manifestations associated with each case of endometriosis. In the Classic Fu Ren Kyu Pang, endometriosis is referred to as menstrual pain due to accumulation of menstrual blood in the lower abdominal cavity (Classic Fu Ren Kyu Pang). This early theory is not so different from the Western understanding of endometriosis by Sampson <sup>[6]</sup> and D' Hooghe <sup>[7]</sup>. Both authors suggest the widely accepted theory that the primary mechanism of endometriosis is involved from retrograde menstruation and implantation of the endometrial tissue in ectopic sites.

Traditional Chinese Medicine classifies endometriosis into unique categories of stagnation and obstruction: Qi Stagnation and Blood Stasis, Qi Deficiency and Blood Stasis, Heat Obstruction and Blood Stasis, Cold Retention and Blood Stasis, Kidney Deficiency and Blood Stasis. Endometriosis is also known one of abdominal Masses are called Ji, Ju (Zheng Jia). The term appears in the Classic of Difficulties, which clearly distinguishes two types:

1. Ji (Zheng): Ji (Zheng) indicates actual abdominal masses which are immovable because it arises from a Yin organ, is associated with pain, its location is fixed and the masses are due to blood stagnation. It is stated in The Golden Cabinet by Zhang Zhong Jing, "Ji masses arise from the Yin organs and they cannot be removed.
2. Ju (Jia): Ju (Jia) indicates abdominal masses which come and go, do not have a fixed location and are movable. If there is an associated pain, it comes and goes and changes location. Such masses are due to stagnation of qi, and they are easier to treat. Another name for abdominal masses is Zheng Jia. Zheng is equivalent to Ji, while Jia represents Ju. The terms Zheng Jia and Ji Ju are used when referring to abdominal masses in woman, but they do occur in men, as well. It is stated in the Simple Questions in Chapter 60 of Huang Di Nei Jing Classics that Ji Ju refers to non-substantial masses from qi stagnation.

Emotional dispositions, such as anger, repression or frustration, cause the formation of abdominal masses due to liver qi stagnation, leading to stasis of liver blood. Liver blood circulates and nourishes a woman's genital area and uterus. Any interruption of the free flow of liver qi eventually causes blood stasis in the uterus. The excessive ingestion of raw foods may lead to the formation of cold in the lower abdomen. Cold nature interferes with the circulation of qi and, especially, blood; it may lead to stasis of blood. Eating greasy foods excessively impairs the spleen and may lead to the formation of dampness and phlegm lodged in the lower abdomen and creating abdominal masses. The interaction between phlegm retention and stasis of blood may lead to or aggravate the

other. Cold invades the lower abdomen and impairs the circulation of blood leading to stasis of blood. Ji masses are due to Cold (The Spiritual Axis Chapter 66). Dampness may invade the channels of the legs and then creep up them to settle in the lower abdomen, and later on transforms into phlegm and may cause abdominal masses. The pathology of endometriosis is characterized by stagnation of qi or stasis of blood. The qi stagnation being non-substantial and the blood stagnation is substantial masses. In addition to stagnation, there may also be phlegm. Masses from phlegm feel soft on palpation and have a fixed location without pain. Additionally, blood stagnation may cause blood stasis and become hard and fixed with or without pain <sup>[8]</sup>.

### 1.2 Treatment of Endometriosis in Traditional Chinese Medicine

In a 1980 landmark study, researchers at the Obstetrics and Gynecology Hospital in China published the first report of a large-scale clinical trial of Chinese herbs for endometriosis. The 156 patients were divided into three groups according to syndrome, and given one of three possible treatments: Group one was given a combination of *sparganium*, *zedoaria*, *gleditsia spine*, *cyperus*, *bupleurum*, *tang-kuei*, *bulrush* (typha), and *pteropus* in decoction, plus an "endometriosis powder" made with earthworm, tabanus, centipede, and leech. Group two was given a similar combination, but the *bupleurum*, *cyperus*, and *tang-kuei* were replaced by *codonopsis*, *astragalus*, and *cimicifuga*. Group three received an intravenous drip of *salvia* extract daily. This rather inconvenient therapy delivers an extract of an herb currently used for normalizing blood circulation. The individuals in this treatment group would usually also receive some herbs in decoction. Each of the groups received the treatment for two to three menstrual cycles.

In this study 128 of the women (82%) had their symptoms mostly or entirely alleviated, while 28 of the women (18%) had either no effect or the benefits of the treatment were lost soon after stopping use of the herbs. Considerable laboratory analysis was also done, investigating the condition of the blood contents before and after treatment and in different phases of the menstrual cycle, but while the results were suggestive, not enough of the women were analyzed by these means to draw firm conclusions <sup>[9]</sup>.

