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Research Progress on the Treatment of Polycystic Ovary Syndrome with Traditional Chinese Medicine

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Abstract: ***The root cause of this disease lies in an internal imbalance of the zang-fu organs, while phlegm-dampness and blood stasis serve as the manifest pathogenic factors; consequently, clinical manifestations often exhibit a mixture of deficiency and excess, characterized by a manifest excess with an underlying deficiency. In terms of treatment, Traditional Chinese Medicine (TCM) approaches include syndrome differentiation and treatment, flexible modification of classical formulas, acupuncture and moxibustion, and various specialized TCM therapies. Although these methods are safe and effective, they currently face several limitations: (1) While there are many small-sample studies on the treatment of polycystic ovary syndrome (PCOS) with TCM and acupuncture, there is a lack of large-scale, multicenter clinical validation; (2) Much of the research data comes from a single hospital, resulting in insufficient representativeness of the sample, small sample sizes, and a lack of overall comprehensiveness; (3) Insufficient sample sizes and observation periods make it difficult to assess long-term clinical outcomes. Future research should focus on the following areas: (1) Conducting systematic, scientifically sound, and rigorously designed multicenter studies with large sample sizes to enhance the persuasiveness of research findings; (2) Diversifying data sources as much as possible to avoid reliance on a single source, increasing sample size, extending the duration of follow-up, and improving representativeness; (3) While administering pharmacological treatment, attention should also be paid to patients' psychological well-being to foster positive mindset changes, thereby facilitating adherence to long-term treatment regimens.***

Keywords: Polycystic ovary syndrome, Syndrome differentiation and treatment, Treatment with modified classical formulas, Acupuncture, Distinctive TCM therapies.

1. Introduction

Polycystic ovary syndrome (PCOS) is the most common endocrine and metabolic disorder in gynecological practice. Its core pathological features include hyperandrogenism (abnormally elevated androgen levels at the biochemical level), persistent ovulatory dysfunction, and polycystic ovarian morphology. The condition is often accompanied by insulin resistance and overweight or obesity. Currently, the exact pathogenesis has not been fully elucidated, but the academic community generally tends to believe that it may result from the interaction of a genetic predisposition with various environmental factors. This syndrome was first reported by Stein and Leventhal in 1935; consequently, it is also clinically referred to as Stein-Leventhal syndrome. From a clinical perspective, the condition stems from an endocrine imbalance, with hyperandrogenism serving as the primary biochemical marker; the resulting infrequent ovulation or anovulation is the key factor leading to menstrual irregularities and infertility. Research and clinical experience have shown that polycystic ovary syndrome (PCOS) most commonly occurs during adolescence, with menstrual irregularities as the primary symptom. The most prominent clinical manifestation of this condition is an abnormal menstrual cycle, often presenting as oligomenorrhea or amenorrhea. For women of childbearing age, impaired ovulation can further lead to difficulty conceiving or even infertility. The most typical signs of hyperandrogenism are hirsutism and acne, with hirsutism primarily affecting the pubic and axillary regions; pubic hair becomes noticeably denser and tends to follow a masculinized distribution pattern. More than half (approximately 50% or more) of patients are overweight, with a body mass index (BMI) of 25 or higher, and fat tends to accumulate in the abdominal area, with a waist-to-hip ratio typically ≥0.80. In addition, symmetrical, grayish-brown hyperpigmented patches may appear in skin folds such as the labia, nape of the neck, armpits, lower breast margins, and groin; the skin in these areas gradually thickens and becomes soft to the touch. In terms of Western medical treatment strategies, ovulation-inducing drugs such as clomiphene are primarily used to induce ovulation, while formulations such as Diane-35 are used to lower androgen levels, combined with metformin to alleviate insulin resistance, thereby improving menstrual patterns and promoting ovulation. However, this approach does not provide a cure and carries risks such as low pregnancy rates and fetal malformations [1]. In recent years, numerous studies have shown that Western medicine still presents certain side effects in the treatment of PCOS, such as a high recurrence rate, adverse reactions, and complications. Furthermore, most patients have a low acceptance of hormonal medications. Therefore, in the treatment of polycystic ovary syndrome, Traditional Chinese Medicine (TCM) offers distinct clinical characteristics and advantages, with promising prospects for development. The following is a review of recent research progress in the treatment of polycystic ovary syndrome using Traditional Chinese Medicine.

