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Overview of Clinical Applications of Guizhi Fuling Pills

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Abstract: *Guizhi Fuling Pill is a classic formula from Zhang Zhongjing's "The Essentials of the Golden Chamber", which has the effect of activating blood circulation and removing blood stasis, etc. In recent years, Guizhi Fuling Pill has been widely used in the domestic clinic, which can not only treat gynecological diseases such as uterine fibroids, ovarian cysts, polycystic ovary syndrome, endometriosis, pelvic inflammatory disease, and adenomyosis, but also play a positive therapeutic role in diseases such as prostatic hyperplasia, coronary artery disease, chronic obstructive pulmonary disease, and hyperlipoproteinemia. Lipoproteinaemia and other diseases have also played a positive therapeutic role. This paper summarises and analyses the clinical application of Guizhi Fuling Pills in recent years to provide a basis for further broadening the scope of clinical use.*

Keywords: *Guizhi Fuling Pill; Clinical application; Research progress; Gynecology*

1. Introduction

Guizhi Fuling Pill (GFP) originated from the book "The Essentials of the Golden Chamber" by Zhang Zhongjing, a medical doctor of the Eastern Han Dynasty. The formula is based on five Chinese herbs, namely, Guizhi, Poria, Mudanpi, Peach Kernel and Paeonia lactiflora, which are made into honey pills for use, which has the unique effects of activating blood circulation, removing blood stasis and regulating qi and blood. In recent years, with the development of clinical experimental research, the clinical application and scope of GFP has been widely expanded, and nowadays GFP can effectively treat various diseases, including but not limited to internal medicine, surgery and gynaecological diseases. This paper summarises and analyses the clinical application of Gui Zhi Fu Ling Wan in recent years to provide a basis for further broadening the scope of clinical use.

2. Clinical application

2.1 Gynaecological diseases

2.1.1 Uterine fibroids

Uterine fibroids, also known as smooth muscle tumours, are the most common type of benign tumour in the female reproductive system. They are formed by the overgrowth of smooth muscle cells in the myometrium, which contain a large amount of extracellular matrix, such as collagen, cadherins and proteoglycans. It affects about 20% of women, with the highest prevalence in the 30-50 age group. The pathogenesis is unclear, and most scholars believe that fibroids are related to estrogen and progesterone, the environment, genetics, and immunity.[1] [2] In 150 patients with uterine fibroids, mifepristone was used in the control group, and GFP was used in the observation group.The results showed that the whole blood high blood viscosity (HBV), whole blood low blood viscosity (LBV), platelet aggregation rate (PAR), platelet aggregation rate (PA), platelet aggregation rate (PA), and platelet aggregation rate (PA) of the observation group were all significantly higher than those of the control group after treatment. Rate (PAR), plasma viscosity (PV), haemoglobin (Hb) and leiomyosarcoma volume levels were significantly improved ($P<0.05$), which was significantly better than that of the control group, and symptoms such as weakness, breast swelling and abdominal distension were greatly relieved in the observation group;[3] In the control group, 134 patients with uterine fibroids were treated with hormone-releasing levonorgestrel intrauterine slow-release system (LNG-IUS), while the observation group was treated with LNG-IUS in combination with GFP. The results of the study showed that the amount of menstrual flow, diameter of the fibroids, and volume of the uterus in the observation group decreased, dysmenorrhoea and anaemia were improved, and the levels of estradiol (E2), follicle-stimulating

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hormone (Follicle-stimulating Hormone (FSH) and Luteinising Hormone (LH) levels were reduced, the total effective rate of treatment was significantly higher than that of the control group (P<0.05), and the incidence of adverse reactions (irregular bleeding, abdominal pain, breast pain, amenorrhoea, etc.) and the recurrence rate 1 year after treatment were significantly lower than that of the control group. Modern pharmacological studies have shown that Poria polysaccharide and Gui Zhi volatile oil in GFP can be anti-tumour, paeoniflorin can diastole the smooth muscle of the uterus, and danpi phenol can enhance cellular immunity, effectively enhancing the immunity of patients with uterine fibroids,[4] which effectively improved the quality of life of patients with uterine fibroids.