Prior literature reveals a variety of formulas recommended for the treatment of endometriosis. Tao Hong Si Wu Tang is a renowned blood stasis-relieving formula. Four-Substance Decoction with *Safflower* and *Persica* Seed is used to treat blood deficiency and blood stasis. Ge Xia Zhu Yu Tang, which translates to Driving out Blood Stasis below the Diaphragm Decoction, is a stagnation/stasis-relieving formula. It is a formula from the famous physician Wang Qing Ren, who practiced in the latter part of the 19<sup>th</sup> century and expounded upon the theory of blood stasis for the treatment of endometriosis. The traditional prescription can be "updated" for the treatment of endometriosis, but is more frequently used for fullness and distension in the epigastric region. Xue Fu Zhu Yu Tang is a formula from the famous physician Wang Qing Ren, and pertains to the theory of heat obstruction and blood stasis for the treatment of endometriosis. The theory is that qi stagnation occurs first, followed by stagnation of blood. Shao Fu Zhu Yu Tang is another formula by Wang Qing Ren, developed in the latter part of the 19<sup>th</sup> century. Shao Fu Zhu Yu Tang, which translates to the decoction for driving out blood stasis from the Lower Abdomen, is used when a blood stagnation syndrome, such as endometriosis, is caused by a cold syndrome, which may be caused by environmental factors or diet <sup>[10]</sup>. In one study Shao Fu Zhu Yu Tang was used for 60 endometriosis patients, and the

results showed 97.5% improvement<sup>[11, 12]</sup>. Tao Ren Cheng Qi Tang is a formulation for treating acute abdominal pain based on the purgative and blood vitalizing herbs. This formula is used for conditions in which a heat syndrome causes the blood to escape and cause obstruction. The author of this analysis cited treating a woman with a diagnosis of endometriosis, or “nodules on the posterior uterine wall.” With this formula; after three months the woman was relieved of symptoms and became pregnant<sup>[10]</sup>.

Another formula often used in the treatment of endometriosis, Dai Deying, was studied in 1982 at the Shanghai College of Traditional Chinese Medicine. The basic formula for patients with endometriosis having dysmenorrhea was *bupleurum*, red peony, moutan, salvia, corydalis, melia, *cyperus*, *saussurea*, *patrinia*, *prunella*, *rubus*, oyster shell, bulrush, and *pteropus*. Across 30 cases of endometriosis the effective rate was observed to be 80%. Nei Yi Fang (Endometriosis Formula) was used with 43 cases of endometriosis in Shanghai, by workers at the First People’s Hospital and at the Hangkou District Hospital. The formulas were modified according to specific symptoms that were present. The effectiveness rate was 88%, with four of the women getting pregnant<sup>[11]</sup>.

In review of the endometriosis work by Tang<sup>[13]</sup> with excerpts published in the International Journal of Oriental Medicine in 1992, the formula of tripterygium had been used in treating endometriosis, with an effective rate of 80%. It functions as an immune-suppressive anti-inflammatory, acting much like prednisone. Its success suggests that the autoimmune hypothesis for endometriosis is correct. The herb formula was able to “thin the blood” reducing the abnormally high viscosity and RBC electrophoretic time. It acts to reduce excess populations of immunoglobulin’s, C3 (complement protein), and T8 cells in peripheral blood. The Shanghai College of Traditional Chinese Medicine affiliated hospital reported in 1991 an apparently successful treatment for endometriosis with the use of Nei Yi Wan #1 (Endometriosis pill) three herbs, using turtle shell, vinegar-treated rhubarb, and succinum. The study involved 76 cases of endometriosis, with 61 “effectively treated,” a rate of 80%.

Along similar lines, workers at the Xuzhou Medical College (21) gave endometriosis patients a basic formula of aconite, evodia, fennel, *dipsacus*, *dioscorea*, tang-kuei, *salvia*, *corydalis*, *cnidium*, and *persica*. This formulation would be modified for various syndromes, including the use of *epimedium* and *cinnamon* bark for kidney yang deficiency, *rehmannia* and *ligustrum* for kidney yin deficiency, *pteropus* and bulrush for pain. Of 54 women treated by this method, 25 were reported cured, and 26 others showed improvement, with a total effective rate of 94%.

A report from the Heilongjiang College of Traditional Chinese Medicine affiliated hospital in Harbin in 1992, once again showed that blood-vitalizing herbs were the key ingredient. The study involved 64 patients who were treated with a decoction of salvia, *pteropus*, sparganium, zedoaria, *cyperus*, *corydalis*, and *loranthus*. Modifications were made as deemed necessary, and

treatment was generally continued for two to three menstrual cycles, without interruption. It was reported that 18 were cured (28%), 26 markedly improved, 16 patients improved, and 4 did not respond. Blood and plasma viscosity levels and red blood cell electrophoretic time were noted to be high in women with endometriosis before treatment compared to normal values, and these were reduced to near normal levels after treatment.