2. The Perspective of Traditional Chinese Medicine on PCOS

Although the term "polycystic ovary syndrome" does not exist in traditional Chinese medicine, based on its clinical manifestations, the condition can be classified under categories such as "infertility," "scanty menstruation," "delayed menstruation," "amenorrhea," and "masses in the abdomen." In the Song Dynasty, Wang Yinjun's "Essentials of Health Preservation" states: "In women, amenorrhea and leukorrhea… are all attributed to phlegm-related conditions."

In the Yuan Dynasty, Zhu Danxi's "Danxi's Heart Method" states: "Obese women, endowed with a robust constitution, indulge in food and drink; their menstrual flow is irregular, and they are unable to conceive. This is referred to as 'excessive body fat overflowing and obstructing the uterus'; treatment should focus on dispelling dampness, drying, and resolving phlegm." In the Ming Dynasty, Song Lingao's "Essentials of Song's Gynecology" states: "Generally speaking, a woman's inability to conceive is often due to… obesity leading to an excess of phlegm, with bodily fat overflowing and obstructing the uterus." In the Qing Dynasty, Wu Liben's "Essentials of Gynecology" states: "Obese, fair-skinned women who experience amenorrhea must be suffering from obstruction caused by damp phlegm and an excess of body fat [2]." From this, it can be seen that ancient medical practitioners had long identified damp phlegm as a key factor leading to infertility, amenorrhea, metrorrhagia, and masses, thereby providing a theoretical foundation for treating PCOS from the perspective of damp phlegm.

3. Etiology and Pathogenesis

Based on ancient and modern medical classics as well as contemporary clinical research findings, and in accordance with characteristics widely recognized in Traditional Chinese Medicine (TCM), the pathogenesis of PCOS from a TCM perspective is fundamentally rooted in internal functional disorders of the zang-fu organs, while the obstruction of meridians by pathological products such as phlegm-turbidity and blood stasis serves as the external manifestation. Consequently, clinical presentations often exhibit a pattern of both deficiency and excess coexisting, characterized by superficial excess and underlying deficiency. The onset of this disease is closely related to functional disorders of the three organs—the Kidney, Spleen, and Liver—with Kidney deficiency and Spleen deficiency being particularly critical factors. On this basis, secondary pathological factors such as the accumulation of phlegm-dampness and the stagnation of blood further disrupt the body's functions, leading to the disruption of the balance in the reproductive regulatory axis of "Kidney—Tian Gui—Chong and Ren Vessels—Uterus," which ultimately triggers the disease.

3.1 Kidney Deficiency

The kidneys are responsible for storing essence; they both receive congenital essence and nourish acquired essence. If kidney qi is deficient, the generation of essence and blood is insufficient, making it difficult to support the normal development of the reproductive system in adolescent females. This results in the Tian Gui failing to arrive on schedule, the uterus lacking proper nourishment, and abnormal accumulation and overflow in the Blood Sea. Consequently, symptoms such as delayed menstruation, reduced menstrual flow, and even amenorrhea may occur, and it becomes difficult to conceive. At the same time, insufficiency of kidney qi impairs its ability to consolidate and contain, causing menstrual blood to lose its constraints and deviate from its normal course, which may also induce or exacerbate the onset of this condition.

3.2 Spleen Deficiency with Phlegm and Stasis

The spleen is the foundation of postnatal life; it governs the transformation and transportation of the essence of food and drink, serving as the source of qi and blood generation. If spleen qi is deficient, the source of qi and blood generation is insufficient, the uterus lacks nourishment, and menstrual blood cannot descend properly, resulting in delayed menstruation, reduced menstrual flow, and even amenorrhea. On the other hand, the spleen is also the organ responsible for generating phlegm; by nature, it prefers dryness and abhors dampness. When spleen qi is deficient, its transport and transformation functions are impaired, leading to the retention of water and dampness, which into phlegm. Phlegm-dampness and greasy substances obstruct the Chong and Ren meridians, hindering the smooth flow of qi and blood, causing abnormal accumulation and overflow in the Blood Sea. This, too, can result in delayed menstruation, scanty flow, or even amenorrhea. If phlegm-dampness obstructs the uterus internally, the union of sperm and egg becomes difficult, hindering the conception process and ultimately leading to infertility; this may also trigger polycystic ovary syndrome.