2.1.2 Polycystic ovary syndrome (PCOS)

Polycystic Ovary Syndrome (PCOS) is a pathological condition caused by endocrine and metabolic disorders, which is characterised by prolonged anovulation, hyperandrogenism and insulin resistance. The prevalence of PCOS in Chinese women during their reproductive years is about 5.6%, and the prevalence of PCOS in adolescent women ranges from 3.69% to 12.82%.[5] . Currently, western medicine treats PCOS by reducing hyperandrogenemia, promoting ovulation, improving insulin resistance, and adjusting the menstrual cycle, etc. [6]Divided 92 PCOS patients into control group (ethinylestradiol cyproterone tablets + metformin hydrochloride tablets treatment) and observation group (ethinylestradiol cyproterone tablets + metformin hydrochloride tablets + GFP treatment) to observe their treatment effects respectively. Results Patients in the observation group had significantly lower levels of fasting blood glucose (FBG), fasting insulin (FINS), LH, FSH, T and insulin resistance index (HOMA-IR) than those in the control group, and the peripheral blood expression levels of p-PI3K, p-AKT, p-mTOR were higher than those of the control group, and the peripheral blood expression levels of p-PI3K, p-AKT and p-mTOR were higher than those of the control group. expression levels were all higher than those of the control group, and the total effective rate of treatment reached 93.02%, and ultrasound monitoring showed that the patients in the observation group had an increased ovulation rate and a reduced ovarian volume. Relevant animal experiments show that GFP may improve glucose metabolism abnormality and insulin resistance in phlegm-damp PCOS model rats, down-regulate serum estrogen level, and reduce ovarian polycystic changes by up-regulating the gene expression of aromatase (CYP19a1) in the ovary and glucose transport protein 4 (Glut4) in the uterine tissue[7]. Modern pharmacological studies have confirmed that GFP treatment of PCOS can promote ovulation, regulate the level of sex hormone and improve insulin resistance.

2.1.3 Endometriosis

Endometriosis (EMT) is a hormone-dependent chronic reproductive disease in which endometrial tissue with growth function appears outside the coated mucosa of the uterine cavity and the myometrium, and is accompanied by a variety of symptoms such as dysmenorrhoea, infertility, and painful intercourse.[8] Hormone-dependent chronic reproductive disorders. Currently, hormone therapy (including progestin analogues, birth control pills, gonadotropin-releasing hormone agonists, and levonorgestrel intrauterine extended-release system) is used by Western medicine[9] as the first-line treatment for patients with EMT.[10] Selected 65 cases of EMT patients, the control group was treated with oral dextroprogesterone tablets, and the combined group was treated with GFP on the basis of the control group, the results showed that the total effective rate of treatment in the combined group was 96.97%, compared with 75.00% in the control group, and the serum FSH, LH, E2, and the serum levels of nerve growth factor (NGF), vascular endothelial growth factor (VEGF), and E2 were lower than those in the control group. growth factor (VEGF), hypoxia-inducible factor-1 (HIF-1), and matrix metalloproteinase (MMP-2) levels were all reduced, indicating that GFP combined with dydrogesterone in the treatment of EMT can reduce the level of sex hormones and inhibit the growth of endometrial tissues; [11] took 90 EMT patients as research subjects, the control group took oral dienogest tablets, and the treatment group combined with GFP on the basis of the control group, and the results of the study showed that the total effective rate of the treatment group reached 88.89%, while the total effective rate of the control group was 66.67%. In the treatment group, the diameter of ectopic lesions, the degree of abdominal pain, and the levels of E2 and LH decreased significantly, while the levels of vascular cell adhesion factor-1 (VCAM1), VEGF, and serum glycan antigen 125 (CA125) were significantly lower than those of the control group (P<0.05), which indicated that the treatment of EMT with GFP combined with dienogest relieved the symptoms of the patients and improved the clinical efficacy.