English language information about Chinese medical treatment of endometriosis first appeared in 1983, and there have been reports in journals and books appearing regularly since about 1988. The Institute for Traditional Medicine has mentioned this literature and received reports about the experience of treating endometriosis patients in the early 1990’s. The two endometriosis studies were organized by Arthur Shattuck, an acupuncturist and herb specialist. In the first study, 17 patients participated, all had endometriosis confirmed by laparoscopy, and the total effective rate was 75%. Nei Yi Wan #1 was produced in tablet form (Turtle Shell Tablets, Seven Forests) for evaluation in the United States in 1993. Initial reports from ITM’s An Hao Natural Health Care Clinic in Portland, Oregon were favorable. Arthur Shattuck initiated a treatment program involving four sites in 1993 (two in Wisconsin and two in Illinois), using the *Lindera* 15 and *Corydalis* 5, plus Turtle Shell Tablets in some patients, 14 clients under care all described a decrease in symptoms during the initial treatment period. He found that many people discontinued treatment after getting some relief, so that while the benefits were obvious, the full research project was not completed<sup>[14]</sup>.

### 1.3 Qing Bao Zhu Yu Tang Formula

The prescription that is the focus of the current study is named “Qing Bao Zhu Yu Tang.” For many years the current researcher has used this formula for the treatment of endometriosis and the associated symptoms of menstrual pain, pelvic pain, infertility, complications of ovarian cysts and others associated problems. The translated meaning of the Qing Bao Zhu Yu Tang formula is simply “Clean and Drive out Blood Stasis from Uterus.” The Qing Bao Zhu Yu Tang formula contains: *Flos Lonicerae Japonica* (Jin Yin Hua), *Semen Coicis Lachryma-Jobi* (Yi Yi Ren), *Herba Cum Racice Patriniae* (Bai Jiang Cao), *Radix Dipsacis Asoeri* (Xu Dan), *Rhizoma Cyperi Rotundi* (Xiang Fu Zi), *Spica Pruncelle Vulgaris* (Xia Ku Cao), *Thallus Algae* (Kun Bu), *Radix Niuxi* (Niu Xi), *Radix Angelicae Sinensis* (Dang Gui), *Radix Paeoniae Rubrae* (Chi Shao Yao), *Rhizoma Sparagnii Stoloniferi* (San Ling), *Rhizoma Curcumae Ezhu* (E-Zhu), *Radix Ligustici Chuanxiong* (Chuan Xiong), *Cortex Moutan Radicis* (Mu Dan Pi), *Rhizoma Corydallis Yanhusuo* (Yan Hu Suo), *Excrementum Trogopteri Seu Peromi* (Wu Ling Zhi), *Fructus Cragrantis* (Shan Zha), *Massa Fermentata* (Shen Qu), *Fructus Hordei Vulgaris Germinantus* (Mai Ya), *Fructus Immaturus Citri Aurantii* (Zhi Ke), *Radix Glycyrrhizae* (Gan Cao).

The chart below describes the formula Qing Bao Zhu Yu Tang, including each herb’s function<sup>[10]</sup> and pharmaceutical effect<sup>[15]</sup>.

The Function and Pharmacological Effect of Herbs in Qing Bao Zhu Yu Tang

Herb Contents (Pinyin Name)	Function of herbs	Pharmacological effect & chemical composition
<i>Flos Lonicerae Japonica</i> (Jin Yin Hua)	Clear heat and relieve fire toxicity, Clear damp heat	Antibacterial, inhibit bacteria, salmonella, antiviral effect
<i>Semen Coicis Lachryma-Jobi</i> (Yi Yi Ren)	Clear heat expels pus, clear damp heat, treats plantar warts	Effect on neoplastic cells, also effect on striated muscle, treats mayoma.
<i>Herba Cum Racice Patriniae</i>	Clear heat, relieves toxicity, expels pus, dispels blood stasis & stops	Treat mumps, suppurative abscesses, remove internal abscess & remove pain