3.3 Qi Stagnation and Blood Stasis

The liver stores blood and governs the free flow of qi. When liver qi is not smooth, emotional distress causes stagnation of qi, resulting in qi stagnation. The obstruction of qi and blood flow impeding the circulation of qi and blood. This leads to stagnation of qi and blood in the Chong and Ren meridians; when blood flow is weak and blood fails to follow its normal course, it manifests as stasis. Stagnant blood obstructing the uterus and its meridians causes scanty menstruation or amenorrhea; when it obstructs the ovaries, it hinders egg release, ultimately resulting in this condition.

4. Traditional Chinese Medicine Treatment for PCOS

4.1 Syndrome Differentiation and Treatment

Syndrome differentiation and treatment is one of the fundamental principles of Traditional Chinese Medicine and plays a vital role in the treatment of various diseases. Polycystic ovary syndrome is caused by a combination of factors; therefore, the selection and adjustment of herbal formulas must be flexible and tailored to each individual's specific condition to achieve optimal therapeutic outcomes. Mo Tingting et al. [3] selected 83 patients with PCOS-related infertility classified as the "Kidney Deficiency and Liver Qi Stagnation" pattern based on TCM pattern differentiation. The control group consisted of 41 patients who received conventional Western medication—oral letrozole for ovulation induction—while the observation group comprised 42 patients treated with the "Kidney-Tonifying, Qi-Stagnation-Resolving, and Chong Vessel-Regulating Formula." After continuous monitoring of ovulation for 3 to 6 months, it was found that, compared with the control group, patients in the observation group showed significant improvements in both ovulation rates and pregnancy success rates. At the same time, their acne symptoms, anxiety and depression, and TCM syndrome scores were significantly alleviated. When comparing the observation group's pre- and post-treatment data, both ovarian volume and follicle count were significantly reduced after treatment; Serological testing

revealed significant decreases in luteinizing hormone (LH), the LH/follicle-stimulating hormone (FSH) ratio, testosterone, prolactin, and Kiss1 levels, while dopamine (DA) and serotonin (5-HT) levels increased significantly; the differences in all these indicators were statistically significant. Chen Yan et al. [4] treated 96 patients with PCOS of the phlegm-dampness obstruction type using Zuoguiwan combined with Cangfu Daotan Decoction, and found that this combination can regulate reproductive function at multiple levels: it promotes the release of hormones by the hypothalamus, enhances pituitary responsiveness, and increases the sensitivity of corresponding hormone receptors in the ovaries. Consequently, it effectively regulates hormonal secretion disorders and improves hormone levels in these patients, effectively alleviating clinical symptoms, regulating sex hormone levels, and improving clinical efficacy and the rate of spontaneous pregnancy. The results were superior to those of the conventional Western medicine group. Guo Lihong et al. [5] selected 80 patients with polycystic ovary syndrome, whose primary syndrome pattern was liver qi stagnation with stomach heat, and divided them into a study group and a control group, with 40 patients in each group. The control group received acupuncture treatment, while the study group was treated with Da Chai Hu Tang with modifications. After a 4-week observation period, it was found that the combined use of acupuncture and Da Chai Hu Tang with modifications has good clinical utility for treating PCOS of the "Liver Qi Stagnation and Stomach Heat" pattern. It can regulate hormonal secretion disorders, promote the normalization of patients' menstrual cycles and ovarian function, and warm and tonify the liver and kidneys while strengthening the spleen and harmonizing the stomach, thereby alleviating the degree of ovarian dysfunction and further improving patients' clinical symptoms.