2.1.4 Inflammatory diseases of the pelvis

Pelvic Inflammatory Disease (PID), i.e., infectious diseases affecting the female upper reproductive tract and its surrounding tissues (uterus, fallopian tubes, ovaries, parietal tissues, and peritoneum), is considered by Western medicine to be the main pathogens of PID, Chlamydia trachomatis (CT) and

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Neisseria gonorrhoeae (NG)[12], treatment is based on antibiotics. [13] Observed the treatment effect of 50 CPID patients, the reference group was treated with levofloxacin plus metronidazole, and the experimental group was treated with traditional Chinese medicine GFP on the basis of the reference group, as a result, the patients in the experimental group had a significant improvement in pain symptoms and inflammatory reactions, and the adverse reactions such as nausea, vomiting, diarrhoea, and decreased appetite were significantly reduced, which indicated that the combination of GFP with western medicine had high safety and precise effect in the treatment of PID. In the formula of GFP, Gui Zhi warms the blood and promotes the flow of fluid, Tao Ren and Dampi invigorate the blood and disperse blood stasis, Poria strengthens the spleen and disperses dampness and expels phlegm, and Paeoniae Alba clears heat, dries dampness and removes toxins.[14] The combination of all the drugs can eliminate the inflammatory reaction.

2.1.5 Ovarian cysts

Ovarian cyst is a common female genital tumour. Physiological cysts are follicular cysts, corpus luteum cysts, etc., which usually disappear on their own, while pathological cysts include plasma cystadenoma of the ovary, mucinous cystadenoma, endometriotic cyst, teratoma, etc., which are commonly found in women between 20 and 50 years of age with abdominal discomfort, menstrual disorders and abnormalities.[15] [16] 107 cases of elderly ovarian cyst patients were divided into observation group and control group for treatment, the control group took gynecological Qianjin capsule orally, and the observation group used gynecological Qianjin capsule combined with GFP, the results of the observation group's total effective rate was 94.44%, which was significantly higher than that of the control group's 81.13%, and the observation group patients' nitric oxide (NO), TNF-alpha, and E2 levels were significantly lower than that of the control group, and the levels of LH and FSH were higher than that of the control group, indicating that patients with gynecological Qianjin capsule had higher levels than that of the control group. were higher than those of the control group, indicating that gynaecological Qianjin capsule plus GFP had a good regulating effect on serum NO, TNF-α and sex hormones in patients with ovarian cysts; [17] 84 patients with ovarian cysts were divided into control group and observation group, patients in the control group were given Jiawei Yuchin Pill, while the observation group was treated with GFP added on top of the control group.

2.1.6 Adenomyosis

Adenomyosis (AM) is a common gynaecological disease characterised by abnormal proliferation of endometrial cells in the basal layer of the uterus, which invade the myometrium to form a certain degree of diffuse or restricted lesions. The occurrence of AM is associated with factors such as heredity, uterine cavity damage, and hyperoestrogenism, and it is accompanied by progressive aggravation of dysmenorrhoea, menstrual bleeding, and infertility. [18] Selected 80 patients with AM for treatment; the control group was given progesterone and the observation group was treated with a combination of GFP and progesterone. It was found that the degree of dysmenorrhoea was significantly improved in the observation group, menstrual flow was reduced, and the expression levels of IL-6 and IL-8, as well as the expression of JAK2 and STAT3 proteins and mRNAs in the endometrial tissues were decreased compared with those of the control group, which showed that the treatment of AM with GFP in combination with pregnenolone was effective in relieving the symptoms of dysmenorrhoea and menstrual overload. Observe the treatment effect of 90 cases of AM patients, mifepristone treatment in the control group and GFP combined with mifepristone treatment in the observation group, the results of the observation group, the levels of E2, FSH, progesterone (progesterone, P), serum CA125 and VEGF decreased, the uterine volume was reduced, and the incidence of adverse reactions was less, and the effective rate of the treatment in the observation group (95.56%) was much higher than that in the control group (The effective rate of treatment in the observation group (95.56%) was much higher than that in the control group (77.78%), indicating that the treatment of AM with mifepristone combined with GFP could regulate hormone levels, improve the menstrual cycle and promote ovulation, and restore ovarian function.