(Bai Jiang Cao)	pain	
<i>Radix Dipsaci Asoeri</i> (Xu Dan)	Promote blood, alleviates pain, strengthens bones, reduce swelling & abscess	Beta-sitosterol, hedragenin, uroaldehyde, urilic acid & vitamin E effects
<i>Rhizoma Cyperi Rotundi</i> (Xiang Fu Zi)	Regulate menstruation & alleviates pain, spread qi	Volatile oil contains estrogen like substance, beta-pinene etc.
<i>Spica Pruncelle Vulgaris</i> (Xia Ku Cao)	Clear heat & dissipates nodules, lipoma, neck lumps	Increase secretion of ACTH, Glucocorticoid, antibiotic effect, effect on lipoma.
<i>Thallus Algae</i> (Kun Bu)	Reduce phlegm, swelling, softens hardness, promotes urination, regulate water circulation.	Effects to ardio vascular, hypoglycemic, serum cholesterol and triglyceride. Contains algin, laminine, iron, potassium, iodine.
<i>Radix Niu xi</i> (Niu Xi)	Dispels blood stasis, invigorates blood, direct fire down & clear damp heat in the lower burner	Effect on uterus causes uterine dilation, cardiovascular effect by inhibit peripheral vasodilation
<i>Radix Angelicae Sinensis</i> (Dang Gui)	Invigorate & harmonize blood, reduce swelling, expels pus, generate flesh and alleviates pain	Relaxes uterus, anti platelet, antibiotic, phagocytic, ant-inflammatory by secretion of acetylsalicylic acid.
<i>Radix Paeoniae Rubrae</i> (Chi Shao Yao)	Invigorate blood, dispels blood stasis, clear liver fire, cools blood	Vasodilator effect , anti-inflammatory, antibiotic and effect on CNS from strychnine
<i>Rhizoma Sparagnii Stoloniferi</i> (San Ling)	Forcefully break up blood stasis, dissolve accumulation of severe abdominal pain and distension	Anti-neoplastic, inhibit aggregation of platelets and prolong thrombin time
<i>Rhizoma Curcumae Ezhu</i> (E-Zhu)	Break up blood stasis, remove masses, activate circulation and relieves pain.	Anti-neoplastic, antibiotic, hematological function. Treat sarcoma and cervical cancer
<i>Radix Ligustici Chuanxiong</i> (Chuan Xiong)	Invigorate blood and promotes the movement of qi. Remove stagnation of qi & blood stasis	Hypertonic barbiturate effect. Antibacterial, antifungal and antihypertensive effect.
<i>Cortex Moutan Radicis</i> (Mu Dan Pi)	Invigorate blood & cools blood. Dispel stasis, drain pus, reduces swelling, clear fire from deficiency	Inhibitory staphylococcus, bacillus. Reduce permeability of the capillaries & has hypnotic and tranquilizing effect.
<i>Rhizoma Corydallis Yanhusuo</i> (Yan Hu Suo)	Remove pain due to blood stasis such as menstrual pain, promotes qi and invigorate the blood	Analgesic effect as morphine of corydaline. Hypnotic sedative, acts to cortex of grey mater.
<i>Excrementum Trogopteri Seu Peromi</i> (Wu Ling Zhi)	Disperse blood stasis & alleviate pain, transform stasis and stops bleeding, childhood nutritional impairment with focal distention.	Relieves muscle spasm of smooth muscle. Contains vitamin A, uric acid, urea, resin
<i>Fructus Cragrantis</i> (Shan Zha)	Remove meat stagnation from alcoholism. Transforms blood stasis and dissipate clumps. Stops diarrhea	Remove Glycoprotein, antihypertensive, antibiotic effects. Contains tartaric acide
<i>Massa Fermentata</i> (Shen Qu)	Reduce food stagnation of alcoholism, epigastric fullness	Gastro-intestinal effect release enzyme to facilitate digestion of starches and carbohydrate, yeast.
<i>Fructus Hordei Vulgaris Germinantus</i> (Mai Ya)	Reduce food stagnation & facilitate stomach qi flow, inhibit lactation	Uses for hyper lactic hormone, contains amylase, maltose, Invertase, dextrin. Treat hepatitis
<i>Fructus Immaturus Citri Aurantii</i> (Zhi Ke)	Relives distension, break up stagnation, resolve accumulation	Contains Naringin. Effects to cardiovascular, respiratory (synephrine), antiplatelet, and antineoplastic(nobiletin)
<i>Radix Glycyrrhizae</i> (Gan Cao).	Clear heat & relieves fire toxicity. Moderate spasm and alleviates pain, tonifies spleen & arguments the qi. Moistern Lung & stops coughing	Effects as Mineralocorticoid, glucocorticoid. Treat Addison's disease by excretion of 17-ketosteriods. Treat diabetes insipidus, chronic bronchial asthma, detoxifying effect.

The value of the above detailed formula is that it not only invigorates the blood and transforms stasis from the wei, qi, ying, and xue at all four levels, but it also invigorates blood without consuming it and dispels blood stasis while encouraging the

generation of new blood. The formula is contraindicated during pregnancy and during excessive menstrual bleeding. The book of Nei Jing states, "If the qi circulates, then the blood will circulate."

The actions of the Qing Bao Zhu Yu Tang formula can be summarized as follows:

- Invigorates the blood, break up and dissolve blood stasis
- Clear heat and expel damp, pus and toxicity
- Disperses blood stasis, dissipates nodules such as lumps or nodules
- Disperses qi stagnation and regulate liver qi
- Alleviates pain
- Promote the circulation of blood
- Thins blood viscosity
- Generates new blood
- Helps digestion and dissolve glycol-protein

#### 1.4 Indications of the Use of Qing Bao Zhu Yu Tang

The Qing Bao Zhu Yu Tang formula is most appropriate for the treatment of blood stasis accumulating in the lower abdomen characterized by palpable masses which may or may not be painful. It is also indicated in cases of lower abdominal pain without palpable masses, lower abdominal distention during menstruation, or frequent menstruation (3-4 times per month) in which bleeding is due to blood stagnation and blood stasis. This formula is specifically designed for the prevention and treatment of endometriosis. The formula can also be used to treat patients with diagnoses of ovarian cysts, obstruction of fallopian tubes, inflammation of the uterus, vaginal discharges, appendicitis, ruptured ovarian cyst, polycystic ovarian syndrome, uterus cancer, dysmenorrhea, amenorrhea, uterus fibrosis, uterus myoma, high platelet count, thinning blood viscosity. It is also used for the prevention of habitual miscarriage and for the prevention of endometriosis. While the current researcher's clinical experience affirms the efficacy of the Qun Bao Zhu Yu Tang formula in the treatment of endometriosis, there have been no published studies which have systematically examined the impact of the Qing Bao Zhu Yu Tang formula specifically for the treatment of endometriosis. The current study will begin to fill that blind spot in the current literature.