4.2 Treatment with Modified Classical Formulas

Research on the treatment of polycystic ovary syndrome using classical formulas focuses on the therapeutic effects of Bai Zhu Fu Zi Tang, Cang Fu Dao Tan Tang with modifications, and Jia Wei Gui Shen Tang. Bai Zhu Fu Zi Tang [6], also known as "Gui Zhi Fu Zi Tang without Cinnamon and with Atractylodes," is derived from the "Jin Gui Yao Lue". Composed of Atractylodes macrocephala, Aconite, licorice, ginger, and jujube, this formula has the effects of warming yang, unblocking the meridians, dispelling wind, and eliminating dampness. Cangfu Daotan Decoction [6] is derived from "Ye Tianshi's Complete Book of Gynecology". The original formula consists of Atractylodes lancea, Cyperus rotundus, Pinellia ternata, Citrus reticulata, Poria cocos, Bile-processed Pinellia, Fructus Aurantii, Ginger, and Fried Licorice, and is effective in drying dampness and transforming phlegm. The Enhanced Gui Shen Decoction [7]is derived from "The True Interpretation of Surgery", Volume 1. The original formula consists of Rehmannia glutinosa (prepared), Cornus officinalis, Lycium barbarum, deer antler gelatin, Panax ginseng, Angelica sinensis, Ligusticum chuanxiong, Paeonia lactiflora, and Glycyrrhiza uralensis, and is effective in tonifying the kidneys and nourishing essence. Yu Tianhua [8] divided clinically selected patients into a control group and an observation group. The control group received treatment with conventional Western medicine, while the observation group was treated with a modified Bai Zhu Fu Zi Decoction in addition to conventional Western medicine. After 3 months, it was found that, compared to before treatment, the patients' symptoms had significantly improved; their ovarian reserve function and ovarian hemodynamic indicators had returned to normal levels, and clinical efficacy had greatly improved. Li Xiaomei [9] selected 125 patients with PCOS for clinical study, assigning them to receive either conventional Western medication or modified Cangfu Daotan Pills. After 12 weeks of treatment, it was found that the patients' TCM symptoms had significantly alleviated, sex hormone levels had markedly improved, inflammatory responses had substantially decreased, and the patients showed good recovery. Tang Yahui [10] selected 78 patients with polycystic ovary syndrome who met the inclusion criteria and divided them into two groups of 39 patients each. The control group was treated with ethinyl estradiol and cyproterone acetate tablets, while the treatment group received Jiawei Guishen Decoction in addition to the Western medication used by the control group. The results showed that, compared with conventional Western medication, treatment with Jiawei Guishen Decoction significantly improved clinical efficacy, reduced ovarian volume, decreased follicle count, regulated sex hormone levels, and altered ovarian hemodynamics, demonstrating remarkable therapeutic effects.

4.3 Acupuncture Treatment

Acupuncture is one of the key therapeutic methods in ancient and modern traditional Chinese medicine. It produces significant therapeutic effects, manifested through unblocking meridians, harmonizing yin and yang, and strengthening the body's vital energy while expelling pathogenic factors. By regulating both systemic (hypothalamus – pituitary – ovarian axis) and locally (the uterus and ovaries), thereby improving ovulation and conception rates in patients with polycystic ovary syndrome. Acupuncture offers distinct advantages over other treatments; for example, it takes effect rapidly, has minimal side effects, and does not place an additional burden on liver or kidney function. Furthermore, it is cost-effective and convenient to administer, requiring only simple tools, making it highly suitable for widespread clinical implementation. Liu Shanshan [11] applied acupuncture to treat polycystic ovary syndrome (PCOS) of the spleen deficiency with phlegm-dampness pattern. They selected 100 patients as study subjects, divided into two groups of 50 each. The control group received the "Menstrual Cycle Regulation Method" as treatment, while the observation group received acupuncture in addition to this method. By selecting the following acupoints: Taixi, Taichong, Guanyuan, Guilai, Zhongji, Fenglong, Yintang, Sanyinjiao, and Zusanli. After three months of systematic treatment and clinical observation, the study found that the combined therapy of the Menstrual Cycle Regulation Method and acupuncture could more effectively regulate hormone levels and improve pregnancy success rates. Li Xuyan [12] applied acupuncture combined with Traditional Chinese Medicine (TCM) constitutional regulation to treat PCOS. After three months of treatment, the results showed that this combined approach achieved ideal outcomes, significantly improving treatment efficacy, alleviating menstrual symptoms, and mitigating the adverse effects of polycystic ovary syndrome. Wang Renyang [13] treated patients with PCOS and kidney yang deficiency using

a combination of acupuncture and ginger-separated moxibustion on the Eight Liang Points. After three months of treatment, they found that this clinical approach reduced patients' MBI and sex hormone levels, alleviated TCM symptoms, significantly improved clinical efficacy, and demonstrated a high degree of safety.