2.2 Male Diseases

[19] Using GFP plus or minus combined with finasteride to treat 84 patients with prostatic hyperplasia, the control group used finasteride alone, the result was that the total effective rate of the treatment group was 95.24%, which was significantly higher than that of the control group, which was 73.81%.[20] 128 patients with chronic epididymitis as the research object, the treatment group took GFP plus and minus, the observation group used western medicine levofloxacin, the results of the treatment group recovery rate of 73.8%, the control group was 40.0%; Hu Shixiang with GFP plus and minus to treat 60 cases of

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chronic prostatitis, the results of the total effective rate of 90.0%[21] [22] Observe the treatment effect of 54 cases of semen non-liquefaction patients, the treatment group used GFP plus flavour, the control group was given Zhi Bai Di Huang Wan and vitamin C, the result was that the total effective rate of the treatment group (80.5%) was higher than that of the control group (55.6%)[23].

2.3 Cardiovascular diseases

[24]Treating 60 cases of coronary heart disease patients, the control group was given isosorbide mononitrate tablets, aspirin enteric-coated tablets, nitroglycerin tablets, and the experimental group was given GFP combined with the above mentioned western medicines, and the result of the experimental group's total clinical effective rate was 93.3%; [25] Observed the treatment effect of 116 patients with cognitive dysfunction of cerebrovascular disease (CCVI), the control group was given donepezil hydrochloride tablets, and the observation group was given GFP, and the result was that the total effective rate of the observation group was 91.38%, which was higher than that of the control group (68.96%) ($P < 0.05$), which indicated that GFP could help to enhance the cognitive ability of the patients and reduce the production of cholinergic energy; [26] Seventy-two patients with hyperlipoproteinemia were divided into a traditional Chinese medicine GFP treatment group and a western medicine control group, resulting in a total effective rate of 93.34% in the treatment group much higher than that in the control group (68.34%), suggesting that GFP can down-regulate plasma cholesterol and triglyceride to treat hyperlipoproteinemia. An experiment on GFP against chronic heart failure in rats[27]. An experiment on GFP against chronic heart failure in rats showed that GFP could down-regulate the level of ALT, inhibit the expression of TGF-β and AngII in myocardial tissue, and reduce myocardial injury.

2.4 Diseases of the respiratory system

[28]Observed the therapeutic effect of 102 patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD), the control group was treated with western medicines, and the observation group was treated with flavoured GFP in combination with western medicines, the results of the observation group's improvement in serum amyloid A (SAA), procalcitoninogen (PCT), hs-CRP, plasma D-dimer (D-dimer, D-D), and pulmonary arterial pressure was better than that of the control group[29]. Treated 128 patients with bronchial asthma, the control group was given budesonide formoterol powder inhaler, and the study group was given Xiao Chaihu Tang combined with GFP, the results of which showed that the total effective rate, the first second forced expiratory volume (FEV1), the peak expiratory flow rate (PEF), and the serum gamma-interferon (IFN-gamma, which has antiviral, anti-tumour, and immune-modulating properties) were higher in the study group than in the control group, and the IL-8 and IL-13 levels were lower than those of the control group, indicating that Xiao Chaihu Tang combined with GFP could improve the functional status of the lungs and regulate the levels of inflammatory factors. According to Jin Dianchun, GFP is the basic formula for the treatment of pulmonary nodules, because pulmonary nodules are caused by phlegm and stagnant phlegm, and tangible evils are deposited in the lungs, GFP plays the functions of activating blood and eliminating phlegm, dispelling dampness and resolving phlegm, and is accompanied by traditional Chinese medicines to tonify the kidneys, dredge the liver, and protect the spleen and the stomach, which together can slow down the condition and reduce the size of the nodules.[30] The effect is to slow down the disease and reduce the size of the nodules.

2.5 Other diseases

In addition to the above diseases, GFP has also played a good role in the treatment of cerebral oedema, liver fibrosis, diabetes, proctitis, breast enlargement, melasma and other diseases.

3. Conclusion

Guizhi Fuling Pill, as a classic formula for activating blood circulation and removing blood stasis in "The Essentials of the Golden Chamber", is widely used in gynaecology such as uterine fibroids, ovarian cysts, pelvic inflammatory disease, polycystic ovary syndrome, etc. According to the principle of "treating the same disease with the same treatment" of the motherland medicine, this formula is also used in men's diseases, cardio-cerebral and cerebral vascular system, respiratory system, etc. It has been widely used with remarkable efficacy. According to the principle of "treating different diseases together" in Chinese medicine, this formula is also applied to male, cardio-cerebral vascular system, respiratory

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system and other diseases, which are widely used with remarkable curative effect.

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