## 2. Materials and Method

The current study used chart review method to obtain data from the archived files of 120 patients with the diagnosis of endometriosis. Charts were reviewed and data were systematically gathered from patients that had been treated with Qing Bao Zhu Yu Tang or a modification of that formula. The method of retrospective chart review method is a recognized qualitative procedure, was chosen as the means for achieving the research objective of the current study [16].

### 2.1 Chart Selection

The sample used in the current study may be described as a "convenience sample." A convenience sample is not based on random or probability selection. Nonetheless, a convenience sample has the potential to provide good representation of a focused and defined population. Non-probability sampling is used because of the very specific inclusion criteria and the location of the current study limits the availability of data to clinical charts from a busy Traditional Chinese Medicine Clinic in Los Angeles. The study began with an analysis of 275 charts of patients who suffered and sought treatment for endometriosis from May 2008 to December 2010 at the designated Los Angeles clinic. All charts of female patients who sought treatment for endometriosis were screened for inclusion in the study. Patients' charts were selected for data collection in the current study according to the inclusion

and exclusion criteria detailed in the sections below.

### 2.2 Inclusion Criteria:

- Women
- Age 18 years old to 45 years old
- Must have intact uterus
- Seen as a patient for the treatment of endometriosis between May of 2008 to December of 2010.
- Treatment included taking the Qing Bao Zhu Yu Tang formula for ten days or longer
- Chart data includes pain and satisfaction survey data

### 2.3 Data Recording Form

The clinical Charts comprised of the intake form, the patient's history of treatment, doctor's notes, diagnosis of traditional Chinese medicine, treatment principle regarding each patient, as well as any laboratory test data available in the charts. A two page data collection instrument was developed by the researcher to capture data relevant to the objectives of the current study. The form that was developed included a patient identification number with no patient names, age of the patient, TCM, Western and other diagnoses, indication of the treatment phase as well as other clinical and observational data. A copy of the data collection instrument is included in the appendix of this study.

### 2.4 Procedures

Using the data collection instrument detailed above, the researcher pulled and examined approximately 275 charts with 120 files meeting the inclusion criteria of the current study. All charts were reviewed February 2011 and July 2011. The proposal for the current study was reviewed and approved by the Institution Review Board (IRB) of Yo San University.

## 3. Results

Of the 275 female charts reviewed, 120 charts were yielded with the diagnosis of endometriosis. Each of the 120 patients had been treated with Qing Bao Zhu Yu Tang or a modification of that formula. In the process of treating the patients for endometriosis eighteen different categories of associated symptoms were observed. Four of the categories of associated symptoms were considered primary because of the number of cases observed. The four categories include women whose endometriosis was also associated with infertility, polycystic ovarian syndrome (PCOS), vaginal discharge, and ovarian cysts. For each of the four categories between seven and fifty-three cases were observed. This study will proceed by analyzing the data that were observed from three of the four primary groups—Infertility, Ovarian Cysts and PCOS. Because it's a common and non-specific symptom, data regarding the fourth group, the Vaginal Discharge group, were not included in the statistical analyses conducted in this study. The data reported included the age of each patient, as well as the "phases" or length of time that they took the Qing Bao Zhu Yu Tang formula. Patients categorized as Phase One patients took the formula for 10 days; Phase Two patients took the formula for 20 days; Phase Three patients took the formula for 30 days and Phase Four patients took the formula for 40 days. The data are reported regarding the original Qing Bao Zhu Yu Tang formula, for the Qing Bao Zhu Yu Tang modified formula as well as for those patients who took both the original as well as the modified Qing Bao Zhu Yu Tang formulas.

### 3.1 Data Summaries for the Study Variables

1. Demographic Data-Age: From the full sample of 120 cases of the age distribution observed the mean age 36.51, SD 7.33,

minimum age of 19 year, Maximum age of 45 year. The pain effectiveness survey observed mean score of 3.87, SD 1.06 from the scale of minimum 1 to maximum 5. The satisfaction survey observed mean score was 3.91, SD 0.88 from the scale of minimum 1 to maximum 5.

2. Formula taken for 10 days and formula taken longer than 10

days: The frequency distributions for formula taken 10 days from the full sample of 120 cases yielded 72 cases (60%); 48 cases (40%) took the formula longer than ten days. T-Tests were computed to discern if there were differences between those who took the formula for ten days, and those who took the formula longer than ten days.

**Table 2:** T Test data regarding formula by number days taken

	Ten days	N	Mean	SD	T	df	p-value
Pain effect	10 days	72	3.74	1.05	-1.664	118	.099
	> 10 days	48	4.06	1.06			
Satisfaction	10 days	72	3.82	0.84	-1.361	118	.176
	> 10 days	48	4.04	0.92			

There was no significant difference between those who took the formula for ten days compared to those who took the formula for longer than ten days. However, there was a trend ( $p < .10$ ) in the expected direction for the reduction in pain to be greater for those who took the formula for longer than ten days.