4.4 Distinctive TCM Therapies

TCM culture boasts a long history and a rich cultural system; its distinctive therapies are profound and extensive, widely practiced both nationwide and worldwide. This section primarily discusses the clinical application of distinctive TCM therapies in the treatment of polycystic ovary syndrome. Acupoint thread implantation is a distinctive TCM therapy characterized by long-lasting efficacy, low cost, and minimal adverse reactions. [14] Xu Ying [15] enrolled 156 patients with polycystic ovary syndrome (PCOS) in their study, dividing them into a control group and an observation group. During the observation period, 8 patients were lost to follow-up due to poor patient compliance and other reasons; thus, the total number of enrolled cases was 148, with 74 patients in each group. The observation group received additional treatment via acupoint thread implantation. The study demonstrated that this treatment can regulate patients' metabolism and hormone levels, improve ovarian reserve function, and effectively modulate reproductive hormones, yielding significant therapeutic effects. Kuang Heng [16] selected 80 patients with PCOS-related infertility as study subjects and treated them with either conventional Western medicine (letrozole) or auricular acupressure with bean-sized pellets. The results indicated that the combination of auricular acupressure with bean-sized pellets and letrozole demonstrated significant clinical efficacy in the treatment of PCOS, with overall therapeutic effects markedly superior to those of letrozole monotherapy. This combination therapy effectively promotes follicular development and maturation, optimizes follicular morphology and endometrial condition, alleviates TCM-related syndromes, and helps regulate androgen levels, thereby facilitating ovulation and improving pregnancy success rates. Ding Ningmin [17] enrolled 120 patients with PCOS and randomly assigned them to two groups of 60 each. All patients received standard Western medical treatment; in addition, the control group was treated with a proprietary formula called "Kidney-Nourishing and Menstrual-Regulating Decoction," while the observation group received warm acupuncture on the Governor Vessel in addition to the control group's treatment regimen. After several months of intervention, the results showed that the treatment strategy combining warm acupuncture on the Governor Vessel with the self-formulated Kidney-Nourishing and Menstrual Regulation Decoction had a definite therapeutic effect on PCOS. It not only significantly optimized TCM syndrome scores but also effectively improved androgen metabolism indicators, increased ovulation and pregnancy rates, and demonstrated good clinical application value.

5. Conclusion

In summary, existing research findings indicate that traditional Chinese medicine (TCM) is effective to a certain extent in treating polycystic ovary syndrome (PCOS). Compared to Western medicine, TCM offers unique therapeutic benefits. Through TCM's syndrome differentiation and treatment, the modification of classic formulas, and various distinctive TCM therapies, it is possible to achieve therapeutic outcomes comparable to those of Western medicine. Furthermore, TCM has a long history, is highly safe, and has significantly fewer side effects than Western medicine. However, a review of currently published literature reveals several shortcomings in the treatment of this condition: (1) While there are many small-sample studies on the use of TCM and acupuncture to treat PCOS, there is a lack of large-scale, multicenter clinical validation; (2) Much of the research data comes from a single hospital, resulting in insufficient representativeness of the sample, small sample sizes, and a lack of overall comprehensiveness; (3) Insufficient sample sizes and observation periods make it difficult to assess long-term clinical outcomes. In future research, efforts should be focused on the following areas: (1) Conducting systematic, scientifically sound, and rigorously designed multicenter studies with large sample sizes to enhance the persuasiveness of research findings; (2) Diversify data sources as much as possible to avoid reliance on a single source, increase sample size, extend the study duration, and enhance representativeness; (3) While administering drug therapy, attention should also be paid to patients' psychological well-being to foster a positive mindset, which is conducive to maintaining long-term treatment adherence.

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