3. Formula taken alone with no modification to the formula vs. the formula taken with modification: For the formula taken alone with no modification 87 cases were observed (72.5%); for the formula taken with any modification there were 33 cases (27.5%) (See Table 3).

**Table 3:** T-Tests Comparing Those Taking the Formula Alone with Those Taking the Formula with Modifications

	Formula Alone	N	Mean	SD	t	Df	p-value
Pain effect	Formula alone, no modification	87	3.83	1.12	-.654	118	.515
	Formula with any modification	33	3.97	0.88			
Satisfaction	Formula alone, no modification	87	3.86	0.92	-.935	118	.351
	Formula with any modification	33	4.03	0.77			

No significant differences found

4. Pain effectiveness study variance: From the full sample of 120 cases the pain effectiveness survey response range was from 0% to 100%; 4 cases (3.3%) responded at the 0% effectiveness level; 12 cases (10%) responded at the 30% effectiveness level; 16 patients (13.3%) responded at the 50% effectiveness level; 52 patients (43.3%) responded at the 70% effectiveness level; 36 patients (30%) responded at the 100% effectiveness level. The overall effectiveness rating for the entire sample of 120 patient charts shows that 116 patients (96.7%) responded with indication of some level of effectiveness.

satisfaction survey yielded a response range from “not satisfied” to “very satisfied” using a rating of 1 for “not satisfied” up to a rating of 5 for “very satisfied. The results yielded 2 patients (1.7%) indicating a rating of “not satisfied.” There were 7 patients (5.8%) indicating “not satisfied- but it was worth try.” There were 19 patients (15.8%) who indicated “moderately satisfied,” and 64 patients (53.3%) who indicated “satisfied,” as well as 28 patients (23.3%) who indicated that “very satisfied.” Overall from the total sample of 120 patients, 9 patients (7.5%) responded in the “not satisfied” range, and 111 patients (92.5%) responded in the “satisfied” range.

5. Satisfaction data: From the full sample of 120 cases the

**Table 4:** Pearson Correlations-Pain Effect and Satisfaction (n=120)

		Pain Effect	Satisfaction
Age	r	0.017	-.049
	p-value	0.850	.597
Pain Effect	r		0.852
	p-value		< .001

There is no significant relationship observed between age and the reduction in pain or level of satisfaction with treatment. As expected there is a highly significant relationship between the reduction in pain and level of satisfaction with treatment ( $r = 0.852, p < .001$ )

6. For the four designated study variables subgroups the following statements summarize the observed data:

- 1) Ovarian Cysts study variable: From the full sample of 120 cases, 38 cases (31.7%) had ovarian cysts observed. All of those cases (100%) reported that they were helped by the formula. Of the 120 cases, 82 patients (68.3%) had no ovarian cysts.
- 2) Infertility study variable: From the full sample of 120 cases, 30 (25%) reported that they were trying to get pregnant, and that the formula helped them to achieve that goal. Of the 120 cases, 23 (19.2%) reported that they were trying to get pregnant, and that the formula

- 3) Vaginal discharge study variable: From the full sample of 120 cases, 19 (15.8%) had vaginal discharge and reported that the formula helped to relieve that symptom. Of the 120 cases, 101(84.2 %) did not have vaginal discharge.
- 4) PCOS study variable: From the full sample of 120 cases, 7 (5.8%) had a diagnosis of PCOS, and reported that the formula helped. Of the 120 cases 113 (94.2 %) had no PCOS diagnosis.

**Table 5:** Data summaries for Subgroups: Ovarian Cyst, PCOS, and Vaginal Discharge

Had ovarian cyst and formula helped		
10 days	17	44.7%
> 10 days	21	55.3%
Total	38	100.0%
Had ovarian cyst and formula helped		
Formula alone, no modification	21	55.3%
Formula with any modification	17	44.7%
Total	38	100.0%
Had PCOS and formula helped		
10 days	3	42.9%
> 10 days	4	57.1%
Total	7	100.0%
Had PCOS and formula helped		
Formula alone, no modification	6	85.7%
Formula with any modification	1	14.3%
Total	7	100.0%
Had vaginal discharge and formula helped		
10 days	11	57.9%
> 10 days	8	42.1%
Total	19	100.0%
Had vaginal discharges and formula helped		
Formula alone, no modification	11	57.9%
Formula with any modification	8	42.1%
Total	19	100.0%

**Comparisons for those trying to get Pregnant (table 5 continued)**

			Trying to get pregnant and formula helped	Trying to get pregnant and formula did not help	Total
Length of time	10 days	Count	20	17	37
		%	54.1%	45.9%	100.0%
	> 10 days	Count	10	6	16
		%	62.5%	37.5%	100.0%
Total		Count	30	23	53
		%	56.6%	43.4%	100.0%

**Pearson Chi-square = 0.32, df = 1, p = .569** – no significant difference found

Protocol			Trying to get pregnant and formula helped	Trying to get pregnant and formula did not help	Total
Formula alone, no modification		Count	25	19	44
		%	56.8%	43.2%	100.0%
Formula with any modification		Count	5	4	9
		%	55.6%	44.4%	100.0%
Total		Count	30	23	53
		%	56.6%	43.4%	100.0%

**3.2 Fisher's Exact Test**

Results of Fisher’s Exact Test yielded a 1.00 value. Slightly more of those who were trying to get pregnant were helped by taking the formula (56.6%) compared to those who were trying to get

pregnant but were not helped (43.4%) by the formula. However, no significant differences were found based on how long the formula was taken (ten days vs. longer), or regarding whether or not modifications were added to the formula.

**Table 6:** Frequency Distributions for Study Variable-Length of Time Taking Formula

			Trying to get pregnant and formula helped	Trying to get pregnant and formula did not help	Total
Ten days	10 days	Count	20	17	37
		%	54.1%	45.9%	100.0%
	> 10 days	Count	10	6	16
		%	62.5%	37.5%	100.0%
Total		Count	30	23	53
		%	56.6%	43.4%	100.0%

Table 7 displays the data that emerged from the current study that were subjected to statistical analyses. While there were four categories of data collected, only data from three categories (the Infertility, PCOS and Ovarian Cyst groups) were subjected to

statistical analysis. As indicated above, because the Vaginal Discharge group represents a very common and non-specific symptom, the data from that group were not included in the statistical analysis summarized in Table 7.

**Table 7: Frequency Distribution for Formula Alone and Formula Modified**

<b>10 days</b>		<b>Frequency</b>	<b>Percent</b>
	10 days	72	60.0
	> 10 days	48	40.0
	Total	120	100.0
<b>Formula Alone</b>		<b>Frequency</b>	<b>Percent</b>
	Formula alone, no modification	87	72.5
	Formula with any modification	33	27.5
	Total	120	100.0
<b>Pain Effect</b>		<b>Frequency</b>	<b>Percent</b>
	0%	4	3.3
	30%	12	10.0
	50%	16	13.3
	70%	52	43.3
	100%	36	30.0
	Total	120	100.0
<b>Satisfaction</b>		<b>Frequency</b>	<b>Percent</b>
	Not satisfied	2	1.7
	2	7	5.8
	Moderately satisfied	19	15.8
	4	64	53.3
	Very Satisfied	28	23.3
	Total	120	100.0
<b>Ovarian Cyst</b>		<b>Frequency</b>	<b>Percent</b>
	Had ovarian cyst and formula helped	38	31.7
	NA	82	68.3
Total		120	100.0

<b>Pregnancy</b>		<b>Frequency</b>	<b>Percent</b>
	Trying to get pregnant and formula helped	30	25.0
	Trying to get pregnant and formula did not help	23	19.2
	Total	53	44.2
	NA	67	55.8
Total		120	100.0
<b>PCOS</b>		<b>Frequency</b>	<b>Percent</b>
	Had PCOS and formula helped	7	5.8
	NA	113	94.2
Total		120	100.0

The sample included a total of 98 cases that constituted the three subgroups designated for analysis (Ovarian Cysts, PCOS and Infertility). Those 98 cases had an observed mean age of 36.57 years. For the infertility subgroup the mean age was 37.26 years. For the ovarian cyst subgroup the mean age was 38.84 years, and for the PCOS subgroup the mean age was 32.14.

**Endometriosis:** For the 120 cases observed, 87 were treated with the original formula alone, and 33 were treated with the modified formula. For those patients who were treated with the original formula for ten days, the largest number, 72, appears in phase 1 (ten days) followed by 48 in phase two (twenty days).

**Infertility:** Patients in the sample who also had a diagnosis of infertility constituted the largest group with 53 cases observed. Because these patients in this sub-group also had the diagnosis of infertility, and expressed a desire to become pregnant, additional data regarding full term pregnancy were gathered. Of the 53 cases, the review of charts manifested 30 cases that experienced a full term pregnancy. Of the thirty who experienced a full term pregnancy, 19 had taken the Qing Bao Zhu Yu Tang original formula for phase one. All of the other phases were low (not more than three). The data regarding the infertility sub-group are reported in Table 5.



**Ovarian Cysts:** Patients in this group had the accompanying condition of ovarian cysts. There were 38 cases in this subgroup, and for each of the 38 cases, chart review indicated verification of the resolution of the ovarian cysts. For these groups there were ten cases each at the Phase 1 and Phase 2 level. For the modified and the combined original and modified groups there were no more than 4 cases observed. See Table 5.

**PCOS:** There were seven cases where patients had the accompanying condition of polycystic ovarian syndrome (PCOS). For all seven of the cases the chart review manifested resolution of the PCOS condition. For this sub-group the highest number observed in any one phase was three in Phase 2. Because the number in this category was so small, it is difficult to make any definitive statements. See Table 5.

#### 4. Discussion

Since the Qing Bao Zhu Yu Tang formula is new and not widely used in Traditional Chinese Medicine practice, the findings of the current study have implications for herbal formula practice and application, especially in terms of the impact of the formula on infertility, ovarian cysts, PCOS, the removal of blood stagnation and blood stasis, relieving menstrual pain during and before the menstrual period starts and uterine tract infections.

Infertility is the most common associated byproduct of endometriosis. Forty percent of endometriosis cases also include the presence of infertility. In the current study, 53 of the 120 endometriosis patients (44.2 %) also had infertility. In the current study with the use of the Qing Bao Zhu Yu Tang formula, 30 of the 53 (56%) patients were able to get pregnant. The results of the current study complement the work of Marrs<sup>[17]</sup> Ling<sup>[1]</sup> and Farquhar<sup>[18]</sup> by providing a preliminary systematic study showing that the effective treatment of endometriosis using herbals can result in pregnancy.

The condition of ovarian cysts was observed in 38 of 120 cases (31.7%) in the current study. Every one of the 38 cases reported improvement with treatment using the Qing Bao Zhu Yu Tang formula. The data observed in the current study are consistent with the data yielded in the study by Flower et al., (2010) which showed that 40% of endometriosis cases also manifested the condition of ovarian cysts. The results of the current study have strong implications for TCM practitioners who treat women with endometriosis with accompanying ovarian cysts. Practitioners should give careful consideration to the use of the Qing Bao Zhu Yu Tang formula when dealing with similar cases. This is an area that has not been engaged in prior literature. As a result, the findings of the current study are groundbreaking in relation to the treatment of endometriosis cases when ovarian cysts are present.

While in the current study the number of cases of endometriosis that also included the condition of PCOS was small (n=7), the data show that each of those seven cases reported that the PCOS condition disappeared or was helped significantly by the treatment with the Qing Bao Zhu Yu Tang formula. Even though the numbers were small regarding the impact of the formula on the condition of PCOS, there is clear indication that further research is needed in this area. Further research is important in this area since PCOS is not only associated with infertility, but also with a higher incidence of insulin resistance (Type 2 Diabetes), no ovulation, amenorrhea and hyper-secretion of androgen (testosterone).

Because it is such a commonly occurring and often non-specific symptom, data regarding the symptom of vaginal discharge were not formally analyzed in the current study. However, in the current study, 19 charts of endometriosis patients also included the

symptoms of excessive vaginal discharge. Again the implications of TCM theory are much clearer in treatment of endometriosis than Western Medicine. The Qing Bao Zhu Yu Tang formula provides a viable alternative for treating both non-specific and endometriosis related excessive vaginal discharge.

#### 4.1 Limitations

A limitation of the current study is the limited sample size used, as well as the geographic factor of the location of the clinic where the chart review originated. Because all samples come from one clinic in Los Angeles, there is the possibility that those who sought treatment at this clinic might not reflect the general population. However this factor is not likely since the patients seen at the designated clinic represent a wide range of ages, ethnicities and presenting problems.

#### 4.2 Recommendations for Future Research

Since the current study involved chart review method, the next step in the path of research would be to design and conduct single blind and possibly double blind studies regarding the use of the formula. Those studies should include placebo and no treatment groups to verify the effectiveness of the Qing Bao Zhu Yu Tang formula. Additional research needs to be done with further control for the factor of ethnicity. Further, more controlled clinical studies will be needed to clarify the clinical efficacy of natural medicinal herbs in the treatment of endometriosis-associated pain and investigate herb-herb and, the interaction of Traditional Chinese Medicine with hormones drug-herb interactions and other toxicities. It is critical to establish streamlined registration procedures for natural medicinal products, particularly herbal ones that have a long tradition of safe use.

#### 5. Conclusions

As indicated by the data generated in the current study it is observed that the Qing Bao Zhu Yu Tang formula is effective in the treatment of endometriosis. It is also effective in the treatment of infertility, PCOS and ovarian cysts, vaginal discharges. Consistent with the findings of the current study, TCM practitioners who treat ob-gyn cases should consider using the Qing Bao Zhu Yu Tang formula.

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**Appendix A:**

Copy of Data Collection Instrument

• Was the patient treated for endometriosis with Chinese herbs?	Yes	No	
• Was the patient satisfied with the treatment process?	Yes	No	
• Did the patient experience symptom relief?	Yes	No	
• Was the patient taking hormones?	Yes	No	
• Did the patient have a diagnosis of endometriosis previously?	Yes	No	
• Did the patient had surgery previously?	Yes	No	
• Is this treatment for recurrent condition?	Yes	No	
• Was the patient taking pain medication?	Yes	No	
• Write the name of pain medication?			
• Modified Qing Bao Zhu Yu Tang	Formula alone	Yes	
	Modified according to constitution	Yes	
• Questions about Pain	Pelvic pain		
	During sexual intercourse	Yes	No
	Before menstrual period	Yes	No
	During menstrual period	Yes	No
	After menstrual period	Yes	No
	During defecation	Yes	No